BIDDING DOCUMENT

Procurement of Insulin & Allied Items on Rate Contract Basis

N.I.T No. DUHS/DP/2016/ 11 Dated 19 September 2016

Dow University of Health Sciences Karachi

PROCUREMENT OF INSULIN & ALLIED ITEMS

on Rate Contract Basis

N.I.T No. DUHS/DP/2016/ 11 Dated 19 September 2016

COST OF BIDDING DOCUMENT:	Rs. 2000/= Rupees Two Thousand Only (Non-Refundable)
PURCHASING DATE:	From the date of publishing to 08 October 2016.
BID DELIVERY DATE AND TIME	10 October 2016 at 11.00 a.m.
BID OPENING DATE AND TIME	10 October 2016 at 11.30 a.m.
BID DELIVERY AND OPENING PLACE:	At Dow University of Health Sciences, Ojha Campus, Prof. Masood Hameed Khan Library Block, Suparco Road, off Main University Road,Gulzar-e-Hijri, Scheme # 33, Karachi.

Note: No tender will be accepted after closing of the Tender box, what so ever reason may be.

Bidders are required to comply with all the clauses mentioned in the Terms and Conditions of the Bid Documents and any deviation will forbid them from competing in the tender.

Terms & Conditions

Bid will be valid for 90 days from the date of opening for technical and financial evaluation. The bidders shall quote their prices inclusive of all applicable duties and Taxes / transportation etc. and all other expenses on free delivery to Consignee's end. Price should be quoted in Figures & Words both as per sample proforma given below, failing which the offer will be ignored.

SAMPLE PROFORMA FOR TECHNICAL BID

Item #	Nomenclature/ Generic Name	Brand Name	Name of Manufacturer	Registration #

SAMPLE PROFORMA FOR FINANCIAL BID

Item #	Nomenclature/ Generic Name	Brand Name	Name of Manufacturer	Trade Price	Quoted price per unit	
					In figures	In words

DELIVERY PERIOD _____ **VALIDITY _____**

1. **GENERAL CONDITIONS & INSTRUCTIONS:**

1.1. The quoted rates should be in Pak Rupee and must be valid up to **three (03) years** (extendable for further two years with mutual consent) starting from the date of signing of contract.

1.2. The tender shall be submitted with all documents in sealed envelopes. The envelope must contain tender inquiry No. on the top, the name of the Bidder should be affixed on the face of the envelope on the left side. The Bidder should prepare the Tender in form of Technical and Financial proposals

separately in accordance with Rule 46(2) of SPP Rules 2010. The envelope should be marked Technical Proposal and Financial Proposal in BOLD and legible letters to avoid confusion. Envelopes should be sealed and addressed to the Chairman, Procurement Committee, Dow University of Health Sciences, Karachi and inserted in Tender box on the scheduled date and time.

1.3. Technical Proposal should have the following documents:

I. Original Tender receipt.
II. Photocopy of Pay Order *I* Demand Draft of Earnest money in which amount should not be readable, otherwise the bid ignored.
III. Copy of the Bid offer without showing the rates as per Performa given above.
IV. Valid Manufacturing License, Valid Drug Sales License whichever is applicable.
V. NTN / Income Tax Certificate.
VI. Professional Tax Certificate.
VII. GST Registration Certificate if applicable.
VIII. Bidder should submit documentary evidence that they can perform over all business of more than / equal to Rs. 20.000 Million which is a **mandatory requirement**, otherwise bid will be rejected straight away and will not be technically evaluated.
IX. More than 50% of business turnover should be in Non-Government Sector. **(mandatory requirement)**

1.4. Financial Proposal should have the following documents:

I. Original Pay Order *I* Bank Draft of Earnest money
II. Original copy of the Bid offer with Quoted price.
III. Printed Price List of the Manufacturer / Importer indicating Trade Price and Retail Price which should be duly signed and stamped by the Authorized person of the Firm.

1.5. Only Manufacturers / Importers or their authorized distributors can participate in the Tender. The Distributor should submit authorization letter in Original (as per given specimen) addressed to the Dow University of Health Sciences, Karachi.

1.6. (A) For Manufacturer:

All the Bidders (Manufacturers or their Distributors) should fill the Company Profile Performa which should be filled by the Manufacturer, duly signed and stamped and should be submitted at the specified time of Tender submission along with the relevant certificate and documents otherwise the bid will be ignored. The Company Profile Proforma should have the following documents:

I. Photocopy of Drug Registration Certificate issued by Ministry of Health Islamabad.
II. Manufacturing license of the drug.
III. GMP and cGMP Certificate issued by Ministry of Health Islamabad during last 03 years.
IV. The Bio-availability / Bio-equivalence report should be submitted or a certificate of analysis carried by the Sindh Provincial Drugs Testing Laboratories and if that is not available then the Federal Drugs Testing Laboratories certificate be submitted. The consignee shall carry out the physical examination after receipt of supplies and standard test *I* analysis report of the laboratory as mentioned above.(Copy of quality assurance certificate for each batch must be provided along with supplies)
V. Federal Drug Inspector report of the Manufacturer for last 03 years.
VI. Other relevant documents as required in Company Profile Proforma.

