

Dow University of Health Sciences



Bidding Documents

Single Stage – Two Envelope Procedure
As per Rule 46 (2) of SPPR, 2010 (Amended 2019)

IFB / NIT No. DUHS/DP/2021/123 Dated 03 February 2021

**PROCUREMENT OF
MICRO COMPACT FILLING LINE AND
MACRO COMPACT FILLING LINE
FOR BIO-INJECTABLES**

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Part One - Section I
Instructions to Bidders

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Instructions to Bidders

A. Introduction

1. Source of Funds

- 1.1 The Procuring agency has allocated funds / received / applied for loan / grant / federal / provincial / local government funds from the source(s) indicated in the bidding data in various currencies towards the cost of the project / schemes specified in the bidding data and it is intended that part of the proceeds of this loan / grant / funds / will be applied to eligible payments under the contract for which these bidding documents are issued.
- 1.2 Payment by the Fund will be made by procuring agency from university funds or only at the request of the Procuring agency and upon approval by the Government of Sindh., and in case of a project will be subject in all respect to the terms and conditions of the agreement. The Project Agreement prohibits a withdrawal from the allocated fund account for the purpose of any payment to persons or entities, or for any import of goods, if such payment or import, to the knowledge of the Federal Government / Sindh Government, is prohibited by a decision of the United Nations Security Council taken under Chapter VII of the Charter of the United Nations. No party other than the Procuring agency shall derive any rights from the Project Agreement or have any claim to the allocated fund proceeds.

2. Eligible Bidders

- 2.1 This Invitation for Bids is open to all suppliers from eligible source as defined in the SPP Rules, 2010 (Amended 2019) and its Bidding Documents except as provided hereinafter.
- 2.2 Bidders should not be associated, or have been associated in the past, directly or indirectly, with a firm or any of its affiliates which have been engaged by the Procuring agency to provide consulting services for the preparation of the design, specifications, and other documents to be used for the procurement of the goods to be purchased under this Invitation for Bids.
- 2.3 Government-owned enterprises in the Province of Sindh may participate only if they are legally and financially autonomous, if they operate under commercial law, and if they are not a dependent agency of the Government of Sindh.
- 2.4 Bidders shall not be eligible to bid if they are under a declaration of ineligibility for corrupt and fraudulent practices issued by the any government organization in accordance with sub clause 34.1.

3. Eligible Goods and Services

- 3.1 All goods and related services to be supplied under the contract shall have their origin in eligible source countries, defined in the SPP Rules, 2010 (Amended 2019) and its Bidding Documents, and all expenditures made under the contract will be limited to such goods and services.
- 3.2 For purposes of this clause, “origin” means the place where the goods are mined, grown, or produced, or the place from which the related services are supplied. Goods are produced when, through manufacturing, processing, or substantial and major assembly of components, a commercially-recognized product results that is

substantially different in basic characteristics or in purpose or utility from its components.

3.3 The origin of goods and services is distinct from the nationality of the Bidder.

4. Cost of Bidding

4.1 The Bidder shall bear all costs associated with the preparation and submission of its bid, and the Procuring agency named in the Bid Data Sheet, hereinafter referred to as “the Procuring agency,” will in no case be responsible or liable for those costs, regardless of the conduct or outcome of the bidding process.

B. The Bidding Documents

5. Content of Bidding Documents

5.1 the bidding documents include:

- (a) Instructions to Bidders (ITB)
- (b) Bid Data Sheet
- (c) General Conditions of Contract (GCC)
- (d) Special Conditions of Contract (SCC)
- (e) Schedule of Requirements
- (f) Technical Specifications
- (g) Bid Form and Price Schedules
- (h) Bid Security Form
- (i) Contract Form
- (j) Performance Security Form
- (k) Manufacturer’s Authorization Form

5.2 The Bidder is expected to examine all instructions, forms, terms, and specifications in the bidding documents. Failure to furnish all information required by the bidding documents or to submit a bid not substantially responsive to the bidding documents in every respect will be at the Bidder’s risk and may result in the rejection of its bid.

6. Clarification of Bidding Documents

6.1 An interested Bidder requiring any clarification of the bidding documents may notify the Procuring agency in writing. The Procuring agency will respond in writing to any request for clarification of the bidding documents which it receives no later than five working days prior to the deadline for the submission of bids prescribed in the Bid Data Sheet. Written copies of the Procuring agency’s response (including an explanation of the query but without identifying the source of inquiry) will be sent to all interested bidders that have received the bidding documents.

7. Amendment of Bidding Documents

7.1 At any time prior to the deadline for submission of bids, the Procuring agency, for any reason, whether at its own initiative or in response to a clarification requested by a interested Bidder, may modify the bidding documents by amendment.

7.2 All interested bidders that have received the bidding documents will be notified of the amendment in writing, and will be binding on them.

- 7.3 In order to allow interested bidders reasonable time in which to take the amendment into account in preparing their bids, the Procuring agency, at its discretion, may extend the deadline for the submission of bids.

C. Preparation of Bids

8. Language of Bid

- 8.1 The bid prepared by the Bidder, as well as all correspondence and documents relating to the bid exchanged by the Bidder and the Procuring agency shall be written in the language specified in the Bid Data Sheet. Supporting documents and printed literature furnished by the Bidder may be in another language provided they are accompanied by an accurate translation of the relevant passages in the language specified in the Bid Data Sheet, in which case, for purposes of interpretation of the Bid, the translation shall govern.

9. Documents Comprising the Bid

- 9.1 The bid prepared by the Bidder shall comprise the following components:
- a) a Bid Form and a Price Schedule completed in accordance with ITB Clauses 10, 11, and 12;
 - b) documentary evidence established in accordance with ITB Clause 13 that the Bidder is eligible to bid and is qualified to perform the contract if its bid is accepted;
 - c) documentary evidence established in accordance with ITB Clause 14 that the goods and ancillary services to be supplied by the Bidder are eligible goods and services and conform to the bidding documents; and
 - d) bid security furnished in accordance with ITB Clause 15.

10. Bid Form

- 10.1 The Bidder shall complete the Bid Form and the appropriate Price Schedule furnished in the bidding documents, indicating the goods to be supplied, a brief description of the goods, their country of origin, quantity, and prices.

11. Bid Prices

- 11.1 The Bidder shall indicate on the appropriate Price Schedule the unit prices (where applicable) and total bid price of the goods it proposes to supply under the contract.
- 11.2 **For goods offered within the purchaser's country**, prices indicated on the relevant Price Schedule shall be on delivered duty paid (DDP) and/or **For goods offered from outside the purchaser's country**, prices indicated on the relevant Price Schedule shall be on CFR / CNF / C&F / CPT – Karachi basis. The price of other (incidental) services, if any, listed in the Bid Data Sheet will be entered separately
- 11.3 The Bidder's separation of price components in accordance with ITB Clause 11.2 above will be solely for the purpose of facilitating the comparison of bids by the Procuring agency and will not in any way limit the Procuring agency's right to contract on any of the terms offered.
- 11.4 Prices quoted by the Bidder shall be fixed during the Bidder's performance of the

contract and not subject to variation on any account, unless otherwise specified in the Bid Data Sheet. A bid submitted with an adjustable price quotation will be treated as nonresponsive and will be rejected, pursuant to ITB Clause 24. If, however, in accordance with the Bid Data Sheet, prices quoted by the Bidder shall be subject to adjustment during the performance of the contract, a bid submitted with a fixed price quotation will not be rejected, but the price adjustment would be treated as zero.

12. Bid Currencies

12.1 Prices shall be quoted in Pak Rupees unless otherwise specified in the Bid Data Sheet.

13. Documents Establishing Bidder's Eligibility and Qualification

13.1 Pursuant to ITB Clause 9, the Bidder shall furnish, as part of its bid, documents establishing the Bidder's eligibility to bid and its qualifications to perform the contract if its bid is accepted.

13.2 The documentary evidence of the Bidder's eligibility to bid shall establish to the Procuring agency's satisfaction that the Bidder, at the time of submission of its bid, is from an eligible country as defined under ITB Clause 2.

13.3 The documentary evidence of the Bidder's qualifications to perform the contract if its bid is accepted shall establish to the Procuring agency's satisfaction:

- (a) that, in the case of a Bidder offering to supply goods under the contract which the Bidder did not manufacture or otherwise produce, the Bidder has been duly authorized by the goods' Manufacturer or producer to supply the goods in the Procuring agency's country;
- (b) that the Bidder has the financial, technical, and production capability necessary to perform the contract;
- (c) that, in the case of a Bidder not doing business within the Procuring agency's country, the Bidder is or will be (if awarded the contract) represented by an Agent in that country equipped, and able to carry out the Supplier's maintenance, repair, and spare parts-stocking obligations prescribed in the Conditions of Contract and/or Technical Specifications; and
- (d) that the Bidder meets the qualification criteria listed in the Bid Data Sheet.

14. Documents Establishing Goods' Eligibility and Conformity to Bidding Documents

14.1 Pursuant to ITB Clause 9, the Bidder shall furnish, as part of its bid, documents establishing the eligibility and conformity to the bidding documents of all goods and services which the Bidder proposes to supply under the contract.

14.2 The documentary evidence of the eligibility of the goods and services shall consist of a statement in the Price Schedule of the country of origin of the goods and services offered which shall be confirmed by a certificate of origin issued at the time of shipment.

- 14.3 The documentary evidence of conformity of the goods and services to the bidding documents may be in the form of literature, drawings, and data, and shall consist of:
- a. a detailed description of the essential technical and performance characteristics of the goods;
 - b. a list giving full particulars, including available sources and current prices of spare parts, special tools, etc., necessary for the proper and continuing functioning of the goods for a period to be specified in the Bid Data Sheet, following commencement of the use of the goods by the Procuring agency; and
 - c. an item-by-item commentary on the Procuring agency's Technical Specifications demonstrating substantial responsiveness of the goods and services to those specifications, or a statement of deviations and exceptions to the provisions of the Technical Specifications.
- 14.4 For purposes of the commentary to be furnished pursuant to ITB Clause 14.3(c) above, the Bidder shall note that standards for workmanship, material, and equipment, as well as references to brand names or catalogue numbers designated by the Procuring agency in its Technical Specifications, are intended to be descriptive only and not restrictive. The Bidder may substitute alternative standards, brand names, and/or catalogue numbers in its bid, provided that it demonstrates to the Procuring agency's satisfaction that the substitutions ensure substantial equivalence to those designated in the Technical Specifications.

15 Bid Security

- 15.1 Pursuant to ITB Clause 9, the Bidder shall furnish, as part of its bid, a bid security in the amount specified in the Bid Data Sheet.
- 15.2 The bid security is required to protect the Procuring agency against the risk of Bidder's conduct which would warrant the security's forfeiture, pursuant to ITB Clause 15.7.
- 15.3 The bid security shall be in Pak. Rupees and shall be in one of the following forms:
- (a) a bank guarantee or an irrevocable letter of credit issued by a reputable bank located in the Procuring agency's country, in the form provided in the bidding documents or another form acceptable to the Procuring agency and valid for thirty (30) days beyond the validity of the bid; or
 - (b) irrevocable encashable on-demand Bank call-deposit.
- 15.4 Any bid not secured in accordance with ITB Clauses 15.1 and 15.3 will be rejected by the Procuring agency as nonresponsive, pursuant to ITB Clause 24.
- 15.5 Unsuccessful bidders' bid security will be discharged or returned as promptly as possible but not later than thirty (30) days after the expiration of the period of bid validity prescribed by the Procuring agency pursuant to ITB Clause 16.
- 15.6 The successful Bidder's bid security will be discharged upon the Bidder signing the contract, pursuant to ITB Clause 32, and furnishing the performance security, pursuant to ITB Clause 33.

- 15.7 The bid security may be forfeited:
- (a) if a Bidder withdraws its bid during the period of bid validity specified by the Bidder on the Bid Form; or
 - (b) in the case of a successful Bidder, if the Bidder fails:
 - (i) to sign the contract in accordance with ITB Clause 32;
 - or**
 - (ii) to furnish performance security in accordance with ITB Clause 33.

16 Period of Validity of Bids

- 16.1 Bids shall remain valid for the period specified in the Bid Data Sheet after the date of bid opening prescribed by the Procuring agency, pursuant to ITB Clause 19. A bid valid for a shorter period shall be rejected by the Procuring agency as nonresponsive.
- 16.2 In exceptional circumstances, the Procuring agency may solicit the Bidder's consent to an extension of the period of validity. The request and the responses thereto shall be made in writing. The bid security provided under ITB Clause 15 shall also be suitably extended. A Bidder may refuse the request without forfeiting its bid security. A Bidder granting the request will not be required nor permitted to modify its bid, except as provided in the bidding document.

17 Format and Signing of Bid

- 17.1 The Bidder shall prepare an original and the number of copies of the bid indicated in the Bid Data Sheet, clearly marking each "ORIGINAL BID" and "COPY OF BID," as appropriate. In the event of any discrepancy between them, the original shall govern.
- 17.2 The original and the copy or copies of the bid shall be typed or written in indelible ink and shall be signed by the Bidder or a person or persons duly authorized to bind the Bidder to the contract. All pages of the bid, except for un-amended printed literature, shall be initialed by the person or persons signing the bid.
- 17.3 Any interlineations, erasures, or overwriting shall be valid only if they are initialed by the person or persons signing the bid.
- 17.4 The Bidder shall furnish information as described in the Form of Bid on commissions or gratuities, if any, paid or to be paid to agents relating to this Bid, and to contract execution if the Bidder is awarded the contract.

D. Submission of Bids

18 Sealing and Marking of Bids

- 18.1 The Bidder shall seal the original and each copy of the bid in separate envelopes, duly marking the envelopes as "ORIGINAL" and "COPY." The envelopes shall then be sealed in an outer envelope.
- 18.2 The inner and outer envelopes shall:
- (a) be addressed to the Procuring agency at the address given in the Bid Data Sheet; and

- (b) bear the Project name indicated in the Bid Data Sheet, the Invitation for Bids (IFB) title and number indicated in the Bid Data Sheet, and a statement: “DO NOT OPEN BEFORE,” to be completed with the time and the date specified in the Bid Data Sheet, pursuant to ITB Clause 2.2.

18.3 The inner envelopes shall also indicate the name and address of the Bidder to enable the bid to be returned unopened in case it is declared “late”.

18.4 If the outer envelope is not sealed and marked as required by ITB Clause 18.2, the Procuring agency will assume no responsibility for the bid’s misplacement or premature opening.

19 Deadline for Submission of Bids

19.1 Bids must be received by the Procuring agency at the address specified under ITB Clause 18.2 no later than the time and date specified in the Bid Data Sheet.

19.2 The Procuring agency may, at its discretion, extend this deadline for the submission of bids by amending the bidding documents in accordance with ITB Clause 7, in which case all rights and obligations of the Procuring agency and bidders previously subject to the deadline will thereafter be subject to the deadline as extended.

20 Late Bids

20.1 Any bid received by the Procuring agency after the deadline for submission of bids prescribed by the Procuring agency pursuant to ITB Clause 19 will be rejected and returned unopened to the Bidder.

21 Modification and Withdrawal of Bids

21.1 The Bidder may modify or withdraw its bid after the bid’s submission, provided that written notice of the modification, including substitution or withdrawal of the bids, is received by the Procuring agency prior to the deadline prescribed for submission of bids.

21.2 The Bidder’s modification or withdrawal notice shall be prepared, sealed, marked, and dispatched in accordance with the provisions of ITB Clause 18. by a signed confirmation copy, postmarked not later than the deadline for submission of bids.

21.3 No bid may be modified after the deadline for submission of bids.

21.4 No bid may be withdrawn in the interval between the deadline for submission of bids and the expiration of the period of bid validity specified by the Bidder on the Bid Form. Withdrawal of a bid during this interval may result in the Bidder’s forfeiture of its bid security, pursuant to the ITB Clause 15.7.

E. Opening and Evaluation of Bids

22 Opening of Bids by the Procuring agency

22.1 The Procuring agency will open all bids in the presence of bidders’ representatives who choose to attend, at the time, on the date, and at the place specified in the Bid Data Sheet. The bidders’ representatives who are present shall sign a register evidencing their attendance.