1.6 (B) For Importer:

All the bidders (Importer or their authorized distributors) should fill the Sole Agent proforma duly signed and stamped and should be submitted at the specified time of tender submission along with the relevant documents as required in the proforma otherwise the bid offer will be ignored.

1.7. Tenders must be completed by typing in the column provided / on separate Letter Head duly signed. Soft copies of tender form, Company profile and Sole Agent proforma may be downloaded from procuring agency's website i.e. www.duhs.edu.pk.

1.8. The tender must be free from erasing, cutting and over writing. In case of erasing, cutting and over writing, authorized person should initial it duly stamped, else the offer will not be entertained.

1.9. The rates of each item should be written in figures as well as in words. Arithmetical errors will be rectified on this basis. If there is a discrepancy between the unit price and the total price that is

obtained by multiplying the unit price and the quantity, the unit price shall prevail and the total price shall be corrected. In case of discrepancy the price in words will be authenticated and final.

1.10. Conditional Tenders against the Govt. Rules / policy will not be considered / entertained / accepted.

1.11. The Bidder should not be involved in arbitration or other litigation with procuring agency in last five years, otherwise their bid shall not be considered / entertained / accepted and rejected straight away.

1.12. Tenders shall be accompanied by bid security **@ 02%** of the value of store(s) quoted by them in form of Pay Order / Demand Draft in favor of Dow University of Health Sciences, Karachi.

1.13. Original purchase receipt must be enclosed with their offer.

1.14. Bidders shall purchase separate tender documents and furnish original Tender Purchase Receipt and prescribed Bid Security for each alternate offer in case they want to submit alternate offer. All the bids with alternate offers without separate Tender Purchase Receipt (original) and prescribed Bid Security shall not be considered and both bids, original and alternate will be rejected.

1.15. All Bidders should provide at least two samples free of cost of the quoted products.

1.16. The bidders are required to supply the goods in accordance with the prescribed packing and printing instructions of the procuring agency.

1.17. The tendered rate should be inclusive of all applicable prevailing taxes to Federal & Provincial Govt. or local bodies and will be deducted from the bill of the contractors / suppliers.

1.18. Successful bidder(s) shall have to sign a written contract with the University on the judicial stamp paper amounting to Rs. 500/-. The Bidder shall pay the prevailing Service Charges as per the article 22-A (Contract) of the schedule of stamp act 1899.

1.19. If the Contractors / Suppliers require Tax exemption facility regarding non deduction of Advance Income Tax. The exemption certificate issued by the concerned authority must be attached and on C.I.F basis a copy of Bill of Entry & Tax paid Challan copy should be attached with the bill.

1.20. The items have to be quoted on the Proforma (given above); duly filled stamped & signed by the authorized bidder. Only those items shall, be typed on the Proforma/separate letter head (as per serial of proforma) for which the rates are to be quoted. Any alteration / correction must be initialed and each page is to be signed and stamped at the bottom.

1.21. Procuring Agency will evaluate and compare the bids on package basis exclusively. Itemized bids will not be considered and rejected straight away.

1.22. Schedule is prepared with the generic name; however the bidder may also mention the brand name against the generic name.

1.23. The dosage form, strength and pack size offered for bidding in the tender shall be those which are registered / approved by the Ministry of Health. The dosage form, strength and pack size quoted by the bidder shall confirm to the ones mentioned in the tender form, Dose should be submitted for quoted items.

1.24. Registration number, make or origin of the country of the drug must be mentioned for each item, for which quotation is given, otherwise it will not be considered. The bidder will also provide original warranty of Manufacturer / Importer with Batch number and Quantity at the time of supply of medicines.

1.25. The quoted rates once offered by the firms will not be changed during the contract period.

1.26. It is mandatory that drugs quoted are registered with the Federal Ministry of Health.

1.27. The supplies should be in commercial pack as per drug act 1976 and delivered at the consignee's end by the authorized representative of the firm at the risk and cost of the bidder. Any breakage or shortage of stock will be recovered from the supplier.

1.28. All documents should be submitted duly paginated / flagged and the detailed of the documents should also be mentioned in front of the Index.

2. SPECIAL CONDITIONS:

2.1. Stores are required as early as possible. The bidder may, however, give their short guaranteed delivery period not more than one month from the date of issue of supply order, by which the supply will be completed positively. The Liquidated / damages in the event of completion beyond the given schedule shall be 0.1% for each day of delay from the targeted period.

2.2. The bidders shall quote their firm and final price both in figure and in words on free delivery basis to consignee's end including all the prevailing taxes (Federal / Provincial / Local bodies).

2.3. Distributor once nominated by the manufacturer / importer will be for the whole contract period and manufacturer / importer cannot change its distributor during the contract period. In exceptional cases the tendering authority may approve changes.

2.4. No manufacturer / importer shall authorize their distributor / agent / any firm or person to quote the same item, which the manufacturer is quoting itself in any tender. Failing those offers of both the manufacturer as well as other bidder shall be ignored.

2.5. The manufacturer / importer of sub-standard adulterated spurious, counterfeit, misbranded or contaminated medicine(s) item(s) etc, may be black listed by the competent authority as per judgment of the drugs court or any other authority whose decision will be final and in accordance with the offence and hence their bid security may not be released till the case is decided by the court or any other authority.

2.6. If goods are declared sub-standard the Manufacturer and their Distributor are equally responsible and are bound to supply additional quantity of whole batch free of cost.

2.7. The successful bidder shall sign the **Rate Contract agreement** with the procuring agency on judicial stamp paper of Rs. 100/- as per approved format.

2.8. The successful bidder shall pay the testing fees directly to the Provincial Drug Testing Lab. for the batches to be supplied and should supply extra quantity of drug / drugs used for testing purpose.

2.9. The drugs shall be accompanied by the necessary warranty on Form 2-A (on non-judicial stamp paper) in accordance with the provision of the Drugs Act 1976 and rules framed there under.

2.10. The sample of the drugs supplied by the vendors will be drawn by the concerned Inspector of Drugs for test and analysis purpose under Drugs Act 1976.

2.11. The supply should be executed in minimum number of batches.

2.12. Part payment against part supplies will be permissible.

2.13. The vendors who quote dispensing items (Methylated spirit, paraffin etc.) must possess re-packing License issued from Ministry of Health Islamabad or their offer will be ignored.

2.14. The Technical evaluation carried out by the Committee will be final, which will be assessed on clinical experience basis of the consultant (s) in the relevant specialty.

2.15. Only technically qualified bids will be considered by the Procurement Committee.

2.16. Only those item's Financial offer will be announced / considered which were technically qualify by the Committee, If any firm wants to give the separate item wise financial bid they are advised to give separate item wise sealed envelope (s) of every item and should mention the name of the item and tender serial number on the front in **BOLD and legible letters** to avoid confusion, else the Financial Proposal Envelope will be opened on qualified item basis and it will not be challenged by the Suppliers / Contractors to open the Financial Proposal of the disqualified items.

2.17. In case, the rates of two or more bidders found equal, all will be accepted on equal sharing basis.

2.18. If a sample of a batch of drug or item is declared in contravention of section 3 / 23 of drugs act 1976 on the basis of test analysis report of CDL, Karachi or on presence of any foreign particle seen by the competent authority, those will be destroyed and payment will not be made to the supplier. The supplier will be responsible to provide the fresh stock of standard quality within 45 days against the rejected batch. Otherwise amount equivalent to the supplied quantity of defective goods will be deducted from their bill and action will be initiated against the offending firm according to the Drugs Act. 1976 on terms and condition of the tender, whichever is applicable.

2.19. Manufacturer / Importer will issue an authorization letter as per attached sample proforma along with technical proposal.

2.20. Manufacturer / Importer of vaccines, Sera and recombinant DNA products should submit Lot Release certificate issued by Federal Government Analyst National Control Laboratory for Biologicals (NCLB), WHO approved vaccines, will be considered only.

2.21. Manufacturers & Importers will directly supply as per supply order along with Bill of Warranty and Quality Certificate of each batch.

3. PURCHASER'S RIGHT TO ACCEPT ANY BID AND REJECT ANY OR ALL BIDS:

The Central Procurement Committee reserves the right to approve / drop any item or scrap / cancel the tender as per relevant rules of SPPRA-2010.\

4. PERFORMANCE SECURITY:

The successful bidders will have to deposit the requisite performance security in shape of pay order / demand draft @ 05% of value of the orders awarded to them. The same will be released after successful completion of stores against purchase order(s).

The successful bidders may also deposit Rs. 1,000,000/- as retention money against their approved bid. The retention money will be returned on satisfactory performance of the contract award.

5. SHELF LIFE REQUIRED:

No supply will be accepted having expiry date less than 75% of shelf life for the National manufacturer and for imported items (wherever applicable). The drugs / medicines should have shelf life of 75% for national manufacturer and imported items.