- 22.2 The bidders' names, bid modifications or withdrawals, bid prices, discounts, and the presence or absence of requisite bid security and such other details as the Procuring agency, at its discretion, may consider appropriate, will be announced at the opening. No bid shall be rejected at bid opening, except for late bids, which shall be returned unopened to the Bidder pursuant to ITB Clause 20.
- 22.3 Bids (and modifications sent pursuant to ITB Clause 21.2) that are not opened and read out at bid opening shall not be considered further for evaluation, irrespective of the circumstances. Withdrawn bids will be returned unopened to the bidders.
- 22.4 The Procuring agency will prepare minutes of the bid opening.

23 Clarification of Bids

- 23.1 During evaluation of the bids, the Procuring agency may, at its discretion, ask the Bidder for a clarification of its bid. The request for clarification and the response shall be in writing, and no change in the prices or substance of the bid shall be sought, offered, or permitted.

24 Preliminary Examination

- 24.1 The Procuring agency will examine the bids to determine whether they are complete, whether any computational errors have been made, whether required sureties have been furnished, whether the documents have been properly signed, and whether the bids are generally in order.
- 24.2 Arithmetical errors will be rectified on the following basis. If there is a discrepancy between the unit price and the total price that is obtained by multiplying the unit price and quantity, the unit price shall prevail, and the total price shall be corrected. If the Supplier does not accept the correction of the errors, its bid will be rejected, and its bid security may be forfeited. If there is a discrepancy between words and figures, the amount in words will prevail.
- 24.3 The Procuring agency may waive any minor informality, nonconformity, or irregularity in a bid which does not constitute a material deviation, provided such waiver does not prejudice or affect the relative ranking of any Bidder.
- 24.4 Prior to the detailed evaluation, pursuant to ITB Clause 25 the Procuring agency will determine the substantial responsiveness of each bid to the bidding documents. For purposes of these Clauses, a substantially responsive bid is one which conforms to all the terms and conditions of the bidding documents without material deviations. Deviations from, or objections or reservations to critical provisions, **such as** those concerning Bid Security (ITB Clause 15), Applicable Law (GCC Clause 30), and Taxes and Duties (GCC Clause 32), will be deemed to be a material deviation. The Procuring agency's determination of a bid's responsiveness is to be based on the contents of the bid itself without recourse to extrinsic evidence.
- 24.5 If a bid is not substantially responsive, it will be rejected by the Procuring agency and may not subsequently be made responsive by the Bidder by correction of the nonconformity.

25 Evaluation and Comparison of Bids

- 25.1 The Procuring agency will evaluate and compare the bids which have been determined to be substantially responsive, pursuant to ITB Clause 24.
- 25.2 The Procuring agency's evaluation of a bid will be on delivered duty paid (DDP) price inclusive of prevailing taxes and duties and/or on CFR / CNF / C&F / CPT – Karachi basis and will exclude any allowance for price adjustment during the period of execution of the contract, if provided in the bid.
- 25.3 The Procuring agency's evaluation of a bid will take into account, in addition to the bid price quoted in accordance with ITB Clause 11.2, one or more of the following factors as specified in the Bid Data Sheet, and quantified in ITB Clause 25.4:
- (a) incidental costs
 - (b) delivery schedule offered in the bid;
 - (c) deviations in payment schedule from that specified in the Special Conditions of Contract;
 - (d) the cost of components, mandatory spare parts, and service;
 - (e) the availability Procuring agency of spare parts and after- sales services for the equipment offered in the bid;
 - (f) the projected operating and maintenance costs during the life of the equipment;
 - (g) the performance and productivity of the equipment offered; and/or
 - (h) other specific criteria indicated in the Bid Data Sheet and/or in the Technical Specifications.
- 25.4 For factors retained in the Bid Data Sheet pursuant to ITB 25.3, one or more of the following quantification methods will be applied, as detailed in the Bid Data Sheet:
- (a) Incidental costs provided by the bidder will be added by Procuring agency to the delivered duty paid (DDP) price at the final destination.
 - (b) *Delivery schedule.*
 - (i) The Procuring agency requires that the goods under the Invitation for Bids shall be delivered at the time specified in the Schedule of Requirements which will be treated as the base, a delivery "adjustment" will be calculated for bids by applying a percentage, specified in the Bid Data Sheet, of the DDP price for each week of delay beyond the base, and this will be added to the bid price for evaluation. No credit shall be given to early delivery.
 - or**
 - (ii) The goods covered under this invitation are required to be delivered (shipped) within an acceptable range of weeks specified in the Schedule of Requirement. No credit will be given to earlier deliveries, and bids offering delivery beyond this range will be treated as nonresponsive. Within this acceptable range, an adjustment per week, as specified in the Bid Data Sheet, will be added for evaluation to the bid price of bids offering deliveries later than the earliest delivery period specified in the Schedule of Requirements.

or

- (iii) The goods covered under this invitation are required to be delivered in partial shipments, as specified in the Schedule of Requirements. Bids offering deliveries earlier or later than the specified deliveries will be adjusted in the evaluation by adding to the bid price a factor equal to a percentage, specified in the Bid Data Sheet, of DDP price per week of variation from the specified delivery schedule.

(c) *Deviation in payment schedule.*

- (i) Bidders shall state their bid price for the payment schedule outlined in the SCC. Bids will be evaluated on the basis of this base price. Bidders are, however, permitted to state an alternative payment schedule and indicate the reduction in bid price they wish to offer for such alternative payment schedule. The Procuring agency may consider the alternative payment schedule offered by the selected Bidder.

or

- (ii) The SCC stipulates the payment schedule offered by the Procuring agency. If a bid deviates from the schedule and if such deviation is considered acceptable to the Procuring agency, the bid will be evaluated by calculating interest earned for any earlier payments involved in the terms outlined in the bid as compared with those stipulated in this invitation, at the rate per annum specified in the Bid Data Sheet.

(d) *Cost of spare parts.*

- (i) The list of items and quantities of major assemblies, components, and selected spare parts, likely to be required during the initial period of operation specified in the Bid Data Sheet, is annexed to the Technical Specifications. The total cost of these items, at the unit prices quoted in each bid, will be added to the bid price.

or

- (ii) The Procuring agency will draw up a list of high-usage and high-value items of components and spare parts, along with estimated quantities of usage in the initial period of operation specified in the Bid Data Sheet. The total cost of these items and quantities will be computed from spare parts unit prices submitted by the Bidder and added to the bid price.

or

- (iii) The Procuring agency will estimate the cost of spare parts usage in the initial period of operation specified in the Bid Data Sheet, based on information furnished by each Bidder, as well as on past experience of the Procuring agency or other procuring agencies in similar situations. Such costs shall be added to the bid price for evaluation.

(e) *Spare parts and after sales service facilities in the Procuring agency's country.*

The cost to the Procuring agency of establishing the minimum service facilities and parts inventories, as outlined in the Bid Data Sheet or elsewhere in the bidding documents, if quoted separately, shall be added to the bid price.

(f) *Operating and maintenance costs.*

Since the operating and maintenance costs of the goods under procurement form a major part of the life cycle cost of the equipment, these costs will be evaluated in accordance with the criteria specified in the Bid Data Sheet or in the Technical Specifications.

(g) *Performance and productivity of the equipment.*

(i) Bidders shall state the guaranteed performance or efficiency in response to the Technical Specification. For each drop in the performance or efficiency below the norm of 100, an adjustment for an amount specified in the Bid Data Sheet will be added to the bid price, representing the capitalized cost of additional operating costs over the life of the plant, using the methodology specified in the Bid Data Sheet or in the Technical Specifications.

or

(ii) Goods offered shall have a minimum productivity specified under the relevant provision in the Technical Specifications to be considered responsive. Evaluation shall be based on the cost per unit of the actual productivity of goods offered in the bid, and adjustment will be added to the bid price using the methodology specified in the Bid Data Sheet or in the Technical Specifications.

(h) *Specific additional criteria indicated in the Bid Data Sheet and/or in the Technical Specifications.*

The relevant evaluation method shall be detailed in the Bid Data Sheet and/or in the Technical Specifications.

Alternative

25.4 Merit Point System:

The following merit point system for weighing evaluation factors can be applied if none of the evaluation methods listed in 25.4 above has been retained in the Bid Data Sheet. The number of points allocated to each factor shall be specified in the Bid Data Sheet.

[In the Bid Data Sheet, choose from the range of]

Evaluated price of the goods	60 to 90
Cost of common list spare parts	0 to 20
Technical features, and maintenance and operating costs	0 to 20
Availability of service and spare parts	0 to 20
Standardization	0 to 20
Total	100

The bid scoring the highest number of points will be deemed to be the lowest evaluated bid.

26 Contacting the Procuring agency

- 26.1 Subject to ITB Clause 23, no Bidder shall contact the Procuring agency on any matter relating to its bid, from the time of the bid opening to the time the contract is awarded. If the Bidder wishes to bring additional information to the notice of the Procuring agency, it should do so in writing.
- 26.2 Any effort by a Bidder to influence the Procuring agency in its decisions on bid evaluation, bid comparison, or contract award may result in the rejection of the Bidder's bid.

F. Award of Contract

27 Post-qualification

- 27.1 In the absence of prequalification, the Procuring agency will determine to its satisfaction whether the Bidder that is selected as having submitted the lowest evaluated responsive bid is qualified to perform the contract satisfactorily, in accordance with the criteria listed in ITB Clause 13.3.
- 27.2 The determination will take into account the Bidder's financial, technical, and production capabilities. It will be based upon an examination of the documentary evidence of the Bidder's qualifications submitted by the Bidder, pursuant to ITB Clause 13.3, as well as such other information as the Procuring agency deems necessary and appropriate.
- 27.3 An affirmative determination will be a prerequisite for award of the contract to the Bidder. A negative determination will result in rejection of the Bidder's bid, in which event the Procuring agency will proceed to the next lowest evaluated bid to make a similar determination of that Bidder's capabilities to perform satisfactorily.

28 Award Criteria

- 28.1 Subject to ITB Clause 30, the Procuring agency will award the contract to the successful Bidder whose bid has been determined to be substantially responsive and has been determined to be the lowest evaluated bid, provided further that the Bidder is determined to be qualified to perform the contract satisfactorily.

29 Procuring agency's Right to Vary Quantities at Time of Award

- 29.1 The Procuring agency reserves the right at the time of contract award to increase or decrease, the quantity of goods and services originally specified in the Schedule of Requirements without any change in unit price or other terms and conditions.

30 Procuring agency's Right to Accept any Bid and to Reject any or All Bids

- 30.1 The Procuring agency reserves the right to accept or reject any bid, and to annul the bidding process and reject all bids at any time prior to contract award, without thereby incurring any liability to the affected Bidder or bidders or any obligation to inform the affected Bidder or bidders of the grounds for the Procuring agency's action.

31 Notification of Award

- 31.1 Prior to the expiration of the period of bid validity, the Procuring agency will notify the successful Bidder in writing by registered letter or by cable, to be confirmed in writing by registered letter, that its bid has been accepted.
- 31.2 The notification of award will constitute the formation of the Contract.
- 31.3 Upon the successful Bidder's furnishing of the performance security pursuant to ITB Clause 33, the Procuring agency will promptly notify each unsuccessful Bidder and will discharge its bid security, pursuant to ITB Clause 15.

32 Signing of Contract

- 32.1 At the same time as the Procuring agency notifies the successful Bidder that its bid has been accepted, the Procuring agency will send the Bidder the Contract Form provided in the bidding documents, incorporating all agreements between the parties.
- 32.2 Within thirty (30) days of receipt of the Contract Form, the successful Bidder shall sign and date the contract and return it to the Procuring agency.

33 Performance Security

- 33.1 Within twenty (20) days of the receipt of notification of award from the Procuring agency, the successful Bidder shall furnish the performance security in accordance with the Conditions of Contract, in the Performance Security Form provided in the bidding documents, or in another form acceptable to the Procuring agency.
- 33.2 Failure of the successful Bidder to comply with the requirement of ITB Clause 32 or ITB Clause 33.1 shall constitute sufficient grounds for the annulment of the award and forfeiture of the bid security, in which event the Procuring agency may make the award to the next lowest evaluated Bidder or call for new bids.

34 Corrupt or Fraudulent Practices

- 34.1 The Government of Sindh requires that Procuring agency's (including beneficiaries of donor agencies' loans), as well as Bidders/Suppliers/Contractors under Government-financed or Procuring Agency-financed contracts, observe the highest standard of ethics during the procurement and execution of such contracts. In pursuance of this policy, the SPPRA, in accordance with the SPP Act, 2009 and Rules made thereunder:
 - (a) defines, for the purposes of this provision, the terms set forth below as follows:
 - (i) "corrupt practice" means the offering, giving, receiving or soliciting of anything of value to influence the action of a public official in the procurement process or in contract execution; and
 - (ii) "fraudulent practice" means a misrepresentation of facts in order to influence a procurement process or the execution of a contract to the detriment of the Procuring agency, and

includes collusive practice among Bidders (prior to or after bid submission) designed to establish bid prices at artificial non- competitive levels and to deprive the Procuring agency of the benefits of free and open competition;

- (b) will reject a proposal for award if it determines that the Bidder recommended for award has engaged in corrupt or fraudulent practices in competing for the contract in question;
- (c) will declare a firm ineligible, either indefinitely or for a stated period of time, to be awarded a Government-financed contract if it at any time determines that the firm has engaged in corrupt or fraudulent practices in competing for, or in executing, a Government-financed contract.

34.2 Furthermore, Bidders shall be aware of the provision stated in sub-clause 5.4 and sub-clause 24.1 of the General Conditions of Contract.

Part One - Section II
General Conditions of Contract

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General Conditions of Contract

1. Definitions

1.1 In this Contract, the following terms shall be interpreted as indicated:

- (a) “The Contract” means the agreement entered into between the Procuring agency and the Supplier, as recorded in the Contract Form signed by the parties, including all attachments and appendices thereto and all documents incorporated by reference therein.
- (b) “The Contract Price” means the price payable to the Supplier under the Contract for the full and proper performance of its contractual obligations.
- (c) “The Goods” means all of the equipment, machinery, and/or other materials which the Supplier is required to supply to the Procuring agency under the Contract.
- (d) “The Services” means those services ancillary to the supply of the Goods, such as transportation and insurance, and any other incidental services, such as installation, commissioning, provision of technical assistance, training, and other such obligations of the Supplier covered under the Contract.
- (e) “GCC” means the General Conditions of Contract contained in this section.
- (f) “SCC” means the Special Conditions of Contract.
- (g) “The Procuring agency” means the organization purchasing the Goods, as named in SCC.
- (h) “The Procuring agency’s country” is the country named in SCC.
- (i) “The Supplier” means the individual or firm supplying the Goods and Services under this Contract.
- (j) “The Project Site,” where applicable, means the place or places named in SCC.
- (k) “Day” means calendar day.

2. Application

2.1 These General Conditions shall apply to the extent that they are not superseded by provisions of other parts of the Contract.

3. Country of Origin

3.1 All Goods and Services supplied under the Contract shall have their origin in the countries and territories eligible under the rules and further elaborated in the SCC or Technical Specifications.

3.2 For purposes of this Clause, “origin” means the place where the Goods were mined, grown, or produced, or from which the Services are supplied. Goods are produced when, through manufacturing, processing, or substantial and major

assembly of components, a commercially recognized new product results that is substantially different in basic characteristics or in purpose or utility from its components.

3.3 The origin of Goods and Services is distinct from the nationality of the Manufacturer / Supplier.

4. Technical Specifications

4.1 The Goods supplied under this Contract shall conform to the standards mentioned in the Technical Specifications, and, when no applicable standard is mentioned, to the authoritative standards appropriate to the Goods' country of origin. Such standards shall be the latest issued by the concerned institution.

5. Use of Contract Documents and Information; Inspection and Audit by the Government

5.1 The Supplier shall not, without the Procuring agency's prior written consent, disclose the Contract, or any provision thereof, or any specification, plan, drawing, pattern, sample, or information furnished by or on behalf of the Procuring agency in connection therewith, to any person other than a person employed by the Supplier in the performance of the Contract. Disclosure to any such employed person shall be made in confidence and shall extend only so far as may be necessary for purposes of such performance.

5.2 The Supplier shall not, without the Procuring agency's prior written consent, make use of any document or information enumerated in GCC Clause 5.1 except for purposes of performing the Contract.

5.3 Any document, other than the Contract itself, enumerated in GCC Clause 5.1 shall remain the property of the Procuring agency and shall be returned (all copies) to the Procuring agency on completion of the Supplier's performance under the Contract if so required by the Procuring agency.

5.4 The Supplier shall permit the Procuring agency to inspect the Supplier's accounts and records relating to the performance of the Supplier and to have them audited by auditors appointed by the procuring agency, if so required.

6. Patent Rights

6.1 The Supplier shall indemnify the Procuring agency against all third-party claims of infringement of patent, trademark, or industrial design rights arising from use of the Goods or any part thereof in the Procuring agency's country.

7. Performance Security

7.1 Within twenty (20) days of receipt of the notification of Contract award, the successful Bidder shall furnish to the Procuring agency the performance security in the amount specified in SCC.

7.2 The proceeds of the performance security shall be payable to the Procuring agency as compensation for any loss resulting from the Supplier's failure to complete its obligations under the Contract.

7.3 The performance security shall be denominated in the currency of the Contract acceptable to the Procuring agency and shall be in one of the following forms:

(a) a bank guarantee or an irrevocable letter of credit issued by a reputable

bank located in the Procuring agency's country, in the form provided in the bidding documents or another form acceptable to the Procuring agency; or

(b) a cashier's or certified check.

7.4 The performance security will be discharged by the Procuring agency and returned to the Supplier not later than thirty (30) days following the date of completion of the Supplier's performance obligations under the Contract, including any warranty obligations, unless specified otherwise in SCC.

8. Inspections and Tests

8.1 The Procuring agency or its representative shall have the right to inspect and/or to test the Goods to confirm their conformity to the Contract specifications at no extra cost to the Procuring agency. SCC and the Technical Specifications shall specify what inspections and tests the Procuring agency requires and where they are to be conducted. The Procuring agency shall notify the Supplier in writing, in a timely manner, of the identity of any representatives retained for these purposes.

8.2 The inspections and tests may be conducted on the premises of the Supplier or its subcontractor(s), at point of delivery, and/or at the Goods' final destination. If conducted on the premises of the Supplier or its subcontractor(s), all reasonable facilities and assistance, including access to drawings and production data, shall be furnished to the inspectors at no charge to the Procuring agency

8.3 Should any inspected or tested Goods fail to conform to the Specifications, the Procuring agency may reject the Goods, and the Supplier shall either replace the rejected Goods or make alterations necessary to meet specification requirements free of cost to the Procuring agency.

8.4 The Procuring agency's right to inspect, test and, where necessary, reject the Goods after the Goods' arrival in the Procuring agency's country shall in no way be limited or waived by reason of the Goods having previously been inspected, tested, and passed by the Procuring agency or its representative prior to the Goods' shipment from the country of origin.

8.5 Nothing in GCC Clause 8 shall in any way release the Supplier from any warranty or other obligations under this Contract.

9. Packing

9.1 The Supplier shall provide such packing of the Goods as is required to prevent their damage or deterioration during transit to their final destination, as indicated in the Contract. The packing shall be sufficient to withstand, without limitation, rough handling during transit and exposure to extreme temperatures, salt and precipitation during transit, and open storage. Packing case size and weights shall take into consideration, where appropriate, the remoteness of the Goods' final destination and the absence of heavy handling facilities at all points in transit.

9.2 The packing, marking, and documentation within and outside the packages shall comply strictly with such special requirements as shall be expressly provided for

in the Contract, including additional requirements, if any, specified in SCC, and in any subsequent instructions ordered by the Procuring agency.

10. Delivery and Documents

10.1 Delivery of the Goods shall be made by the Supplier in accordance with the terms specified in the Schedule of Requirements. The details of shipping and/or other documents to be furnished by the Supplier are specified in SCC.

10.2 Documents to be submitted by the Supplier are specified in SCC.

11. Insurance

11.1 The Goods supplied under the Contract shall be delivered duty paid (DDP) / CFR / CNF / C&F / CPT – Karachi under which risk is transferred to the buyer after having been delivered at consignees end or Karachi Port, hence insurance coverage is sellers responsibility.

12. Transportation

12.1 The Supplier is required under the Contract to transport the Goods to a specified place of destination outside and within the Procuring agency's country, transport to such place of destination in the Procuring agency's country, including insurance and storage, as shall be specified in the Contract, shall be arranged by the Supplier, and related costs shall be included in the Contract Price.

13. Incidental Services

13.1 The Supplier may be required to provide any or all of the following services, including additional services, if any, specified in SCC:

- (a) performance or supervision of on-site assembly and/or start-up of the supplied Goods;
- (b) furnishing of tools required for assembly and/or maintenance of the supplied Goods;
- (c) furnishing of a detailed operations and maintenance manual for each appropriate unit of the supplied Goods;
- (d) performance or supervision or maintenance and/or repair of the supplied Goods, for a period of time agreed by the parties, provided that this service shall not relieve the Supplier of any warranty obligations under this Contract; and
- (e) training of the Procuring agency's personnel, at the Supplier's plant and/or on-site, in assembly, start-up, operation, maintenance, and/or repair of the supplied Goods.

13.2 Prices charged by the Supplier for incidental services, if not included in the Contract Price for the Goods, shall be agreed upon in advance by the parties and shall not exceed the prevailing rates charged for other parties by the Supplier for similar services.

14. Spare Parts

14.1 As specified in SCC, the Supplier may be required to provide any or all of the following materials, notifications, and information pertaining to spare parts

manufactured or distributed by the Supplier:

- (a) such spare parts as the Procuring agency may elect to purchase from the Supplier, provided that this election shall not relieve the Supplier of any warranty obligations under the Contract; and
- (b) in the event of termination of production of the spare parts:
 - (i) advance notification to the Procuring agency of the pending termination, in sufficient time to permit the Procuring agency to procure needed requirements; and
 - (ii) following such termination, furnishing at no cost to the Procuring agency, the blueprints, drawings, and specifications of the spare parts, if requested.

15. Warranty

- 15.1 The Supplier warrants that the Goods supplied under the Contract are new, unused, of the most recent or current models, and that they incorporate all recent improvements in design and materials unless provided otherwise in the Contract. The Supplier further warrants that all Goods supplied under this Contract shall have no defect, arising from design, materials, or workmanship (except when the design and/or material is required by the Procuring agency's specifications) or from any act or omission of the Supplier, that may develop under normal use of the supplied Goods in the conditions prevailing in the country of final destination.
- 15.2 This warranty shall remain valid for twelve (12) months or according to the requirement of extended warranty period after the Goods, or any portion thereof as the case may be, have been delivered to and accepted at the final destination indicated in the Contract. In any case this period shall not exceed six (06) months beyond the warranty expiration period from the date of taking over of goods by the procuring agency, unless specified otherwise in SCC.
- 15.3 The Procuring agency shall promptly notify the Supplier in writing of any claims arising under this warranty.
- 15.4 Upon receipt of such notice, the Supplier shall, within the period specified in SCC and with all reasonable speed, repair or replace the defective Goods or parts thereof, without costs to the Procuring agency.
- 15.5 If the Supplier, having been notified, fails to remedy the defect(s) within the period specified in SCC, within a reasonable period, the Procuring agency may proceed to take such remedial action as may be necessary, at the Supplier's risk and expense and without prejudice to any other rights which the Procuring agency may have against the Supplier under the Contract.
- 15.6 The provisions of this Clause include all the expenses that the bidder may have to incur for delivery and installation of such replacement parts, material and equipment as are needed for satisfactory operation of the goods at the consignees end.
- 15.7 During the period of warranty, the bidder shall remedy, at his / her expense all

defects in design, material and workmanship that may develop or are revealed under normal use of the goods upon receiving writing notice from the procuring agency; the notice shall indicate in what respect the goods are faulty.

- 15.8 The bidder shall provide warranty / guarantee for supply of reagents, kits and chemicals, consumables, films and ancillaries for at least 10 years (where applicable).
- 15.9 The bidder shall remain responsible for providing after sale services even after expiry of warranty / guarantee period and sign a Service Contract including parts or without parts with Procuring Agency for 05 years (minimum). Bidder shall separately quote the price of service contract (in terms of percentage) inclusive of parts and without parts, separately.
- 15.10 In case of consumable items, reagents, kits, chemicals, films etc. the contractor shall remain responsible for specificity, efficacy & sensitivity with maximum period of expiry as much allowed by manufacturer.
- 15.11 The Procuring Agency shall promptly notify the Bidder in writing of any claims arising out of this warranty.
- 15.12 The bidder shall be responsible to ensure the 90% uptime of the machinery / equipment during the warranty period.

16. Payment

- 16.1 The method and conditions of payment to be made to the Supplier under this Contract shall be specified in SCC.
- 16.2 The Supplier's request(s) for payment shall be made to the Procuring agency in writing, accompanied by an invoice describing, as appropriate, the Goods delivered and Services performed, and by documents submitted pursuant to GCC Clause 10, and upon fulfillment of other obligations stipulated in the Contract.
- 16.3 Payments shall be made promptly by the Procuring agency, but in no case later than sixty (60) days after submission of an invoice or claim by the Supplier.
- 16.4 The currency of payment shall be in Pak. Rupees for Goods supplied from within the Procuring Agency's country on DDP basis and payment shall be made in Foreign Currency. through irrevocable letter of credit for Goods supplied from outside the Procuring Agency's country on CFR / CNF/ C&F / CPT Karachi Basis.

17. Prices

- 17.1 Prices charged by the Supplier for Goods delivered and Services performed under the Contract shall not vary from the prices quoted by the Supplier in its bid, with the exception of any price adjustments authorized in SCC or in the Procuring agency's request for bid validity extension, as the case may be.

18. Change Orders

- 18.1 The Procuring agency may at any time, by a written order given to the Supplier

pursuant to GCC Clause 31, make changes within the general scope of the Contract in any one or more of the following:

- (a) drawings, designs, or specifications, where Goods to be furnished under the Contract are to be specifically manufactured for the Procuring agency;
- (b) the method of shipment or packing;
- (c) the place of delivery; and/or
- (d) the Services to be provided by the Supplier.

18.2 If any such change causes an increase or decrease in the cost of, or the time required for, the Supplier's performance of any provisions under the Contract, an equitable adjustment shall be made in the Contract Price or delivery schedule, or both, and the Contract shall accordingly be amended. Any claims by the Supplier for adjustment under this clause must be asserted within thirty (30) days from the date of the Supplier's receipt of the Procuring agency's change order.

19. Contract Amendments

19.1 Subject to GCC Clause 18, no variation in or modification of the terms of the Contract shall be made except by written amendment signed by the parties.

20. Assignment

20.1 The Supplier shall not assign, in whole or in part, its obligations to perform under this Contract, except with the Procuring agency's prior written consent.

21. Subcontracts

21.1 The Supplier shall notify the Procuring agency in writing of all subcontracts awarded under this Contract if not already specified in the bid. Such notification, in the original bid or later, shall not relieve the Supplier from any liability or obligation under the Contract.

21.2 Subcontracts must comply with the provisions of GCC Clause 3.

22. Delay in the Supplier's Performance

22.1 Delivery of the Goods and performance of Services shall be made by the Supplier in accordance with the time schedule prescribed by the Procuring agency in the Schedule of Requirements / Contract Award.

22.2 If at any time during performance of the Contract, the Supplier or its subcontractor(s) should encounter conditions impeding timely delivery of the Goods and performance of Services, the Supplier shall promptly notify the Procuring agency in writing of the fact of the delay, its likely duration and its cause(s). As soon as practicable after receipt of the Supplier's notice, the Procuring agency shall evaluate the situation and may at its discretion extend the Supplier's time for performance, with or without liquidated damages, in which case the extension shall be ratified by the parties by amendment of Contract.

22.3 Except as provided under GCC Clause 25, a delay by the Supplier in the performance of its delivery obligations shall render the Supplier liable to the imposition of liquidated damages pursuant to GCC Clause 23, unless an extension of time is agreed upon pursuant to GCC Clause 22.2 without the application of

liquidated damages.

23. Liquidated Damages

23.1 Subject to GCC Clause 25, if the Supplier fails to deliver any or all of the Goods or to perform the Services within the period(s) specified in the Contract, the Procuring agency shall, without prejudice to its other remedies under the Contract, deduct from the Contract Price, as liquidated damages, a sum equivalent to the percentage specified in SCC of the delivered price of the delayed Goods or unperformed Services for each week or part thereof of delay until actual delivery or performance, up to a maximum deduction of the percentage specified in SCC. Once the maximum is reached, the Procuring agency may consider termination of the Contract pursuant to GCC Clause 24.

24. Termination for Default

24.1 The Procuring agency, without prejudice to any other remedy for breach of Contract, by written notice of default sent to the Supplier, may terminate this Contract in whole or in part:

- (a) if the Supplier fails to deliver any or all of the Goods within the period(s) specified in the Contract, or within any extension thereof granted by the Procuring agency pursuant to GCC Clause 22; or
- (b) if the Supplier fails to perform any other obligation(s) under the Contract.
- (c) if the Supplier, in the judgment of the Procuring agency has engaged in corrupt or fraudulent practices in competing for or in executing the Contract.

For the purpose of this clause:

“corrupt practice” means the offering, giving, receiving or soliciting of any thing of value to influence the action of a public official in the procurement process or in contract execution.

“fraudulent practice” means a misrepresentation of facts in order to influence a procurement process or the execution of a contract to the detriment of the Borrower, and includes collusive practice among Bidders (prior to or after bid submission) designed to establish bid prices at artificial non-competitive levels and to deprive the Borrower of the benefits of free and open competition.

24.2 In the event the Procuring agency terminates the Contract in whole or in part, pursuant to GCC Clause 24.1, the Procuring agency may procure, upon such terms and in such manner as it deems appropriate, Goods or Services similar to those undelivered, and the Supplier shall be liable to the Procuring agency for any excess costs for such similar Goods or Services. However, the Supplier shall continue performance of the Contract to the extent not terminated.

25. Force Majeure

25.1 Notwithstanding the provisions of GCC Clauses 22, 23, and 24, the Supplier shall not be liable for forfeiture of its performance security, liquidated damages, or termination for default if and to the extent that its delay in performance or other failure to perform its obligations under the Contract is the result of an event of

Force Majeure.

25.2 For purposes of this clause, “Force Majeure” means an event beyond the control of the Supplier and not involving the Supplier’s fault or negligence and not foreseeable. Such events may include, but are not restricted to, acts of the Procuring agency in its sovereign capacity, wars or revolutions, fires, floods, epidemics, quarantine restrictions, and freight embargoes.

25.3 If a Force Majeure situation arises, the Supplier shall promptly notify the Procuring agency in writing of such condition and the cause thereof. Unless otherwise directed by the Procuring agency in writing, the Supplier shall continue to perform its obligations under the Contract as far as is reasonably practical, and shall seek all reasonable alternative means for performance not prevented by the Force Majeure event.

26. Termination for Insolvency

26.1 The Procuring agency may at any time terminate the Contract by giving written notice to the Supplier if the Supplier becomes bankrupt or otherwise insolvent. In this event, termination will be without compensation to the Supplier, provided that such termination will not prejudice or affect any right of action or remedy which has accrued or will accrue thereafter to the Procuring agency.

27. Termination for Convenience

27.1 The Procuring agency, by written notice sent to the Supplier, may terminate the Contract, in whole or in part, at any time for its convenience. The notice of termination shall specify that termination is for the Procuring agency’s convenience, the extent to which performance of the Supplier under the Contract is terminated, and the date upon which such termination becomes effective.

27.2 The Goods that are complete and ready for shipment within thirty (30) days after the Supplier’s receipt of notice of termination shall be accepted by the Procuring agency at the Contract terms and prices. For the remaining Goods, the Procuring agency may elect:

- (a) to have any portion completed and delivered at the Contract terms and prices; and/or
- (b) to cancel the remainder and pay to the Supplier an agreed amount for partially completed Goods and Services and for materials and parts previously procured by the Supplier.

28. Resolution of disputes

28.1 The Procuring agency and the Supplier shall make every effort to resolve amicably by direct informal negotiation any disagreement or dispute arising between them under or in connection with the Contract.

28.2 If, after thirty (30) days from the commencement of such informal negotiations, the Procuring agency and the Supplier have been unable to resolve amicably a Contract dispute, either party may require that the dispute be referred for

resolution to the formal mechanisms specified in SCC. These mechanisms may include, but are not restricted to, conciliation mediated by a third party, adjudication in an agreed manner and/or arbitration.

29. Governing Language

29.1 The Contract shall be written in the language specified in SCC. Subject to GCC Clause 30, the version of the Contract written in the specified language shall govern its interpretation. All correspondence and other documents pertaining to the Contract which are exchanged by the parties shall be written in the same language.

30. Applicable Law

30.1 The Contract shall be interpreted in accordance with the laws of the Procuring agency's country (Islamic Republic of Pakistan), unless otherwise specified in SCC.