6. REDRESSAL:

Redressal of Grievances & settlement of dispute will be as per SPPRA Rule-2010.

7. BID EVALUATION:

Bid evaluation for Distributor, Pharmaceutical Manufacturers & Importers will be considered based on bid evaluation criteria attached, acquiring 70% or more points shall be eligible to qualify.

Technical Evaluation of the products will be assessed **on quality and clinical experience by the Technical Evaluation Committee.**

9. UNDERTAKING on Rs.100/- Non Judicial Stamp Paper

9.1. I/ we read / understand the conditions specified in the tender inquiry and undertake:

9.2. That I / we will remain bound to supply any item as an additional quantity at the same rate on which said item 1/ we have supplied during the contract period.

9.3. That I / we agree whether our tender accepted for total, partial or enhanced quantity for all or any single item.

9.4. I / we also agree to supply and accept the said item at the rates for the supply of contracted quantity within the stipulated period shown in the contract.

9.5. I / we understand and ensure for the supply of quality medicines. 1/ we also agree to supply the 100% additional quantity without any additional charges, if the supplies/part of the supplies declared sub standard.

9.6. I / we undertake that, if any of the information submitted in accordance to this tender inquiry found incorrect, our contract may be cancelled at any stage on our cost and risk.

9.7. I / we undertake to deposit the Drug Testing fees per batch to the Provincial/Central Drugs Testing Laboratories, the said-fees will be deposited directly to POL / CDL, if the assignment given to the said laboratories.

9.8. I/ we undertake that, 1/ we will replace the drugs three month before its expiry.

9.9. I/ we undertake that, 1/ we have never been black listed.

10. TERMS AND CONDITIONS ACCEPTANCE CERTIFICATE

I / we, M/s._____ is hereby confirmed that we have carefully read all terms and conditions of the tender and also agreed to abide SPPR-2010 for procurement of Surgical Disposable Items etc. during the validity of the tender.

Signature of Vendor_____
Name of Authorized Person _____
Designation_____
Seal and Address _____
Tel No._____ Fax No. _____ E-mail address _____
Witness
1) Name_____ Signature _____
2) Name_____ Signature _____

11. Specimen for Authorization letter by Manufacturer/Importer for their Distributor:

I/We, M/s._____ hereby authorize M/s. _____
Address: _____ as our authorized Distributor for Dow University of Health Sciences, Karachi.

We give undertaking that if there is any sub-standard spurious, counterfeit, misbranded or contaminated and short supply of item(s) by our Distributor, we will be responsible for the same. We also undertake that we have read and understood the terms and conditions of the tender enquiry.

Signature of Manufacturer / Importer _____
Name & Designation._____
Address: _____

Note:

i) All the above said instructions must be read carefully for compliance; else the offer will be ignored.

ii) DUHS reserves the right to ask and verify any document from the participants related with Manufacturer / Importer of item, to assess the quality.

Technical Specifications
(Bill of Quantities)

S.#	DESCRIPTION	SIZE	Unit	Yearly Qty.
1	Human Insulin Regular/Short Acting Insulin	10ml	Vial	150
2	Human Insulin Intermediate Acting/NPH	10ml	Vial	150
3	Human Insulin mixture/Human Insulin 70/30	10ml	Vial	300
4	Human Insulin Regular/Short Acting Insulin	5 x 3ml	Penfill/Cart	60
5	Human Insulin Intermediate Acting/NPH	5 x 3ml	Penfill/Cart	60
6	Human Insulin mixture/Human Insulin 70/30	1 x 3ml	Penfill/Cart	120
7	Analog Basal Insulin	5 x 3ml	Vial/Pen	60
8	Analog Rapid Acting Insulin	5 x 3ml	Vial/Pen	30
9	Analog Mixture 30/70 OR Analog Mixture 25/75	5 x 3ml	Pen	30
10	Analog Mixture 50/50	5 x 3ml	Pen	30
11	Analog GLP1	1 x 3ml	Pen	60
12	Insulin Pen	1	Pen	600
13	Disposable Needle For Pen Devices	100's	Needle	6000

Offered goods must be in compliance-with the following standards / requirements:

1. FDA / EMA / Stringent regulatory body approved.
2. Source or raw material must be from USA or Europe.
3. Product Processed and packed in finished from USA or Europe.
4. Product should be available in full range (Vials, Cartages and Pen Devices).
5. Bio-similar studies of finished product.
6. IMS ranking/rating.
7. Proper Cold chain process.

PHARMACEUTICAL MANUFACTURER PROFILE

Note.

a. Please fill in the correct information carefully, submission of wrong/ vague information may lead to disqualification of the firm.
b. Each page of the Proforma must be duly signed & stamped.
c. Provide a soft copy (CD) along with duly filled Proforma.