31. Notices

31.1 Any notice given by one party to the other pursuant to this Contract shall be sent to the other party in writing or by cable, telex, or facsimile and confirmed in writing to the other party's address specified in SCC.

31.2 A notice shall be effective when delivered or on the notice's effective date, whichever is later.

32. Taxes and Duties

32.1 Supplier shall be entirely responsible for all taxes, duties, license fees, etc., incurred until delivery of the contracted Goods to the Procuring agency in case of Delivered Duty Paid (DDP) basis.

Dow University of Health Sciences



Bidding Documents

Single Stage – Two Envelope Procedure
As per Rule 46 (2) of SPPR, 2010 (Amended 2019)

IFB / NIT No: DUHS/DP/2021/123 Dated 03 February 2021

PROCUREMENT OF MICRO COMPACT FILLING LINE AND MACRO COMPACT FILLING LINE FOR BIO-INJECTABLES

PART TWO (PROCUREMENT SPECIFIC PROVISIONS)

- Invitation for Bids (IFB)
- Bid Data Sheet (BDS)
- Special Conditions of Contract (SCC)
- Schedule of Requirements
- Technical Specifications
- Sample Form
- Eligibility

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Part Two - Section I.

Invitation for Bids

Invitation for Bids (IFB) / Notice Inviting Tender (NIT)

IFB No: DUHS/DP/2021/123 Dated 03 February 2021

Dow University of Health Sciences (DUHS), Karachi invites sealed bids for the “**Procurement of Micro Compact Filling Line and Macro Compact Filling Line for Bio-Injectables**” from the Manufacturers / authorized Sole Agents of Manufacturers, having registration with Federal Board of Revenue (FBR) for Income Tax and Sales Tax.

Tender fee	Rs. 2,000/- (Rupees two thousand only) Non-Refundable
Bidding procedure	Single Stage – Two Envelope Procedure as per rule 46 sub rule 2 of SPP Rules 2010 (Amended 2019)
Bid security	Two (2%) percent of the total bid value.
Tender purchasing date	From the date of publishing to 19 February 2021
Deadline for submission of bids	20 February up to 11:00 Hrs.
Bid Opening Date & Time	20 February 2021 at 11:30 Hrs.

Bidding Document containing detailed terms & conditions can be obtained against non-refundable pay Order / Demand Draft of Rs. 2,000/- being tender fee in favour of Dow University of Health Sciences during office hours. No tender shall be sold on the date of opening of bid. Tender Notice and bidding documents are also available on the websites of Dow University of Health Sciences (www.duhs.edu.pk) and Sindh Public Procurement Regulatory Authority (<http://ppms.pprasindh.gov.pk>), in this situation, bidder is required to enclose Pay Order / Demand Draft of tender fee (Rs. 2000/-) with their bid, which must be issued by a scheduled bank within the tender purchasing date. DUHS may issue the clarifications or amendments in respect of the bidding documents which will be uploaded on the both websites, DUHS will not be responsible of any confusion or misunderstanding in this regard.

In case of any unforeseen situation or government holiday resulting in closure of office on the date of opening, bids shall be submitted / opened on next working day at the given time and venue.

The Dow University of Health Sciences, Karachi (DUHS) reserves the right to reject any or all the bids subject to the relevant provisions of SPP Rules 2010 (Amended 2019).

Address for Purchasing of bidding documents, submission and opening of bids:

Dow University of Health Sciences (Ojha Campus), Procurement Directorate at Library Block, SUPARCO Road, off Main University Road, Gulzar-e-Hijri, Scheme No. 33, Karachi.
Phone No. + 92-21-99261497, Email: director.procurement@duhs.edu.pk

Director Procurement
Dow University of Health Sciences, Karachi

Section II.
Bid Data Sheet

Bid Data Sheet

The following specific data for the goods to be procured shall complement, supplement, or amend the provisions in the Instructions to Bidders (ITB) Part One. Whenever there is a conflict, the provisions herein shall prevail over those in ITB.

Introduction	
ITB 1.1	Name of Procuring Agency: Dow University of Health Sciences, Karachi (DUHS)
ITB 1.1	Name of Project/Scheme/Department/Institute: Dow Institute of Life Sciences.
ITB 1.1	Name of Contract: Procurement of Micro Compact Filling Line and Macro Compact Filling Line for Bio-Injectables
ITB 4.1	Name of Procuring agency: Dow University of Health Sciences, Karachi (DUHS).
ITB 6.1	Postal Address: Dow University of Health Sciences (Ojha Campus), Procurement Directorate at Library Block, SUPARCO Road, off Main University Road, Gulzar-e-Hijri, Scheme No. 33, Karachi. Phone No. + 92-21-99261497, Email: director.procurement@duhs.edu.pk
ITB 8.1	Language of the bid shall be ENGLISH.

Bid Price and Currency	
ITB 11.2	The price quoted shall be in Pakistani Rupee for the Goods offered within the Procuring Agency's Country on delivered duty paid (DDP) Price. The price quoted shall be in foreign Currency for the Goods offered from Outside the Procuring Agency's Country on CFR / CNF/ C&F / CPT Karachi Basis. Price of incidental services, if any, must be included in price of goods
ITB 11.4	The price shall be fixed during the contract period.
ITB 12.1	For the Goods offered within the Procuring Agency's Country: the price quoted shall be in Pak Rupees on delivered duty paid (DDP) basis. For the Goods offered from Outside the Procuring Agency's Country: the price quoted shall be in Foreign Currency on CFR / CNF/ C&F / CPT- Karachi Basis.

Preparation and Submission of Bids		
ITB 13.3 (d)	Qualification requirements	
S#	Qualification Criteria	Requirement
1.	Compliance to the Technical Specifications	Mandatory
2.	Technical Proposal on Bidder's Letterhead	Mandatory
3.	Catalogue / Brochures / technical data sheet (having complete technical specifications of the offered good)	Mandatory
4.	Item-wise / Feature-wise product compliance / deviation sheet / statement.	Mandatory
5.	Valid Manufacturer Authorization in accordance with ITB Clause 13.3(a) Only manufacturer and its sole agent can quote the system, no sub distributors / spot authorized agent is allowed to bid.	Mandatory
6.	Copy of CNIC of signatory of the Bid Forms	Mandatory
7.	Complete Bidding Document, duly signed and stamped on its each/every page as acceptance of all terms & conditions	Mandatory
8.	Compliance to bid validity period	Mandatory
9.	Compliance to payment terms and conditions	Mandatory
10.	Compliance to the delivery schedule	Mandatory
11.	Valid General Sales Tax (GST-FBR) Registration with Active Tax Payer Status on FBR website (<i>for supply of goods</i>)	Mandatory
12.	Valid Income Tax (FBR) Registration with Active Tax Payer Status on FBR website	Mandatory
13.	Professional Tax Certificate	Mandatory
14.	Original Tender Purchase Receipt / Pay Order of Tender Fee	Mandatory
15.	Affidavit on stamp paper of Rs. 100/- duly notarized to the effect that: i. The bidder is neither blacklisted nor suspended by any National / International, including Provincial and Federal Government. ii. Any director or owner of the bidding company is not awarded any punishment from any Court of Law. iii. Bidder has submitted the correct and complete information along with the bid/offer. If any document / information is found forged / engineered / fake / bogus at any stage, the bidder may be declared as Blacklisted in accordance with law and the performance guarantee and payment, if any may be forfeited.	Mandatory
16.	The Bid Form & Price Schedule(s) shall be inserted in the Financial Proposal. However, a copy of the same shall be inserted in the Technical Proposal after hiding the amount.	Mandatory
17.	Bid Security shall be inserted in the Financial Proposal. However, a copy of the same shall be inserted in the Technical Proposal after hiding the amount.	Mandatory
18.	Company Profile of the Bidder	Mandatory
19.	Minimum five national / international installations of the quoted goods must be provided along with the satisfactory performance certificate issued by the end-user duly endorsed by the manufacturer.	Mandatory

S#	Qualification Criteria	Requirement
20.	BY AIR SHIPMENT IN CASE OF CFR / CNF/ C&F / CPT- Karachi basis	Mandatory

ITB 14.3 (b)	Spare parts required for <u>ten (10) years</u> of operation.
ITB 15.1	Amount of bid security shall not be less than 2% of the total bid price of the bidder in the form of a Call Deposit, Bank Draft or a Bank Guarantee issued by a scheduled bank of Pakistan, in favour of the Dow University of Health Sciences, Karachi.
ITB 16.1	Bid validity period shall be <u>90 days</u>
ITB 17.1	Original “Financial and Technical Proposals”
ITB 18.2 (a)	Dow University of Health Sciences (Ojha Campus), SUPARCO Road, off Main University Road, Gulzar-e-Hijri, Scheme No. 33, Karachi.
ITB 18.2 (b)	<p>Name of Project/Scheme/Department /Institute: Dow Institute of Life Sciences.</p> <p>IFB/NIT Title: Procurement of Micro Compact Filling Line and Macro Compact Filling Line for Bio-Injectables</p> <p>IFB/NIT No. DUHS/DP/2021/123 dated 03 February 2021</p> <p>“Must bear the name of the bidder” and a warning “Do Not Opened Before the time and date of bid opening”</p>
ITB 19.1	<p>Deadline for bid submission: Date: 20 February 2021 Time: upto 11:00 Hrs.</p>
ITB 22.1	<p>Date, Time and Place of Bid opening Date: 20 February 2021 Time: 11:30 Hrs. Place: Dow University of Health Sciences (Ojha Campus), Procurement Directorate at Library Block, SUPARCO Road, off Main University Road, Gulzar-e-Hijri, Scheme No. 33, Karachi.</p>

Bid Evaluation	
ITB 25.4	Criteria for bid evaluation.

i. Technical Bids / Proposals Evaluation:

- a. The bids not responsive to the MANDATORY QUALIFICATION CRITERIA provided at ITB Clause 13.3(d) shall not be eligible for further Technical Evaluation.
- b. Conditional Bids, Telegraphic Bids, Bids not accompanied by Bid Security of required amount and form, bids received after specific date and time and bids of Black Listed firms shall be treated as rejected / non-responsive.
- c. If a bidder elects to submit alternative bid without enclosing a separate Bid Security of requisite amount and form, Bid Form and valid Manufacturer Authorization, all such alternative bids will be rejected as nonresponsive.
- d. The bids shall be evaluated and compared on ITEMIZED BASIS.
- e. **Bids are invited as per Single Stage – Two Envelope Procedure** in accordance with sub rule 2 of rule 46 of the Sindh Public Procurement Rules, 2010 (Amended 2019). In case, any bidder encloses the financial bid within the technical bid, the same shall be rejected summarily.
- f. **The Bids in foreign currency on CFR / CNF/ C&F / CPT- Karachi basis must be quoted with Air Lift Freight exclusively, any other mode of shipment shall not be acceptable.**
- g. The following merit point system for weighing evaluation factors / criteria will be applied for technical proposals.
- h. Bidders achieving **minimum 70% points / marks** will be considered only for further process besides compliance of all mandatory clauses. Documentary evidence must be attached in support of your claim.

S#	CRITERIA / PARAMETERS / SUB-PARAMETERS	Total Marks
A.	PRODUCT EVALUATION	
1	Conformity to the Purchaser's Specifications (Mandatory)	30
1.1	Fully compliant with the required specifications	30
1.2	Compliant with minor deviation (up to 5% subject to main function is not effected)	25
2	Product Certification	15
2.1	USD-FDA / TUV / CE mark (MDD) / UL / IEC 601	05
2.2	QMS Certification	05
2.3	cGMP Standards Compliance	05
B.	BIDDER EVALUATION	
3.	Technical Staff	10
3.1	Diploma of Associate Engineer (DAE) in relevant field (Electronics / Biomedical). Copy of Diploma / relevant certificate must be attached (1 mark for each)	02
3.2	Graduate Engineer in relevant field (Electronics / Biomedical). Copy of	04

S#	CRITERIA / PARAMETERS / SUB-PARAMETERS	Total Marks
	Degree Certificate must be attached (2 marks for each)	
3.3	MBBS Doctor OR MS Engineer in relevant field OR Engineer Trained by the manufacturer of the goods. Degree Certificate / Training Certificate must be attached (02 mark for each)	04
4.	Workshop facility Testing / Calibration of Equipment	05
4.1	Availability of Workshop in Sindh Province Workshop location, complete list of testing and calibration tools, detail of spare parts availability in stock.	05
5.	Post Warranty Service Contract	10
5.1	The bidder must quote the price of service contract inclusive of parts as well as excluding the parts for 5 years (post warranty / guarantee period) in percentage (%age) for total contract value. The lowest one will get full (100%) marks.	10
6.	Past Experience / Performance of Last 5 years	10
6.1	Bidder's prior experience for supplying the goods having the similar nature and complexity to the Public Sector / Private Sector / Government / Semi-Government Organizations in Pakistan during the last 5 years . Documentary evidence in shape of Purchase Order / Contract Award and Installation Report / Satisfactory performance report / certificate must be attached. (2 marks for each contract award / purchase order)	10
7.	Average Annual Turnover during last three (03) financial years (Audited Statements of Accounts and Income Tax Return Forms must be attached as supporting documents)	10
7.1	Above PKR 75 million	10
7.2	Above PKR 50 million	06
7.3	Above PKR 25 million	03
7.4	Below PKR 25 million	00
8.	Bonus points	10
8.1	Free of Cost Comprehensive Extended Warranty (in addition to the standard or warranty period required in these bidding documents) at least for one year including parts & services / labour. (Bidder offering greater extended warranty period will get the full marks only)	10
GRAND TOTAL (A + B)		100

ii. Financial Bids / Proposal Evaluation:

- a) Technically qualified/successful bidder(s) shall be eligible for Financial Proposal(s). The Financial bids shall be opened in the presence of the Bidders at the scheduled date, time and venue communicated in advance.
- b) Only those Financial Proposals will be announced / considered which were technically qualified by the Committee. Therefore, bidders are advised to give separate sealed envelope (s) of every quoted item and should mention the name of the item and tender serial number on the front of the sealed envelope in **BOLD and legible letters** to avoid confusion, otherwise, the Financial Proposal Envelope will be opened on qualified item basis and it will not be challenged by the bidder that procuring agency has opened the Financial Proposal of the disqualified items besides qualified items.
- c) Financial Bids / Proposals of Technically disqualified / rejected bidders will not be opened and sealed envelope shall be returned to the bidder.

- d) Bids not accompanied by the Bid Security of required amount and form shall be rejected.
- e) The Bids in foreign currency on **CFR / CNF/ C&F / CPT- Karachi basis** must be quoted with **Air Lift Freight exclusively**, any other mode of shipment shall not be acceptable.
- f) Procuring Agency shall not be responsible for any erroneous calculation of taxes and all differences arising out shall be fully borne by the Successful Bidder.
- g) For the purpose of comparison of bids quoted in different currencies, price shall be converted into Pakistani Rupees. The rate of exchange shall be the selling rate prevailing seven working days before the date of opening of the bids, as notified by the National Bank of Pakistan (NBP) / State Bank of Pakistan (SBP).

Contract Award	
ITB 29.1	Procuring Agency reserves the right to drop any item and increase or decrease the quantity of goods originally specified in Schedule of Requirements / Technical Specifications without any change in unit price and other terms & conditions
ITM 32.1	Successful Bidder and the Procuring Agency will sign the Contract Agreement on the stamp paper with stamp duties as per the article 22-A (Contract) of the schedule of Stamp Act 1899. The expenditure involved on the said contract agreement will be borne by the bidder.

Section III.
Special Conditions of Contract

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Special Conditions of Contract

The following Special Conditions of Contract shall supplement the General Conditions of Contract. Whenever there is a conflict, the provisions herein shall prevail over those in the General Conditions of Contract. The corresponding clause number of the GCC is indicated in parentheses.

1. Definitions (GCC Clause 1)

GCC 1.1 (g)—The Procuring agency is: Dow University of Health Sciences, Karachi.

GCC 1.1 (h)—The Procuring agency's country is: Islamic Republic of Pakistan

GCC 1.1 (i)—The Supplier is: _____

[Name and Address of the Bidder]

2. Country of Origin (GCC Clause 3)

All countries and territories as indicated in Part Two Section VI of the bidding documents, "Eligibility for the Provisions of Goods, Works, and Services in Government-Financed Procurement".

3. Technical Specifications (GCC Clause 4)

The technical specifications of the goods provided in these bidding document are only for widest possible competition and not for favor any single contractor or supplier nor put others at a disadvantage. However, the brand name, catalogue No. / Name etc., if any, has only been used for the reference purpose. Equipment offered "**ATLEAST EQUIVALENT OR HAVING BETTER TECHNICAL SPECIFICATIONS**" shall also be considered.

4. Performance Security (GCC Clause 7)

GCC 7.1—The amount of performance security, as a percentage of the Contract Price, shall be Five (05%) percent of the Contract Price in favor of Dow University of Health Sciences, Karachi.

5. Packing (GCC Clause 9)

GCC 9.2—The following SCC shall supplement GCC Clause 9.2:

The packing, marking and documentation within and outside the packages shall be as per manufacturer standards meeting the safety requirements of the goods.

6. Delivery and Documents (GCC Clause 10)

GCC 10.2—*For Goods supplied from within the Procuring Agency's country:* The Bidder shall provide the following documents at the time of delivery of goods to the Store / Warehouse of the Dow University of Health Sciences, Karachi for verification duly completed in all respects:

- i. Original copies of Delivery Note (Delivery Challan) (in duplicate) showing item's description, make, model, quantity as well as Lot Number, Batch Number, Registration Number, manufacturing and expiry dates (if applicable).
- ii. Original copies of the Bidder's invoices (in duplicate) showing warranty, item's description, make, model as well as Lot Number, Batch Number, Registration Number, manufacturing and expiry dates (if applicable) per unit cost, and total amount.
- iii. Original copies of the Sales Tax Invoices (where applicable) in duplicate showing item's description, quantity, per unit cost without Sales Tax, amount of Sales Tax and total amount with Sales Tax.

- iv. Manufacturer's or Bidder's warranty certificate.
- v. Inspection certificate issued by the nominated inspection committee / Bidder's factory inspection report.
- vi. Certificate of origin.

GCC 10.2—*For Goods supplied from abroad as per INCOTERM CFR / CNF/ C&F / CPT Karachi:* Upon shipment, the Supplier shall notify the Procuring agency the full details of the shipment, including Contract number, description of Goods, quantity and usual transport document. The Supplier shall mail / submit the following documents to the Procuring agency at least one week prior to arrival of the Goods at the port or place of arrival and, if not received, the Bidder will be responsible for any consequent expenses.:

- (i) copies of the Supplier's invoice showing Goods' description, quantity, unit price, and total amount;
- (ii) original and two copies of the usual transport document (for example, a negotiable bill of lading, a non-negotiable sea waybill, an inland waterway document, an air waybill, a railway consignment note, a road consignment note, or a multimodal transport document) which the buyer may require to take the goods;
- (iii) copies of the packing list identifying contents of each package;
- (iv) insurance certificate;
- (v) Manufacturer's or Supplier's warranty certificate;
- (vi) inspection certificate, issued by the nominated inspection agency, and the Supplier's factory inspection report; and
- (vii) certificate of origin.

7. Insurance (GCC Clause 11)

GCC 11.1— *For Goods supplied from within the Procuring Agency's country:* The Goods supplied under the Contract shall be delivered duty paid (DDP) under which risk is transferred to the buyer after having been delivered, hence insurance coverage is sellers responsibility. Since the Insurance is seller's responsibility they may arrange appropriate coverage.

GCC 11.1— *For Goods supplied from abroad as per INCOTERM CFR / CNF/ C&F / CPT Karachi:* The Goods supplied under the Contract shall be *INCOTERM CFR / CNF/ C&F / CPT Karachi* under which risk is transferred to the buyer after the goods reached at Karachi port, hence insurance coverage / marine cover note is sellers responsibility. Since the Insurance / marine cover is seller's responsibility they may arrange appropriate coverage.

8. Spare Parts (GCC Clause 14)

GCC 14.1—Supplier shall carry sufficient inventories to assure ex-stock supply of consumable spares for the Goods. Other spare parts and components shall be supplied as promptly as possible, but in any case within one (1) months of placing the order on DDP basis and in case of import of part within two (2) months after opening the letter of credit.

9. Warranty (GCC Clause 15)

GCC 15.2—In partial modification of the provisions, the warranty period shall be twelve (12) months or as per the extended warranty period from the date of acceptance of the Goods. The Supplier shall, in addition, comply with the performance and/or consumption guarantees specified under the Contract. If, for reasons attributable to the Supplier, these guarantees are not attained in whole or in part, the Supplier shall, at its discretion, either:

- (a) make such changes, modifications, and/or additions to the Goods or any part thereof as may be necessary in order to attain the contractual guarantees specified in the Contract at its own cost and expense and to carry out further performance tests in accordance with GCC 8,

or

- (b) pay liquidated damages to the Procuring agency with respect to the failure to meet the contractual guarantees. The rate of these liquidated damages shall be 0.5% per week or part thereof the total amount of contract.

GCC 15.4 & 15.5—The period for correction of defects in the warranty period is 20 days or earlier.

10. Payment (GCC Clause 16)

GCC 16.1—The method and conditions of payment to be made to the Supplier under this Contract shall be as follows:

i. For Goods supplied from within the Procuring Agency's country:

- (a) Payment shall be made in Pak Rupees.
- (b) 100% of the Contract Price on complete delivery of store within thirty (30) days on submission of claim supported by acceptance certificate from procuring agency declaring Goods have been delivered and that all contracted services have been performed.
- (c) Part payment on part supply may be allowed

OR

ii. For Goods supplied from outside the Procuring Agency's country:

- (a) Payment shall be made in Foreign Currency.
- (b) The Procuring Agency shall pay the Bidder or its Principal through irrevocable letter of credit opened in favor of the Bidder or its Principal in a bank in its country, upon submission of all the requisite documents.
- (c) Bidder will bear the insurance charges and all the additional bank charges inside and outside the Procuring Agency country on account of confirmation of L/C, if he desires to establish a confirmed L/C etc.

11. Prices (GCC Clause 17)

GCC 17.1—No prices adjustment shall be allowed.

12. Liquidated Damages (GCC Clause 23)

GCC 23.1—In case deliveries are not completed within the time frame specified in the schedule of requirements / contract award, a Show Cause Notice will be served on the Bidder which will be following by cancellation of the Contract to the extent of non-delivered portion of installments. No supplies will be accepted and the amount of Performance Guarantee / Security to the extent of non-delivered portion of supplies of relevant installments will be forfeited. If the firm fails to supply the whole installments, the entire amount of Performance Guarantee/Security will be forfeited to the Government Account and the firm will be blacklisted at least for two years for future participation in bids:

The liquidated damage shall be 0.5 % per week or part thereof. The maximum amount of liquidated damages shall be 10% of the amount of contract. Once the cumulative amount of liquidated damages reaches ten percent (10%) of the amount of the contract, the Procuring Agency shall rescind the contract, without prejudice to other courses of action and remedies open to it.

13. Resolution of Disputes (GCC Clause 28)

GCC 28.1—The dispute resolution mechanism to be applied pursuant to GCC Clause 28.2 shall be as follows:

In the case of a dispute between the Procuring agency and the Supplier, the dispute shall be referred to the dispute resolution mechanism as defined in rule 31, 32 and 34 of the SPP Rules, 2010 (Amended 2019).

14. Governing Language (GCC Clause 29)

GCC 29.1—The Governing Language shall be ENGLISH

15. Applicable Law (GCC Clause 30)

GCC 30.1—The Contract shall be interpreted in accordance with the laws of Islamic Republic of Pakistan which includes the following legislation:

**The Employment of Children (ECA) Act 1991
The Bonded Labour System (Abolition) Act of
1992 The Factories Act 1934**

16. Notices (GCC Clause 31)

GCC 31.1—*Procuring agency's address for notice purposes:*

Director Procurement
Dow University of Health Sciences (Ojha Campus)
Procurement Directorate at Library Block,
SUPARCO Road, off Main University Road,
Gulzar-e-Hijri, Scheme No. 33, Karachi.
Phone No. + 92-21-99261497
Email: director.procurement@duhs.edu.pk

Supplier's address for notice purposes:

Name of Bidder: _____

Name of Contact Person & Designation: _____

Phone No. _____

Fax No. _____

Mobile Phone No. _____

Email Address _____

Section IV.
Schedule of Requirements

Schedule of Requirements

1. For Goods supplied from within the Procuring Agency's country (DDP Basis)

S#	Description of Goods	Qty.	Required Delivery Schedule	Location
01.	As per the details of items attached in Section V – Technical Specifications		Delivery & Installation within 10 weeks or earlier from the date of Contact Award	Ojha Campus of Dow University of Health Sciences, Karachi (DUHS)

2. For Goods supplied from outside the Procuring Agency's country (C&F / CFR / CNF / CPT Basis):

S#	Description of Goods	Qty.	Required Delivery Schedule	Location
01.	As per the details of items attached in Section V – Technical Specifications		Delivery & Installation within 12 weeks or earlier from the date of Contact Award / Establishment of Letter of Credit	Karachi Port

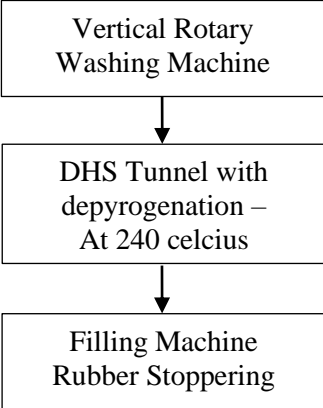
NOTE:

- i. The Bids in foreign currency on **CFR / CNF/ C&F / CPT- Karachi basis** must be quoted with **Air Lift Freight exclusively**, any other mode of shipment shall not be acceptable.
- ii. The shipment schedule shall be submitted along with the offer, and shall be negotiable and subject to approval by the University.
- iii. The bidder must indicate in his offer the port of shipment of goods.

Section V.
Technical Specifications

Technical Specifications

Item No.	Name of Goods, Technical Description, Specifications and Standards
1.	MICRO VIAL FILLING LINE 0.5ML TO 10ML Required Quantity: 01 Unit FOR FURTHER DETAILS REFER ANNEXURE – A (PAGE NO. 68)

1. BASIC REQUIREMENT	
1.1 Name of the Equipment & Synonyms if any Micro Vial Filling Line 0.5ML TO 10ML for injectable with Stoppering (USP Type I); Washing & DHS tunnel	
1.2 No. of Equipment's Required-3 1) Glass Vial washing; 2) Glass vial Filling machine with stoppering; 3) DHS Dry Heat sterilizer tunnel	
2. FUNCTIONAL REQUIREMENT	
2.1 Purpose of the Equipment & Brief Description of process/Equipment	
<p><u>Automatic Filling Line (0.5ml – 10ml)</u></p>  <pre> graph TD A[Vertical Rotary Washing Machine] --> B[DHS Tunnel with depyrogenation - At 240 celcius] B --> C[Filling Machine Rubber Stoppering] </pre>	
<ul style="list-style-type: none"> • Fill volume 0.5ml to 10ml and Vial sizes0 (2R to 10R) accuracy ± ml • Filling and stoppering Machine with pre and post purging. Under LAF • In feed and out feed turn table with LAF including product buffer tank. • Rubbers stoppers/ Flip off seal loading should be under LAF (crimping/sealing) 	
<ul style="list-style-type: none"> I. Should be completely Automation system. II. Buffer tank should be on load cells. III. PLC- (21CFR Part 11 compliant) IV. CIP & SIP systems to be provided for filling machine V. Laminar flow to be provided with compliance to GMP bio sterile products.. VI. Pre and post nitrogen purging with filters.. VII. Equipped with RABS (Restricted Access Barrier System) with Glass/ Acrylic (glove port) 	

3. OPERATIONAL REQUIREMENT
3.1 Suggested capacity Capacity: Output 2000 to 5000 Vials/hr
3.2 Occupancy hours 24 Hours
3.3 Material of Construction of Product Contact Parts/Non-Contact Parts Product Contact Parts: SS316L Non-contact parts: SS304/ SS304
3.4 Preferable Method of Cleaning Water/ WFI (CIP/SIP) (requirement of the quoted system meets with current production)
3.5 Available Utilities Power: 380V-3Ph-60Hz; 220V-1Ph-60Hz Compressed Air (clean air, pressure 9 bar), WFI, DM Water, RO Water
3.6 Online Controls Required PLC Control system (21CFR Part 11 compliant)
3.7 Attachments/Connectivity with Other Equipment's Yes (upstream and downstream machines)
3.8 Available Area for Installation/Environmental Conditions Available Area: Will be decided as per receipt of equipment layout from supplier. temp: 23±2 and humidity: 55±5% Sound level should be described.
4. SAFETY REQUIREMENTS
4.1 Personal Safety Requirements- Comply ISO 14001 EHS/45001 OHSAS requirements.
4.2 Product Safety Requirements Comply ISO 45001 OHSAS /GMP requirements
5. DOCUMENTATION REQUIREMENTS (Wherever required)
5.1 Drawing for approval
5.2 Contact Parts material test Certificates
5.3 DQ/IQ/OQ/PQ Support
5.4 PLC controlled systems, disaster recovery system, with source code
5.5 O&M Manuals
5.6 Calibration Certificates of instruments & Control Systems
5.7 Guarantee Certification for all items involved
5.8 Guarantee and Certification for all Bought Out Items
5.9 As built drawing
5.10 Surface finishes reports and surface area calculation
5.11 FAT & SAT Protocols and compliance

5.12 Pre and post nitrogen purging
5.13 6N vial no fill option to avoided product wastage
5.14 Should be equipped with all filling option
5.15 Interlocking of filling with LAF and nitrogen purging
5.16 Display (HMI), control, emergency stop
5.17 Measurement of filling environment and alarm In process control samples
5.18 FDA certificate for seals, lubricant, oils
5.19 UPS/power backup, power failure restart
5.20 Database to be secured for Audit trail
5.21 Spare parts catalogue with conformity to standards
5.22 Software compliance
5.23 Manufacturer's Warranty in years
5.24 Operational and maintenance training at site
5.25 Labeling and printing
5.26 Utilities interphase is required- Exhaust, airflow and ventilation for DHS- Waste water and drain requirement- should be provided by vendor

Item No.	Name of Goods, Technical Description, Specifications and Standards
2.	MACRO VIAL FILLING LINE 50ML, 100ML, 150ML Required Quantity: 01 Unit FOR FURTHER DETAILS REFER ANNEXURE – B (PAGE NO. 80)

1.	BASIC REQUIREMENT
1.1	Name of the Equipment & Synonyms if any Macro Vial Filling Line 50ml, 100ml, 150 ml for injectable SVP (Infusion type)
1.2	No. of Equipment Required-4 <ol style="list-style-type: none"> a. Vial washing b. Filling machine with stoppering, c. DHS Dry Heat sterilizer tunnel. d. Alu cap sealing machine
2.	FUNCTIONAL REQUIREMENT
2.1	Purpose of the Equipment & Brief Description of process/Equipment <div style="text-align: center; margin: 10px 0;"> <p><u>50ml-100ml-150ml</u></p> <pre> graph TD A[Vertical Rotary Washing Machine] --> B[DHS Tunnel] B --> C[Filling Machine Rubber Stoppering] C --> D[Alu Cap Sealing Machine] </pre> </div> <ol style="list-style-type: none"> i. Should be completely Automation system. ii. Buffer tank should be on load cells. iii. Interlock with upstream and downstream machines. iv. CIP & SIP systems to be provided for filling machine and product line. v. Laminar flow to be provided with compliance to GMP for sterile bio products. vi. Pre and post nitrogen purging with filters. vii. Equipped with RABS (Restricted Access Barrier System) with Glass/ Acrylic
3.	OPERATIONAL REQUIREMENT
3.1	Suggested capacity Capacity: Output 4000 to 8000 bottles/hr
3.2	Occupancy hours 24 Hours

3.3	Material of Construction of Product Contact Parts/Non-Contact Parts Product Contact Parts: SS316L Non contact parts: SS304/ SS304
3.4	Preferable Method of Cleaning Water/ WFI (CIP/SIP)
3.5	Available Utilities Power: 380V-3Ph-60Hz; 220V-1Ph-60Hz Compressed Air, (clean air, pressure 9 bar), WFI, DM Water, RO Water.
3.6	Online Controls Required PLC Control system (21CFR Part 11 compliant)
3.7	Attachments/Connectivity with Other Equipment Yes (upstream and downstream machines)
3.8	Available Area for Installation/Environmental Conditions Available Area: Will be decided as per receipt of equipment layout from supplier. temp: 23±2 and humidity: 55±5%
4.	SAFETY REQUIREMENTS
4.1	Personnel Safety Requirements Comply ISO 14001 EHS/45001 OHSAS requirements
4.2	Machine Safety Requirements Comply ISO 45001 OHSAS /GMP requirements
5.	DOCUMENTATION REQUIREMENTS Drawing for approval
6.	Contact Parts material test Certificates
6.1	DQ/IQ/OQ/PQ Documents and Support
6.2	PLC controlled systems Disaster recovery back up, source code
6.3	O&M Manuals
6.4	Calibration Certificates of instruments & Control Systems
6.5	Guarantee Certification for all items involved
6.6	Guarantee and Certification for all Bought Out Items
6.7	As built drawing
6.8	Surface finish reports and surface area calculation
6.9	FAT&SAT Protocols and compliance Expenses will born by vendor
6.10	No bottle no filling and all filling options
6.11	Pre and post nitrogen purging
6.12	No vial no fill option to avoided product wastage
6.13	Should be equipped with all filling option
6.14	Interlocking of filling with LAF and nitrogen purging
6.15	Display (HMI), control, emergency stop
6.16	Measurement of filling environment and alarm In process control samples
6.17	FDA certificate for seals, lubricant, oils
6.18	UPS/power backup, power failure restart

6.19	Database to be secured for Audit trail
6.20	Spare parts catalogue with conformity to standards
6.21	Software compliance
6.22	Manufacturer's Warranty in years
6.23	Operational and maintenance training at site
6.24	Labeling and printing
6.25	Utilities interphase is required- Exhaust, airflow and ventilation for DHS- Waste water and drain requirement- should be provided by vendor

Section VI.
Sample Forms

Sample Forms

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1. Bid Form and Price Schedules

NIT / IFB N°: _____

Date: _____

To: *[name and address of Procuring Agency]*

Gentlemen and/or Ladies:

Having examined the bidding documents including Addenda Nos. *[insert numbers]*, the receipt of which is hereby duly acknowledged, we, the undersigned, offer to supply and deliver *[description of goods and services]* in conformity with the said bidding documents for the sum of *[total bid amount in words and figures]* or such other sums as may be ascertained in accordance with the Schedule of Prices attached herewith and made part of this Bid.