GENERAL INFORMATION

1.	**Name of the company**				
1.a	**Year of establishment**				
1.b	**Form of the company Annex copy of registration** • Individual • Private limited • Public limited • Partnership • Corporation • Other (specify)				
1.c	**Address of the firm** • Registered office, • Telephone no. • Fax No. E mail address etc.				
1.d	**Location of the firm** Annex certificate • Industrial • Commercial • Residential • Agricultural • Other (specify)				
1.e	**Enlistment with any stock exchange** (in Pakistan / overseas. If any. Annex details)				
1.f	**Blacklisting / complaint against the firm** (by any govt. or other org. if any)				
2.	**Drugs manufacturing license number** (Annex copy of Drugs manufacturing License)				
2.a	**Type of activity being carried out by the company:-** • Formulation • Repacking • Other (specify)				
2.b	**Name & Address of the companies / subsidiaries** and associated companies, **if any,** With whom there is collaboration or joint venture	1 2 3			
2.c	**Annual sales turnover of the firm in the previous 3 years** (In millions)	year	Domestic/Non Government sector sales	Export	Govt Sector
	• **1.**				
	• **2.**				
	• **3.**				
2.d	• **Certificate from bank that manufacturer is capable of doing business up to and** • **financial worth of company**				
3.	**Total area of the unit** (in sq ft)				
3.a	**Total Covered Area** (in sq ft) Annex copy of approved lay out plan by Ministry of Health, Islamabad)				

3.b	**Total covered Area of production** (in sq ft)	
3.c	**Total covered area of quality control department**(Sq ft)	
3.d	**Total covered area of administration block (in Sq ft)**	
3.e	**Plant layout, design & finishes** • Enable avoidance of cross contamination • Enable proper cleaning, drainage, sanitization as per written sanitation program • Enable proper ventilation, air conditioning and maintenance.	
4.	**Income Tax no (NTN)** • Attach copy of certificates, • Attach details of tax paid during past 3 years • Attach copy of last annual income tax return	
5.	**Sales Tax Registration No. (if any. Applicable) Attach copy of certificate, and details of sales tax Paid during past 3 years**	
6.	**G M P compliance certificate & GMP audit report (attach report/ certificate)**	
7.	• **Assay procedure of all product** • **Reference Standard** • **Bio-availability/ Bio-equivalence report of all product**	
8..	**Technical personnel involved in Manufacture of pharmaceutical products** (Attach section wise list with qualification & experience)	
8.a	**Production**	
	• Pharmacist	
	• Chemist	
	• Other technical persons	
8.b	**Quality Control**	
	• Pharmacist	
	• Chemists/ biochemist/ microbiologist	
	• Other Technical Persons	
8.c	**Product/ formulation Development Section**	
	• **Pharmacist/chemist/other**	
9	**Total Employees (including Technical staff)**	
	Management	
	Production	
	Quality control	
	Research & Development Sales and Marketing Administration	
	Others	
	Total Head Count	
10	**Training of personnel** • On job training schedule • Schedule/program for training of technical staff • Schedule/program for training of worker (Including GMP and hygiene)	
11	**Medical checkup of worker:-** • Prior to induction • Annual • Periodic (worker doing optical checking)	
12	**Manufacturing information**	
12. a	**No of registered drugs**	

12.b	**No of drugs being manufactured (active)**		
12.c	**No of PV listed items (Attach list)**		
13.	**Raw materials (Active ingredients)** (Name of the source companies along with country of origin)		
14.	**Dosage form and production capacity**		
	Dosage Forms 1. Solid 2. Liquid 3. Inject able (liquid) 4. Inject able (Dry powder) 5. Ointments/ Creams/ Gels 6. Capsules 7. I V infusions 8. Dialysis solutions **9.** Repacking / External preparations Etc		**Production capacity (per 8 hours)** 1 2 3 4 5 6 7 8 9
15	**Cleanliness & maintenance of :**		
	• Equipments – List		
16	**Emergency power supply arrangements** (For at least critical areas of the unit)		
17	**Drug recalls system** **(volunteer) & SOPs for recall** (Annex details)		
18	**Inspection record of the company**		
	Years	**Inspecting Authority**	**Brief remarks of the inspecting authority**
	1		
	2		
	3		
19	**Market Availability and Since when (mention year)** • Products routinely manufactured • Only occasionally / on request (Annex six batches certificates)		
20	**Number of distributors/ authorized Agents** **(**Attach list indicating name, address / approx sales range of each)		
21	**Source of Raw Material**		

MANUFACTURING INFORMATION

STORES / WARE HOUSES

Covered area_____ (Annex details of each store)