We undertake, if our Bid is accepted, to deliver the goods in accordance with the delivery schedule specified in the Schedule of Requirements.

If our Bid is accepted, we will obtain the guarantee of a bank in a sum equivalent to _____ percent of the Contract Price for the due performance of the Contract, in the form prescribed by the Procuring agency.

We agree to abide by this Bid for a period of *[number]* days from the date fixed for Bid opening under Clause 22 of the Instructions to Bidders, and it shall remain binding upon us and may be accepted at any time before the expiration of that period.

Until a formal Contract is prepared and executed, this Bid, together with your written acceptance thereof and your notification of award, shall constitute a binding Contract between us.

Commissions or gratuities, if any, paid or to be paid by us to agents relating to this Bid, and to contract execution if we are awarded the contract, are listed below:

Name and address of agent	Amount and Currency	Purpose of Commission or gratuity
_____	_____	_____
_____	_____	_____
_____	_____	_____

(if none, state "none")

We understand that you are not bound to accept the lowest or any bid you may receive.

Dated this _____ day of _____ 20_____.

[signature]

[in the capacity of]

Duly authorized to sign Bid for and on behalf of _____

**i. (A) PRICE SCHEDULE IN PAK RUPEES
Delivered Duty Paid (DDP BASIS)**

FOR GOODS OFFERED WITHIN THE PROCURING AGENCY’S COUNTRY

Name of Bidder _____ . IFB / NIT Number _____ .

S#	Detailed Specification of Goods	Model / Cat No.	Name of Manufacturer	Country of Origin	Port of Shipment	Quantity of Stores	Unit	Rate Per Unit	Total Price
1	2	2	4	5	6	7	8	9	10
Total Amount in Pak Rs.									

Name _____
 In the capacity of _____
 Signed _____
 Duly authorized to sign the Bid for and on behalf of _____
 Date _____

NOTE:

Country of origin of “MAJOR PART(S) OF THE EQUIPMENT” must be clearly reflected separately in the Technical and Financial bids. The “Origin” means the place where the “goods” are mined, grown, or produced.

ii. (B) **PRICE SCHEDULE IN FOREIGN CURRENCY – BY AIR SHIPMENT**
 (CFR / CNF/ C&F / CPT - KARACHI BASIS)

FOR GOODS OFFERED FROM OUTSIDE THE PROCURING AGENCY’S COUNTRY

Name of Bidder _____ . IFB / NIT Number _____ .

S#	Detailed Specification of Goods	Model / Cat No.	Name of Manufacturer	Country of Origin	Port of Shipment	Quantity of Stores	Unit	Currency	Rate Per Unit	Total Price
1	2	2	4	5	6	7	8	9	10	11
Total Amount in Foreign Currency										

Name _____

In the capacity of _____

Signed _____

Duly authorized to sign the Bid for and on behalf of _____

Date _____

NOTE:

Port of Shipment and Country of origin of “MAJOR PART(S) OF THE EQUIPMENT” must be clearly reflected separately in the Technical and Financial bids. The “Origin” means the place where the “goods” are mined, grown, or produced.

2. Bid Security Form

Whereas *[name of the Bidder]* (hereinafter called “the Bidder”) has submitted its bid dated *[date of submission of bid]* for the supply of *[name and/or description of the goods]* (hereinafter called “the Bid”).

KNOW ALL PEOPLE by these presents that WE *[name of bank]* of *[name of country]*, having our registered office at *[address of bank]* (hereinafter called “the Bank”), are bound unto *[name of Procuring agency]* (hereinafter called “the Procuring agency”) in the sum of for which payment well and truly to be made to the said Procuring agency, the Bank binds itself, its successors, and assigns by these presents. Sealed with the Common Seal of the said Bank this ___ day of _____ 20_.

THE CONDITIONS of this obligation are:

1. If the Bidder withdraws its Bid during the period of bid validity specified by the Bidder on the Bid Form; or
2. If the Bidder, having been notified of the acceptance of its Bid by the Procuring agency during the period of bid validity:
 - (a) fails or refuses to execute the Contract Form, if required; or
 - (b) fails or refuses to furnish the performance security, in accordance with the Instructions to Bidders;

we undertake to pay to the Procuring agency up to the above amount upon receipt of its first written demand, without the Procuring agency having to substantiate its demand, provided that in its demand the Procuring agency will note that the amount claimed by it is due to it, owing to the occurrence of one or both of the two conditions, specifying the occurred condition or conditions.

This guarantee will remain in force up to and including twenty eight (28) days after the period of bid validity, and any demand in respect thereof should reach the Bank not later than the above date.

[signature & Seal of the bank]

3. Contract Form

THIS AGREEMENT made the _____ day of _____ 20 _____ between [name of Procuring Agency] (hereinafter called “the Procuring Agency”) of the one part and [name of Supplier] of [city and country of Supplier] (hereinafter called “ the Supplier” of the other part:

WHEREAS the Procuring agency invited bids for certain goods and ancillary services, viz., [*brief description of goods and services*] and has accepted a bid by the Supplier for the supply of those goods and services in the sum of [*contract price in words and figures*] (hereinafter called “the Contract Price”).

NOW THIS AGREEMENT WITNESSETH AS FOLLOWS:

1. In this Agreement words and expressions shall have the same meanings as are respectively assigned to them in the Conditions of Contract referred to.
2. The following documents shall be deemed to form and be read and construed as part of this Agreement, viz.:
 - (a) the Bid Form and the Price Schedule submitted by the Bidder;
 - (b) the Schedule of Requirements;
 - (c) the Technical Specifications;
 - (d) the General Conditions of Contract;
 - (e) the Special Conditions of Contract; and
 - (f) the Procuring agency’s Notification of Award.
3. In consideration of the payments to be made by the Procuring agency to the Supplier as hereinafter mentioned, the Supplier hereby covenants with the Procuring agency to provide the goods and services and to remedy defects therein in conformity in all respects with the provisions of the Contract
4. The Procuring agency hereby covenants to pay the Supplier in consideration of the provision of the goods and services and the remedying of defects therein, the Contract Price or such other sum as may become payable under the provisions of the contract at the times and in the manner prescribed by the contract.

IN WITNESS whereof the parties hereto have caused this Agreement to be executed in accordance with their respective laws the day and year first above written.

Signed, sealed, delivered by _____ the_ (for the Procuring agency)

Signed, sealed, delivered by _____ the_ (for the Supplier)

4. Performance Security Form

To: *[name of Procuring agency]*

WHEREAS *[name of Supplier]* (hereinafter called “the Supplier”) has undertaken, in pursuance of Contract No.*[reference number of the contract]* dated _____ 20.____ to supply *[description of goods and services]* (hereinafter called “the Contract”).

AND WHEREAS it has been stipulated by you in the said Contract that the Supplier shall furnish you with a bank guarantee by a reputable bank for the sum specified therein as security for compliance with the Supplier’s performance obligations in accordance with the Contract.

AND WHEREAS we have agreed to give the Supplier a guarantee:

THEREFORE WE hereby affirm that we are Guarantors and responsible to you, on behalf of the Supplier, up to a total of *[amount of the guarantee in words and figures]*, and we undertake to pay you, upon your first written demand declaring the Supplier to be in default under the Contract and without cavil or argument, any sum or sums within the limits of *[amount of guarantee]* as aforesaid, without your needing to prove or to show grounds or reasons for your demand or the sum specified therein.

This guarantee is valid until the _____ day of _____ 20._____.

Signature and seal of the Guarantors

[name of bank or financial institution]

[address]

[date]

5. Bank Guarantee for Advance Payment

To: *[name of Procuring*

agency] [name of Contract]

Gentlemen and/or Ladies:

In accordance with the payment provision included in the Special Conditions of Contract, which amends Clause 16 of the General Conditions of Contract to provide for advance payment, *[name and address of Supplier]* (hereinafter called “the Supplier”) shall deposit with the Procuring agency a bank guarantee to guarantee its proper and faithful performance under the said Clause of the Contract in an amount of *[amount of guarantee in figures and words]*.

We, the *[bank or financial institution]*, as instructed by the Supplier, agree unconditionally and irrevocably to guarantee as primary obligator and not as surety merely, the payment to the Procuring agency on its first demand without whatsoever right of objection on our part and without its first claim to the Supplier, in the amount not exceeding *[amount of guarantee in figures and words]*.

We further agree that no change or addition to or other modification of the terms of the Contract to be performed thereunder or of any of the Contract documents which may be made between the Procuring agency and the Supplier, shall in any way release us from any liability under this guarantee, and we hereby waive notice of any such change, addition, or modification.

This guarantee shall remain valid and in full effect from the date of the advance payment received by the Supplier under the Contract until *[date]*.

Yours truly,

Signature and seal of the Guarantors

[name of bank or financial institution]

[address]

[date]

6. Manufacturer's Authorization Form

[See Clause 13.3 (a) of the Instructions to Bidders.]

Date: _____

To: *[name of the Procuring agency]*

WHEREAS *[name of the Manufacturer]* who are established and reputable manufacturers of *[name and/or description of the goods]* having factories at *[address of factory]* do hereby authorize *[name and address of Agent]* to submit a bid, and subsequently negotiate and sign the Contract with you against **IFB No. *[reference of the Invitation to Bid]*** for the above goods manufactured by us.

We hereby extend our full guarantee and warranty as per Clause 15 of the General Conditions of Contract for the goods offered for supply by the above firm against this Invitation for Bids.

We hereby undertake that we will provide the complete after sale services support in case of agency transfer.

[signature for and on behalf of Manufacturer]

Note: This letter of authority should be on the letterhead of the Manufacturer and should be signed by a person competent and having the power of attorney to bind the Manufacturer. It should be included by the Bidder in its bid.

7. Integrity Pact (AFFIDAVIT)

DECLARATION OF FEES, COMMISSION AND BROKERAGE ETC. PAYABLE BY THE SUPPLIERS OF GOODS, SERVICES & WORKS IN CONTRACTS

M/s. _____, the service provider hereby declared that:

- (a) Its intention not to obtain the procurement / services / work of any contract, right, interest, privilege, or other obligation or benefit from the DUHS or any administrative or financial offices thereof or any other department under the control of the DUHS through any corrupt practice(s).
- (b) Without limiting the generality of the forgoing the bidder / company / firm / agency represents and warrants that it has fully declared the charges, fees, commission, taxes, levies etc, paid or payable to anyone and not given or agreed to give and shall not give or agree to give to anyone within the DUHS directly or indirectly through any means any commission, gratification, bribe, gifts, kickback whether described as consultation fee or otherwise, with the object of obtaining or including the procurement or service contract or order or other obligations whatsoever from the DUHS, except that which has been expressly declared pursuant hereto.
- (c) The bidder / company / firm / agency / accepts full responsibility and strict liability for making any false declaration / statement, not making full disclosure, misrepresenting facts or taking any action likely to degrade the purpose of declaration, representation and warranty. It agrees that any contract / order obtained aforesaid shall without prejudice to any other right & remedies available to the DUHS under any law, contract, or other instrument, be stand void at the discretion of the DUHS.
- (d) Notwithstanding any right and remedies exercised by the DUHS in this regard, bidder / company / firm / agency agrees to indemnify the DUHS for any loss or damage incurred by it on account of its corrupt business practice & further pay compensation to the DUHS in any amount equivalent to the loss of any commission, gratification, bribe, gifts, kickback given by the bidder / company / firm / supplier / agency / service provider as aforesaid for the purpose of obtaining or inducing procurement / work / service or other obligation or benefit in whatsoever from the DUHS.

Dow University of Health Sciences
Signature & Seal

(Name of Security Firm)
Signature & Seal

Note: This integrity pact is mandatory requirement other than auxiliary services / works.

Dow institute of life sciences.

USER REQUIREMENT SPECIFICATIONS

Equipment	MICRO VIAL FILLING LINE 0.5ML TO 10ML	Department	Production
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INTRODUCTION 1:

This document was generated under the authority of **DILS DOW** for the purpose of specifying the user requirement for the Vial Filling Line which will be used in a pharmaceutical environment. This URS is provided to define the important components, variables and options necessary for the supplier to provide a functional Vial Filling Line that meets the **DILS DOW** minimum requirements. The URS is also provided to the supplier for getting the offer for the Vial Filling Line. This URS is an integral part of the procurement agreement with the supplier.

The Vial Filling Line will comprise the following machines

1. **Vial Washing Machine With LAF**
2. **DHS Drying and sterilizing Depyrogenation Tunnel**
3. **Vial Filling and Stoppering Machine with RABS. (Filled volume 0.5ml to 10ml) With rejection control and audit trail.**

The line will be used to fill vials; (Liquid vials) will proceed manually (In mobile LAF trolley) to the lyophilizer .

LINE OVERVIEW :

The Vial Filling Line will carry out the following operations, automatically, and without manual intervention (except loading and unloading of vials).

Washing of vials Rotary vial washing with LAF

- Application 2ml, 15ml vial
- Output vial per minute 130 vial per minute
- Power supply 380V, 60Hz
- Washing cleanliness quality rate More than 99%
- Vial Breaking rate Less 0.3%
- WFI consumption 0.9cbm/h 0.3-0.5mpa
- WFI recycling with filtration and heating
- Power supply 380V/60Hz
- Industrial 4.0 compliance.
- Upstream and downstream compatible.

DHS sterilizing and Depyrogenation tunnel.

- Power supply 380 AC V 3 phase 50 Hz
- Cooling water
- Bottle temperature at outlet less or equal to Room + 20 °C
- Bottle breaking rate less or equal to 0.001%
- Temperature differences. less or equal to ± 5 °C
- Sterilizing temperature (Maximum 350 °C) 300 ~320 °C
- All blowers should be equipped with Inverter.
- Noise <65 Db
- Upstream and downstream compatible.
- Pressure differential control to avoid any cross contamination and pressure disturbance in the area.