S.No	Criteria	Available as per SOPs, GMP or cGMP	Partial	Not available	Remarks
i.	Separate stores for: • Raw material • Labels & packaging material and • Finished products				
ii.	Separate quarantine facilities for :- Incoming raw material Packaging materials				
Iii	Cold rooms facility for: • Vaccines, biological and other controlled temperature products • Cold chain facility				
Iv	Temperature & humidity control facility in the stores.				
V.	Identification slips for raw material: • Approved • Rejected • Quarantine				
Vi	Source of raw materials • Active and • Inactive (Annex list of the source companies with countries of their origin, as at SR No 16)				
Vii	Separate dispensing area & equipment				
Viii	Proper storage of materials as per storage instructions on the label				
Ix	Adequate space for the orderly storage of all materials				
X	Segregation of material as; • Quarantine • Approved, • Rejected • Recalled • Expired material/ drugs				
Xi	Storage of materials:- • On pallet, stands • Shelves / racks • Off the floor, • Off the walls (in all stores)				
Xii	Safe/ separate storage of inflammable / hazardous materials / chemicals				
Xiv	Separate storage facility for expired raw/ other materials				
Xv	Dispensing of materials according to prescribed SOP & GMP requirements				
Xvi	Traceability of specific batch from the distribution / sale records of finished good.				

SYRUPS / LIQUID SECTION

(Please give make, model, type, no & value of the equipment along with availability status, attach complete list)

Total covered area of the section _____ Batch capacity

S.No	Criteria	Available as per SOPs, GMP or cGMP	Partial	Not available	Remarks
I .	Water source City water supply/ deep-well other				
ii.	Water treatment plant Multi effect, fabricated with GMP standard lines, de-ionized water				
iii.	Treated water storage capacity				
Iv.	Equipments washing/ cleaning facility				
V	Mixing equipments				
Vi	Heat source(Electricity, gas o r oil)				
Vii	Storage capacity (No of containers with capacity)				
Viii	In-process production & quality control records				
Ix	Filtration equipment				
X	Water outlets system (concealed or open drain system)				
Xi	Bottles De-Carton ing Room				
Xii	Facility for Bottles; • Washing • Drying • Blowing				
xiii.	Automatic Filling Line & Machines (No, Type & Capacity				
xiv.	Caps Sealing Machines (No, Type & Capacity)				
xv.	Mode of Labeling (Manual / Automatic)				
xvi.	In Process Filling and QC Record				
xvii.	Transfer & Filling Lines Pipes (SS or Other)				
Xviii	Q C Release Certificate				

TABLETS SECTION

(Please give make, model, type, No and value of the equipment along with availability status, attach complete list)

Total covered Area _____ Batch Capacity

S #	Criteria	Available as per SOPs GMP or cGMP	Partial	Not Available	Remarks
I	Mixer (wet and Dry) (type / Capacity)				
Ii	Granulator (wet and Dry) (No, Type / Capacity)				
Iii	Dryers (FB / Tray) (No, Type / Capacity)				
Iv	Quarantine: • Facility and Procedures for storing of granules prior to QC release for compression • Facility and procedures for storing of tables prior to QC release for packing				
V	Compression machines (No, Type & Number)				
Vi	In process QC and compression record [Weight variation / Hardness]				
Vii	Mode of Coating being done (Film / Sugar/ Automatic/ manual				
Viii	Film Coating Machine, if available (Number / capacity)				
iX	Coating pans (Film & sugar) (Number / capacity)				
X	Ventilation & Exhaust system for film coating section [for coating section]				
Xi	Batch Coating Capacity (In consistent with batch capacity				
Xii	Strip Packing Machines (Number / Capacity)				
Xiii	Blister Packing Machines (Number / Capacity)				
Xiv	Printing Machines (Inject / Laser/ Other)				
Xv	QC Batch Release Certificate (prior to packing)				

CAPSULES SECTION

(Please give make, model, type, no & value of the equipment along with availability status, attach complete list)

Total covered area_____ Batch Capacity

S. #	Criteria	Available as per GMP, cGMP &SOPs	Partial	Not available	Remarks
I	Powder Mixer No, Type & Capacity				
Ii	Capsule filling Machine (Auto / semi Auto No, Type, Capacity)				
Iii	Temperature and humidity Control (HV AC System)				
Iv	Dehumidifiers for capsules filling (if being used, type)				
V	In processing filling & QC record				
Vi	Blister packing Machines Number / capacity, Make				
Vii	Blister Batch & Expiry Date Printing Facility (inject, Laser / Other)				
Viii	Quarantine Facility • For storing of material prior to QC release for filling • For storing of Capsules prior to QC release for packing				

DRY POWDER (ORAL)

(Please give make, model, type, no & value of the equipment along with availability status, attach complete list)