Construction and Finishes

- All machines to be constructed from Stainless Steel AISI 304
- All product contact parts shall be constructed from 316L stainless steel or approved silicon or Teflon or Viton. Stainless steel components will have a finish of 0.6µm and be electro polished.
- Stainless Steel electrical and control Panels

Quality Level

- The level quality is defined as follows
 - Maximum level of waste 1 % of hourly production due to all faults.
 - Filled volume 0.5ml to 10ml
 - Maximum product loss 0.5 % of original batch quantity,
 - Dosing tolerance (for each unit) ± 0.5 %

GENERAL CHARACTERISTICS

- Line Speed 2000 to 4000 vials per hour.
- Technical zones should be accessible without passing through the pharmaceutical zones where possible.
- The system should be validatable
- To the latest state of the art.
- F.D.A. guide lines as may be applied to this type of equipment.
- No particle generation allowed at any stage
- Aesthetically pleasing appearance
- All the format change-parts relative to a particular product or packaging component must be marked with the same reference. These references must be engraved.
- From the exit of the .washing machine to the sealing/rubber stoppering stage, loading and unloading of containers must only be exposed to air-flows meeting class A conditions(mobile trolley with LAF)
- All the machines to be well insulated to minimize heat emission into the processing areas. Supplier to provide a figure for the total heat transmission from equipment to the production area.
- Each machine shall be equipped with at least one emergency stop button.
- CE Certification
- The main electrical components to be grouped into one St.St. electrical panel.
- Line to be installed in following areas

- Washing and DHS in Class C area
- Filling/sealing and rubber Stoppering in aseptic areas Class A, filling will be under class A conditions
- Machine/s to stop after preset number of successive faults
- PLC controls
- Touch Screen operating panels
- Recipe System
- Remote connection by modem
- Jogging switch for adjustment
- Diagnostic messages
- Wire Numbering
- Sound absorbing hoods for sorting bowls, sorting bowls to be in separate compartments
- All sensors pressure gauges etc should be easily accessible for calibration

Documentation :

- The supplier shall use the formats described in the current version of the Good Automation Manufacturing Practice (GAMP) supplier guide to produce the documentation. The Supplier shall provide the documentation for preliminary review. The supplier shall provide documentation reflecting “as-built” condition with final delivery. All final documents shall be shipped with transmittals that identify them as contractually required documents. All final documents and drawings shall reflect “as-built” condition.
- Installation, operation, and maintenance instruction documentation for the Vial line shall be developed to an easily comprehensible level.
- The supplier shall provide the documentation for preliminary review.
- All final documents shall be shipped with transmittals that identify them as contractually required documents. All labels on documents and Vial line shall be written only in English language.
- All documents shall be in English language and supplied with hard copies and electronic versions. The following documents shall be needed:
- Software Module Test, Software Integration Test, Controls Test
- Hardware Installation Test
- DQ, IQ, OQ ,FAT ,SAT,PQ,
- Operation, Maintenance and Service Manuals
- Process and Instrumentation Diagram (P&ID)

- Instrument Listing
- Control Schematics
- Control Panel Assembly Drawings
- Vial line / Assembly Drawings
- Bill of Materials, material and weld certificate
- Spare Parts List for two years.
- PLC Program Ladder Diagram, with explanation in English, Printout and Disk File

3 copies should be supplied

General Requirements of The Line

- The specification items constitute the minimum requirements
- The Vial Filling Line shall be guaranteed by the supplier for a period of two years with all parts and services / labor from the date of installation or for three years from shipment date, whichever is shorter.
- All alarms must be audible unless otherwise specified.
- All alarms should stop machine unless otherwise specified.
- All alarms must be acknowledged with possibility of resetting
- All Layout drawings must be approved.
- All components must be to the latest proven technology available
- All dangerous parts and moving components shall be carefully covered and protected by safety contacts unless otherwise agreed.
- The specification for the machine will apply to any complimentary equipment or component or machine necessary for the operation this equipment and this equipment will treated as part of the machine.
- Any complimentary equipment or component or machine necessary for the operation of the machine should be to the latest state of art available on the market.
- All accessories affected by dust or air turbulence or others e.g. printers, scales, IPC units, keyboards, computers, monitors, operator panel switches etc should have proper and accessible protection transparent hoods and covers as necessary.
- All printers to be colored printers unless otherwise specified and the ink used to be of the non-fading type.
- All services to any machine to be connected from one point, bottom entry connections are normally preferred.
- All displays should be clearly and visible and of the nonreflecting type
- Any electrical or Control Panel should have the proper protection against the surroundings

i.e. against dust in dust prawn areas,

- Provision to connect to Factory Computer System to be provided
- All change parts to be engraved
- Reference scales and gauges for all adjustable parts to be provided.
- Aesthetically pleasing appearance
- Machines to be to the latest state of art GMP and FDA. guide lines
- Technical zone to be totally separate from Pharmaceutical zone
- Supplier to supply following:
 - Compressed air requirement
 - Water/s Requirement
 - Nitrogen Requirements
 - Air Extract requirement
 - Power consumption
 - Heat emission from Machines
 - Builder Work requirements including base etc
 - Layout drawings (on diskettes or CD wherever possible)
 - Layout drawings should clearly show all connection points
 - Machine total weight
 - Vibration transmission
 - Drainage
 - Any other requirement
 - Control Cable length as actual.
- The opening of any one of the guards shall immediately cut off the power supply to the machine concerned and cause its immediate stoppage.
- Each machine shall be equipped with at least one emergency stop button.
- Stop Start in phase on loss of power and on application of Emergency stop button.
- Any collected data to be retained on loss of power or application of the Emergency stop button.
- Priced Spare parts list for two year operation for each machine
- Control voltage to be 24 VDC

- For electrical loads over 5 KW, soft start should allowed for.
- Siemens PLC where applicable
- Compressed air filters, regulators, lubricators, gauges etc to be provided.
- Electrical and Control Panels to accord to International Standards e.g. CE Standards, in their design and must have the proper free area and labeling for all components and wiring.
- The Vial filling line machine shall meet the appropriate safety regulations. e.g.: OSHA regulations for the safety of operators and equipment with regards to safety, guarding and noise.
- Wiring on the Vial Filling Line machine and in the control cabinets shall be terminated at both ends and match the numbering shown in the documentation.
- Format change parts shall be identified with the part number and commodity size it will be used for.

Support:

The supplier to provide technical support as follows when and where necessary, start-up, training and follow up.

Availability :

The vial filling line is intended to be operated:

- 16 hours per day (One shift is 8 hours).
- 96 hours per week.

Operation of the vial inspection machine shall be shut down, and the vial inspection machine shall be available for maintenance or service:

- 2 hours per week.
- 1 day per month.
- 2 days per year.

Layout

Drawing showing the layout of the area where the line is expected to be installed.

The supplier will furnish layout drawings showing how the line will fit In the provided area.

The supplier will point out any deficiencies that that may arise from the layout and will provide his proposals.

Technical Requirements

- Filling Volume: 0.5, 1 and 10 ml.
- The volume and type of vials will be as indicated in the commodity table.

Vial Handling

- Dehydrogenated and sterilized vials fed from the DHS will be unscrambled and fed into the Vial Filling and Stoppering Machine.
- Depyrogenated vials are to be run through the Vial Filling and Stoppering Machine without becoming contaminated,

General

- Machine to be designed for aseptic filling
- Accumulation switch at in feed
- Adjustable speed Step Lesley
- Speed Indication, Hours Run Meter, Number of Vials Filled
- Number of Vials Rejected
- Key switch to select output direction, to capping machine in case of liquid vials and to magazine unit if Lyophilized vials
- Interlock with other downstream machine as selected
- Protection against jams both mechanical and electrical

Filling Station

- Operations to be carried out under laminar flow, class A, conditions.
- With RABS,
- Dosage precision approx. $\pm 0.5\%$
- Constant head filling system
- No Container no fill
- No dripping from filling needles
- Safety filtration before the filling needles
- Gas flushing before during and after filling, selectable
- If nitrogen flushing is selected and no nitrogen is detected machine to stop and raise alarm
- Output Indicator
- Machine to be surrounded by a transparent hood with safety switches
- Ability to adjust fill volumes of all filling stations by a single control and the ability to adjust pumps individually.
- The machine to be surrounded at working level with a closed, transparent cabinet with safety doors and a shielded electric light. This cabinet shall be under vertical laminar flow.
- Properly filled vials are defined as those possessing the desired dose as defined in the commodity table ($\pm 0.5\%$ by weight).
- Vials will be filled without dripping onto the external surfaces of the vial or transport system.
- Liquid vials will be filled at the same Vial Filling and Stoppering Machine.

- Monitor Product temperature in tank (2 – 8° C)
- An intermediate insulated product tank of 5 to 10 litres capacity with level control. Monitoring and control of level shall be needed, with alarms and machine stop
- No condensation on tank or any of the machine ancillaries.
- Nitrogen blanketing of tank

Rubber stopper station

- Ability to program stoppering machine to fully or partially insert stopper into vial for conventional or lyophilized stoppers.
- Rejection system to be programmed accordingly.
- Each filled vial will have a stopper placed on it. Properly stoppered vials will be no more than 1 mm higher than a fully seated stopper.
- The rejection rate caused by missing or high stoppers must not exceed 0.01% during the defined one hour.
- The Vial Filling and Stoppering Machine shall stopper vials as mentioned in commodity table
- Stopper bowl to be in stainless steel execution, protected under laminar flow and in a different compartment
- Sorting and orientation of stoppers
- Stoppers Chute
- Rubber Stoppering to be under laminar flow with class A conditions
- No container no stopper
- Minimum Stoppers in chute raise alarm and stop machine
- Vials with missing or with high stoppers shall be rejected.
- The rejection system should have a cross check feature.
- Machine to stop after preset number of successive failures

Laminar Flow

- Laminar flow system should be provided to the Vial Filling and Stoppering Machine, so that the vial loading, filling, rubber stoppering and partially stoppered vial discharge process will be under laminar flow system (Class A).
- Integral lighting at 1000 Lux
- Air velocity measurement, indication and alarm
- DOP or similar test connections

- Differential pressure gauges
- Variable speed stepless
- Speed Indication.
- Correct speed setting to be clearly marked
- Laminar flow shall be interlocked with filling machine

Critical Processes

- Filling volume/weight
- Nitrogen/compressed air pressure/flow
- Temperature of the filling solution in tank (should be 2 – 8 °C)
- Rubber stopper height
- Nitrogen, compressed air filter integrity

Alarms and Warnings:

The Vial Filling and Stoppering Machine shall be equipped with but not limited to the following alarms and warnings:

Alarm #	Alarm Description	Alarm	Stop
1	Emergency Stop		X
2	Barrier Door Interlock		X
3	Air supply pressure low	X	X
4	No Vials		X
5	Stopper Hopper low	X	
6	No Stoppers	X	X
7	Missing Stoppers	X	X
8	Output full	X	X
9	Rejection Failure	X	X
10	Successive failures (Any of above)	X	X
11	Low Nitrogen Supply when selected	X	X
12	Laminar Flow not running	X	X
13	Others		

Performance :

- The Vial Filling and Stoppering Machine is expected to properly fill and stopper vials at production speeds/output to meet the required output.
- The Vial Filling and Stoppering Machine shall be operable by one person.
- Safety related faults shall stop the Vial Filling and Stoppering Machine immediately. The Vial Filling and Stoppering Machine shall not be allowed to restart without operator intervention.
- The Vial Filling and Stoppering Machine changeover between vial sizes by a single operator is expected to take no longer than 60 minutes.

Power Failure and Recovery :

- On power failure, the Vial Filling and Stoppering Machine shall fail into a "safe state".
- Reset required parameter before Vial Filling and Stoppering Machine can be restarted.
- No damage to Vial Filling and Stoppering Machine will occur as a result of going to the safe state.
- On power restoration, the Vial Filling and Stoppering Machine shall not restart without operator or communication-link input.
- Vial Filling and Stoppering Machine shall be designed to retain the PLC program in case of power loss, and be recoverable with minimal operator actions.

Emergency Stop :

Emergency-stop buttons shall be supplied within the reach of the operator at normal operator stations. When activated, the emergency stop shall shut the Vial Filling and Stoppering Machine down immediately in accordance with the following requirements:

- All motion on the Vial Filling and Stoppering Machine shall stop in a safe manner.
- No damage to the Vial Filling and Stoppering Machine will occur as a result of an emergency stop.
- The Vial Filling and Stoppering Machine shall not be allowed to restart without operator intervention. It shall be necessary to restore the emergency stop button to the original state, and reset the system before restarting.

Alarms and Warnings:

In addition to the alarms in the above table, the following controls require alarms:

- All servo motor control faults require alarms.
- All servo motor thermal faults require alarms.
- All motion over travel faults requires alarms.
- All motion control not running faults require alarms.
- All communication faults require alarms

Physical Conditions :

- The Vial Filling and Stoppering Machine shall be installed in a class B clean-room environment.
- The Vial Filling and Stoppering Machine operates within a temperature range of 18 -25°C.
- The Vial Filling and Stoppering Machine operates within a relative humidity range of 30-65% RH. The RH will be raised to 100% during Fumigation.

Data & Security :

SCADA BASEED SYSTEM TO BE QUOTED AS AN OPTION

- Controls provided with a data collection systems intended for use in the manufacture of pharmaceutical products shall comply with European cGMP and US FDA guidelines.
- The Supplier shall stipulate the methods by which the above guidelines are met.

- Control panels housing PLCs or data processors shall be provided with the capability of being locked externally.

Interfaces:

The Programmable Logic Controller / Human Machine Interface system (PLC/HMI) shall include interfaces with the operator, supervisors, external equipment, and the user’s control system to ensure safe, reliable, continuous, automatic operation and easy, safe, reliable configuration.

Interface with Operators :

- The HMI shall control all vial filling and stoppering machine functions.
- The HMI shall display all alarms resulting from the vial filling and stoppering machine controls.
- The HMI shall display the current net weight results from the check weigh system.
- The HMI shall display the current counts from the vial counters.
- The HMI shall include provisions for configuration of new batch recipes, and display of current settings, ranges and limits.

Supervisory Interface (Optional):

Interface to SCADA system :

- Interface to a supervisory control and data acquisition (SCADA) system from the PLC shall be provided.
- Data within the PLC shall be addressed and available to SCADA.

Interface to the Supervisor :

- Batch data shall be available to the Supervisor from the HMI. Accessible data shall include: current net fill weight, status of the vial filling and stoppering machine, alarm history, current vial counts and vial counter reset.

Data Collection :

- Data required for collection by the user supplied SCADA system:
 - *Vial filling and stoppering machine out put*
 - Vial Count
 - Check weigh Data
 - Alarms and Warnings
 - *Vial filling and stoppering machine Status (e.g. “off,” “on,” “standby” states, etc.).*

Dow institute of life sciences.			
USER REQUIREMENT SPECIFICATIONS			
<i>Equipment</i>	MACRO VIAL FILLING LINE 50ML, 100ML, 150ML	<i>Department</i>	<i>Production</i>

INTRODUCTION 1:

This document was generated under the authority of **DILS DOW** for the purpose of specifying the user requirement for the Vial Filling Line which will be used in a pharmaceutical environment. This URS is provided to define the important components, variables and options necessary for the supplier to provide a functional Vial Filling Line that meets the **DILS DOW** minimum requirements. The URS is also provided to the supplier for getting the offer for the Vial Filling Line. This URS is an integral part of the procurement agreement with the supplier.

The Vial Filling Line will comprise the following machines

1. **Vial Washing Machine With LAF**
2. **DHS Drying and sterilizing Depyrogenation Tunnel**
3. **Vial Filling and Stoppering Machine with RABS. (Filled volume 0.5ml to 10ml) With rejection control and audit trail.**
4. **Alu cap sealing machine flip of seal**

The line will be used to fill vials; (Liquid vials) will proceed manually (In mobile LAF trolley) to the lyophilizer .

LINE OVERVIEW :

The Vial Filling Line will carry out the following operations, automatically, and without manual intervention (except loading and unloading of vials).

Washing of vials Rotary vial washing with LAF

- Application 50ml,100ml, 150ml vial
- Output vial per minute 130vial per minute
- Power supply 380V,60Hz
- Washing cleanness quality rate More than 99%
- Vial Breaking rate Less 0.3%
- WFI consumption 0.9cbm/h 0.3-0.5mpa
- WFI recycling with filtration and heating
- Power supply 380V/60Hz
- Industrial 4.0 compliance.
- Upstream and downstream compatible.

DHS sterilizing and Depyrogenation tunnel.

- Power supply 380 AC V 3 phase 50 Hz
- Cooling water
- Bottle temperature at outlet less or equal to Room + 20 °C
- Bottle breaking rate less or equal to 0.001%
- Temperature differences. less or equal to ± 5 °C
- Sterilizing temperature (Maximum 350 °C) 300 ~320 °C
- All blowers should be equipped with Invertor.
- Noise <65 Db
- Upstream and downstream compatible.
- Pressure differential control to avoid any cross contamination and pressure disturbance in the

area.