Covered area_____ Batch Capacity

S. #	Criteria	Available as per SOPs GMP or cGMP	Partial	Not available	Remarks
I	Powder Mixer No, Type & Capacity				
Ii	Temperature and Humidity Control (HV AC System)				
Iii	Filling Machine Manual / Automatic/ Semi				
Iv	Bottles: • De Cartooning • Washing Facility • Drying Facility • Blowing Facility				
V	In process Filling and QC Record				
Vi	Labeling & Packing Manual/ Automatic				
Vii	Quarantine Facilities In process / Finished				
Viii	Maintenance and Cleanliness				

OINEMENTS / CREAMS / GELS/

(Please give make, model, type, no & value of the equipment along with availability status, attach complete list)

Total covered area_____ Batch Capacity

S. #	Criteria	Available as per SOPs GMP or cGMP	Partial	Not available	Remarks
i.	Homogenizer / Mixing equipments (Type / capacity)				
ii.	Preparation & Mixing Equipments (Type / Capacity)				
iii.	Tube Filling / Sealing Equipments [Manual / Semi Automatic/ Automatic]				
iv.	Temperatures / Humidity Control				
V.	Type of preparation being produced [crams, Ointment, Gels]				
vi.	Batch printing Facility (Laser/ Inject / Other)				
vii.	In process Filling Record & QC Record				
viii.	Equipment washing facility				
ix.	Batch Record				
x.	Quarantine Facility				
xi.	Maintenance of the area				

STERILE AREA
[DRY POWDERS VIALS]

(Please give make, model, type, no & value of the equipment along with availability status, attach complete list)

Total covered area_____ Batch Capacity

S. #	Criteria	Available as per SOPs GMP or cGMP	Partial	Not available	Remarks
i.	Dedicated Air Handling Unit (HV AC System) as per requirement of the area				
ii.	Positive Pressure (positive Pressure maintained in each filling room <0.05 inch of water column, Manometer				
iii.	Area. • Sterilization record • Fumigation record • Mopping Record				
iv.	Vials Washing Drying Blowing & Sterilization Facilities (washing with filtered water under HEPA filter, if being washed)				
v.	Laminar Flow Hood (Over the filling machine)				
vi.	Change Rooms Air Lock & Buffers (Before filling / processing room)				
vii.	Nitrogen / Inert gas flushing of the vials/ ampoules, if required so				
viii.	Vials Filling Machine [Number, Type and capacity , & Make]				
ix.	Vials sealing Machine Number type, Capacity Make flip off cap or other				
x.	Written procedure for handling of rejected vials				
xi.	Vials batch over printing facility (Laser, Inject / Other)				
xii.	Labeling & Packing (Automatic semi automatic Manual)				
xiii.	SOPs for the sterile area				
Xiv.	Equipment Cleaning Facility / Scheme				

GENERAL / ANTIBIOTIC
[LIQUID INJECTABLE]

(Please give make, model, type, no & value of the equipment along with availability status, attach complete list)

Total covered area_____ Batch Capacity_____

S. #	Criteria	Available as per SOPs GMP or cGMP	Partial	Not available	Remarks
i.	**Dedicated Air Handling Unit HVAC System** (As per requirement of the area)				
ii.	**Positive pressure** Positive Pressure maintained in each filling room <0.05 inch of water col. Manometer installed				
iii.	**Water Treatment Plant** Multi effect Multi col, Fabricated with GMP standard SS lines & pyrogen free water				
iv.	**Water Storage Facility & Capacity, If stored** (SS storage tank, with sufficient capacity, kept at 80c with 24 hrs circulation through loop under UV light)				
v.	**Filtration of solution** (aseptically, through recommended filter				
vi.	Laminar Flow Hood for filling Machine				
vii.	**Change Rooms & Buffers** (Change Room, air lock and buffer room prior to filling room)				
viii.	Sterilization and de-hydrogenation of filling equipment & their parts (In autoclave prior to use)				
ix.	Bulk Solution held under positive pressure during filling				
x.	Ampoules Filling Machines (Number, Type, Capacity & Make)				
xi.	Equipment cleaning with treated water				
xii.	Aseptic batching area sterilization Facilities / Mechanism				
xiii.	Environmental monitoring program for the aseptic batching area, sterile filling room and filling line				
xiv.	Integrity monitoring System for laminar flow hood and HVAC, serving sterile area				
xv.	Ampoules Batch Printing Facility (Laser / Inject / Other)				
xvi.	Labeling & Packing (Automatic / Manual)				
xvii.	Equipment cleaning Facility/ Scheme				
Xviii	Biological indicators used in sterilization process				
Xix	Record of sterilization cycle (Temp / time)				
Xx	Optical Checking Room Facility				
Xxi	Eye Examination Record of Optical Inspectors				
Xxii	Rejection Record				