Filling, and rubber stoppering under laminar flow.(with RABS) (pre and post nitrogen purging)

- Liquid Filling Machine rubber stoppering under LAF
- Rubber stoppering vibrator bowl loading should be under LAF.
- Output 2000 to 4000 VPH (based on 100 ml fill volume)
- Vial Broken rate $\leq 0.01\%$
- Fill accuracy $\leq \pm 0.5\%$ (based on 1ml WFI fill volume)
- Stoppering qualification rat $\geq 99.97\%$
- Noise $< 65\text{dB}$
- Pre and post nitrogen purging.
- Industrial 4.0 compliance.
- Upstream and downstream compatible.
- With RABS –Restricted Access Barrier System

The outlet of filling machine vials will be loaded in mobile LAF trolley (perforated trays)

ALU CAP SEALING WITH LAF

- Suitable bottle range 50ml , 100ml, 150ml
- Auto cap-adding ratio $\geq 99.9\%$
- Qualified capping ratio $\geq 99.9\%$
- Bottle breakage ratio $\leq 0.1\%$
- Single machine noise $\leq 70\text{Db}$
- Industrial 4.0 compliance
- Upstream and downstream compatible.

Commodity Table :

Vials

50ML, 100 ML ,150ML Infusion Type.

(Subject to the sample.)

Rubber Stoppers

Infusion type.

Aluminum Caps

- The type of caps shall be flip off seals. or infusion vials

All necessary change parts should be included in offer.

Available Services

Compressed air	5 bar
Power Supply	380/3/60
	5 wire system
Water for Injection	
Purified Water	
Clean steam	
Nitrogen	

Construction and Finishes

- All machines to be constructed from Stainless Steel AISI 304
- All product contact parts shall be constructed from 316L stainless steel or approved silicon or Teflon or Viton. Stainless steel components will have a finish of 0.6µm and be electro polished.
- Stainless Steel electrical and control Panels

Quality Level

- The level quality is defined as follows
 - Maximum level of waste 1 % of hourly production due to all faults.
 - Filled volume 50ml ,100ml, 150ml
 - Maximum product loss 0.5 % of original batch quantity,
 - Dosing tolerance (for each unit) $\pm 0.5 \%$

GENERAL CHARACTERISTICS

- Line Speed 4000 to 8000 vials per hour.
- Technical zones should be accessible without passing through the pharmaceutical zones where possible.
- The system should be validatable
- To the latest state of the art.
- F.D.A. guide lines as may be applied to this type of equipment.
- No particle generation allowed at any stage
- Aesthetically pleasing appearance
- All the format change-parts relative to a particular product or packaging component must be marked with the same reference. These references must be engraved.
- From the exit of the .washing machine to the sealing/rubber stoppering stage, loading and unloading of containers must only be exposed to air-flows meeting class A conditions(mobile trolley with LAF)
- All the machines to be well insulated to minimize heat emission into the processing areas. Supplier to provide a figure for the total heat transmission from equipment to the production area.

- Each machine shall be equipped with at least one emergency stop button.
- CE Certification
- The main electrical components to be grouped into one St.St. electrical panel.
- Line to be installed in following areas
 - Washing and DHS in Class C area
 - Filling/sealing and rubber Stoppering in aseptic areas Class A, filling will be under class A conditions
- Machine/s to stop after preset number of successive faults
- PLC controls
- Touch Screen operating panels
- Recipe System
- Remote connection by modem
- Jogging switch for adjustment
- Diagnostic messages
- Wire Numbering
- Sound absorbing hoods for sorting bowls, sorting bowls to be in separate compartments
- All sensors pressure gauges etc should be easily accessible for calibration

Documentation :

- The supplier shall use the formats described in the current version of the Good Automation Manufacturing Practice (GAMP) supplier guide to produce the documentation. The Supplier shall provide the documentation for preliminary review. The supplier shall provide documentation reflecting “as-built” condition with final delivery. All final documents shall be shipped with transmittals that identify them as contractually required documents. All final documents and drawings shall reflect “as-built” condition.
- Installation, operation, and maintenance instruction documentation for the Vial line shall be developed to an easily comprehensible level.
- The supplier shall provide the documentation for preliminary review.
- All final documents shall be shipped with transmittals that identify them as contractually required documents. All labels on documents and Vial line shall be written only in English language.
- All documents shall be in English language and supplied with hard copies and electronic versions. The following documents shall be needed:
 - Software Module Test, Software Integration Test, Controls Test

- Hardware Installation Test
- DQ, IQ, OQ ,FAT ,SAT,PQ,
- Operation, Maintenance and Service Manuals
- Process and Instrumentation Diagram (P&ID)
- Instrument Listing
- Control Schematics
- Control Panel Assembly Drawings
- Vial line / Assembly Drawings
- Bill of Materials, material and weld certificate
- Spare Parts List for two years.
- PLC Program Ladder Diagram, with explanation in English, Printout and Disk File

3 copies should be supplied

General Requirements of The Line

- The specification items constitute the minimum requirements
- The Vial Filling Line shall be guaranteed by the supplier for a period of two years with all parts and services / labor from the date of installation or for three years from shipment date, whichever is shorter.
- All alarms must be audible unless otherwise specified.
- All alarms should stop machine unless otherwise specified.
- All alarms must be acknowledged with possibility of resetting
- All Layout drawings must be approved.
- All components must be to the latest proven technology available
- All dangerous parts and moving components shall be carefully covered and protected by safety contacts unless otherwise agreed.
- The specification for the machine will apply to any complimentary equipment or component or machine necessary for the operation this equipment and this equipment will treated as part of the machine.
- Any complimentary equipment or component or machine necessary for the operation of the machine should be to the latest state of art available on the market.
- All accessories affected by dust or air turbulence or others e.g. printers, scales, IPC units, keyboards, computers, monitors, operator panel switches etc should have proper and accessible protection transparent hoods and covers as necessary.
- All printers to be colored printers unless otherwise specified and the ink used to be of the non-

fading type.

- All services to any machine to be connected from one point, bottom entry connections are normally preferred.
- All displays should be clearly and visible and of the nonreflecting type
- Any electrical or Control Panel should have the proper protection against the surroundings i.e. against dust in dust prawn areas,
- Provision to connect to Factory Computer System to be provided
- All change parts to be engraved
- Reference scales and gauges for all adjustable parts to be provided.
- Aesthetically pleasing appearance
- Machines to be to the latest state of art GMP and FDA. guide lines
- Technical zone to be totally separate from Pharmaceutical zone
- Supplier to supply following:
 - Compressed air requirement
 - Water/s Requirement
 - Nitrogen Requirements
 - Air Extract requirement
 - Power consumption
 - Heat emission from Machines
 - Builder Work requirements including base etc
 - Layout drawings (on diskettes or CD wherever possible)
 - Layout drawings should clearly show all connection points
 - Machine total weight
 - Vibration transmission
 - Drainage
 - Any other requirement
 - Control Cable length as actual.
- The opening of any one of the guards shall immediately cut off the power supply to the machine concerned and cause its immediate stoppage.
- Each machine shall be equipped with at least one emergency stop button.

- Stop Start in phase on loss of power and on application of Emergency stop button.
- Any collected data to be retained on loss of power or application of the Emergency stop button.
- Priced Spare parts list for two year operation for each machine
- Control voltage to be 24 VDC
- For electrical loads over 5 KW, soft start should allowed for.
- Siemens PLC where applicable
- Compressed air filters, regulators, lubricators, gauges etc to be provided.
- Electrical and Control Panels to accord to International Standards e.g. CE Standards, in their design and must have the proper free area and labeling for all components and wiring.
- The Vial filling line machine shall meet the appropriate safety regulations. e.g.: OSHA regulations for the safety of operators and equipment with regards to safety, guarding and noise.
- Wiring on the Vial Filling Line machine and in the control cabinets shall be terminated at both ends and match the numbering shown in the documentation.
- Format change parts shall be identified with the part number and commodity size it will be used for.

Support:

The supplier to provide technical support as follows when and where necessary, start-up, training and follow up.

Availability :

The vial filling line is intended to be operated:

- 16 hours per day (One shift is 8 hours).
- 96 hours per week.

Operation of the vial inspection machine shall be shut down, and the vial inspection machine shall be available for maintenance or service:

- 2 hours per week.
- 1 day per month.
- 2 days per year.

Layout

Drawing showing the layout of the area where the line is expected to be installed.
The supplier will furnish layout drawings showing how the line will fit In the provided area.

The supplier will point out any deficiencies that that may arise from the layout and will provide his proposals.

Technical Requirements

- Filling Volume: 0.5, 1 and 10 ml.
- The volume and type of vials will be as indicated in the commodity table.

Vial Handling

- Dehydrogenated and sterilized vials fed from the DHS will be unscrambled and fed into the Vial Filling and Stoppering Machine.
- Depyrogenated vials are to be run through the Vial Filling and Stoppering Machine without becoming contaminated,

General

- Machine to be designed for aseptic filling
- Accumulation switch at in feed
- Adjustable speed Step Lesley
- Speed Indication, Hours Run Meter, Number of Vials Filled
- Number of Vials Rejected
- Key switch to select output direction, to capping machine in case of liquid vials and to magazine unit if Lyophilized vials
- Interlock with other downstream machine as selected
- Protection against jams both mechanical and electrical

Filling Station

- Operations to be carried out under laminar flow, class A, conditions.
- With RABS,
- Dosage precision approx. $\pm 0.5\%$
- Constant head filling system
- No Container no fill
- No dripping from filling needles
- Safety filtration before the filling needles
- Gas flushing before during and after filling, selectable
- If nitrogen flushing is selected and no nitrogen is detected machine to stop and raise alarm
- Output Indicator
- Machine to be surrounded by a transparent hood with safety switches
- Ability to adjust fill volumes of all filling stations by a single control and the ability to adjust pumps individually.

- The machine to be surrounded at working level with a closed, transparent cabinet with safety doors and a shielded electric light. This cabinet shall be under vertical laminar flow.
- Properly filled vials are defined as those possessing the desired dose as defined in the commodity table (± 0.5 % by weight).
- Vials will be filled without dripping onto the external surfaces of the vial or transport system.
- Liquid vials will be filled at the same Vial Filling and Stoppering Machine.
- Monitor Product temperature in tank (2 – 8° C)
- An intermediate insulated product tank of 5 to 10 litres capacity with level control. Monitoring and control of level shall be needed, with alarms and machine stop
- No condensation on tank or any of the machine ancillaries.
- Nitrogen blanketing of tank

Rubber stopper station

- Ability to program stoppering machine to fully or partially insert stopper into vial for conventional or lyophilized stoppers.
- Rejection system to be programmed accordingly.
- Each filled vial will have a stopper placed on it. Properly stoppered vials will be no more than 1 mm higher than a fully seated stopper.
- The rejection rate caused by missing or high stoppers must not exceed 0.01% during the defined one hour.
- The Vial Filling and Stoppering Machine shall stopper vials as mentioned in commodity table
- Stopper bowl to be in stainless steel execution, protected under laminar flow and in a different compartment
- Sorting and orientation of stoppers
- Stoppers Chute
- Rubber Stoppering to be under laminar flow with class A conditions
- No container no stopper
- Minimum Stoppers in chute raise alarm and stop machine
- Vials with missing or with high stoppers shall be rejected.
- The rejection system should have a cross check feature.
- Machine to stop after preset number of successive failures

Laminar Flow

- Laminar flow system should be provided to the Vial Filling and Stoppering Machine, so that the vial loading, filling, rubber stoppering and partially stoppered vial discharge process will be under laminar flow system (Class A).
- Integral lighting at 1000 Lux
- Air velocity measurement, indication and alarm
- DOP or similar test connections
- Differential pressure gauges
- Variable speed stepless
- Speed Indication.
- Correct speed setting to be clearly marked
- Laminar flow shall be interlocked with filling machine

Critical Processes

- Filling volume/weight
- Nitrogen/compressed air pressure/flow
- Temperature of the filling solution in tank (should be 2 – 8 °C)
- Rubber stopper height
- Nitrogen, compressed air filter integrity

Alarms and Warnings:

The Vial Filling and Stoppering Machine shall be equipped with but not limited to the following alarms and warnings:

Alarm #	Alarm Description	Alarm	Stop
1	Emergency Stop		X
2	Barrier Door Interlock		X
3	Air supply pressure low	X	X
4	No Vials		X
5	Stopper Hopper low	X	
6	No Stoppers	X	X
7	Missing Stoppers	X	X
8	Output full	X	X
9	Rejection Failure	X	X
10	Successive failures (Any of above)	X	X
11	Low Nitrogen Supply when selected	X	X
12	Laminar Flow not running	X	X
13	Others		

Performance :

- The Vial Filling and Stoppering Machine is expected to properly fill and stopper vials at production speeds/output to meet the required output.
- The Vial Filling and Stoppering Machine shall be operable by one person.
- Safety related faults shall stop the Vial Filling and Stoppering Machine immediately. The Vial Filling and Stoppering Machine shall not be allowed to restart without operator intervention.
- The Vial Filling and Stoppering Machine changeover between vial sizes by a single operator is expected to take no longer than 60 minutes.

Power Failure and Recovery :

- On power failure, the Vial Filling and Stoppering Machine shall fail into a "safe state".
- Reset required parameter before Vial Filling and Stoppering Machine can be restarted.
- No damage to Vial Filling and Stoppering Machine will occur as a result of going to the safe state.
- On power restoration, the Vial Filling and Stoppering Machine shall not restart without operator or communication-link input.
- Vial Filling and Stoppering Machine shall be designed to retain the PLC program in case of power loss, and be recoverable with minimal operator actions.

Emergency Stop :

Emergency-stop buttons shall be supplied within the reach of the operator at normal operator stations. When activated, the emergency stop shall shut the Vial Filling and Stoppering Machine down immediately in accordance with the following requirements:

- All motion on the Vial Filling and Stoppering Machine shall stop in a safe manner.
- No damage to the Vial Filling and Stoppering Machine will occur as a result of an emergency stop.
- The Vial Filling and Stoppering Machine shall not be allowed to restart without operator intervention. It shall be necessary to restore the emergency stop button to the original state, and reset the system before restarting.

Alarms and Warnings:

In addition to the alarms in the above table, the following controls require alarms:

- All servo motor control faults require alarms.
- All servo motor thermal faults require alarms.
- All motion over travel faults requires alarms.
- All motion control not running faults require alarms.
- All communication faults require alarms

Physical Conditions :

- The Vial Filling and Stoppering Machine shall be installed in a class B clean-room environment.
- The Vial Filling and Stoppering Machine operates within a temperature range of 18 -25°C.
- The Vial Filling and Stoppering Machine operates within a relative humidity range of 30-65% RH. The RH will be raised to 100% during Fumigation.

Data & Security :

SCADA BASEED SYSTEM TO BE QUOTED AS AN OPTION

- Controls provided with a data collection systems intended for use in the manufacture of pharmaceutical products shall comply with European cGMP and US FDA guidelines.
- The Supplier shall stipulate the methods by which the above guidelines are met.
- Control panels housing PLCs or data processors shall be provided with the capability of being locked externally.

Interfaces:

The Programmable Logic Controller / Human Machine Interface system (PLC/HMI) shall include interfaces with the operator, supervisors, external equipment, and the user's control system to ensure safe, reliable, continuous, automatic operation and easy, safe, reliable configuration.

Interface with Operators :

- The HMI shall control all vial filling and stoppering machine functions.
- The HMI shall display all alarms resulting from the vial filling and stoppering machine controls.
- The HMI shall display the current net weight results from the check weigh system.
- The HMI shall display the current counts from the vial counters.
- The HMI shall include provisions for configuration of new batch recipes, and display of current settings, ranges and limits.

Supervisory Interface (Optional):

Interface to SCADA system :

- Interface to a supervisory control and data acquisition (SCADA) system from the PLC shall be provided.
- Data within the PLC shall be addressed and available to SCADA.

Interface to the Supervisor :

- Batch data shall be available to the Supervisor from the HMI. Accessible data shall include: current net fill weight, status of the vial filling and stoppering machine, alarm history, current vial counts and vial counter reset.

Data Collection :

- Data required for collection by the user supplied SCADA system:
 - Vial filling and stoppering machine out put
 - Vial Count
 - Check weigh Data
 - Alarms and Warnings
 - Vial filling and stoppering machine Status (e.g. “off,” “on,” “standby” states, etc.).