Xxiii	Ampoule Printing Facility (overprinting)				
Xxiv	**Area and Environment Monitoring Record & SOPs** • installation, Operational & Performance of all equipment being conducted & maintained • Aseptic filling process monitoring through media fill and broth fill trial performed (biannually minimum) • sterilizers integrity checked and maintained • Calibrations of all measuring and monitoring devices being conducted / maintained regularly				
Xxv	Class of the Sterile Area (As per std requirement of the areas)				
Xxvi	Quarantine for the product waiting QC release				

QUALITY CONTROL / QUALITY ASSURANCE

Equipment

(Please give make, model, type, no & value of the equipment along with availability status, attach complete list)

covered area_____

S. #	Criteria	Available as per SOPs GMP or cGMP	Partial	Not Available	Remarks
1.	UV , Spectrophotometer				
2.	HPLC				
3.	Moisture Analyzer				
4.	PH Meter				
5.	Disintegration Apparatus				
6.	Dissolution Apparatus				
7.	Friability Testing Apparatus				
8.	Hardness tester				
9.	Melting point apparatus				
10.	Electric Ovens				
11.	Digital balance				
12.	Gas Chromatography				
13.	Floury Meter				
14.	Refract meter				
15.	Polari meter				
16.	I R Spectrophotometer				
17.	Micro Lab				
18.	Pyrogen Testing Apparatus / Facility				
19.	Laminar Flow Hood & Sterility Testing Facility				
20.	Particle Counter				
21.	Colony Counter				
22.	Incubators Hot & cool				
23.	Electric Ovens				
24.	Quality Control Procedures and Analytical Methods				
25.	Analytical Record Of: • Active Raw Material • Inactive Material • In process products • packing & Packaging Materials • Finished Products				
26.	Shelf Life / Stability Studies				
27.	Complete Batch History and Record				
28.	Batch Release Certificates Record				
29.	In process Q C Inspector [Appointed or Not]				
30.	No of Technical personal working in the Lab with qualification (attach list) • Chemist • pharmacists • Biochemist • Microbiologist • Others				
31.	Quality Standards being followed • United State Pharmacopoeia • British Pharmacopoeia				

	• Japanese Pharmacopoeia • Pakistan Pharmacopoeia • Chinese Pharmacopoeia • Any other / Own specifications				
32.	Retention samples of each batch in its original container				
33.	Quality Control tests invariably conducted for: • Active • Non Active and • Packaging Materials • In process / Intermediate • Bulk and • Finished products				
34.	SOPs / Prescribed procedure for approval of vendor / source of starting materials				
35.	Procedures for releasing finished products SOP's				
36.	Person responsible for release of batch (qualification & experience)				
37.	Time period for retention of control samples (till expiry or one year after expiry)				
38.	Other details of quality assurance/ QC procedures, if any (Annex Details)				
39..	Stability tests and shelf life studies (for each products)				
40.	Testing from each container of active starting material or other random sampling				

Signature_____
[With name and Designation]
Stamp of Company

IMPORTER / SOLE AGENT

Note.

a. Please fill in the correct information carefully, submission of wrong/ vague information may Lead to black listing of the firm.
b. Each page of the Performa must be duly signed & stamped.
c. Provide a soft copy (CD) along with duly filled Performa.
d. Company/firm agreement with principle duly signed by embassy is mandatory.

GENERAL INFORMATION

1.	**Name of the company**			
2.	**Year of establishment**			
3.	**Address of the firm** • Registered office, • Telephone no. • Fax No. E mail address etc.			
4.	**Location of the Company** • Industrial • Commercial • Residential			
5.	**Form of the company Annex copy of MOA/ registration** • Individual • Private limited • Public limited • Partnership • Corporation • Other (specify)			
6.	**Blacklisting / Complaint / Litigation against the firm** (By any govt. or other org. if any)			
7.	**Drugs sale license number, if applicable** (Annex copy License)			
8.	**Type of activity being carried out by the company:-** • Manufacturing • Assembly /Repacking • Import • Other (specify)			
9.	**Name & Address of the Principal(s) companies**			
10.	**Capital value of the firm/sole agent;** • Authorized Capital • Paid up capital			
11	**Annual sales turnover of the firm in the previous 3 years** (In millions)	Year	Non-government /Market Sale	Govt. Sector
	• **1.**			
	• **2.**			
	• **3.**			
12.	**Income Tax no (NTN)** • Attach copy of certificates, • Attach details of tax paid during past 3 years • Attach copy of last annual income tax return			
13.	**Sales Tax Registration No. (if any. Applicable)** Attach copy of certificate, and details of sales tax Paid during past 3 years			

14.	**G M P compliance certificate & GMP audit report of the Principal(s)** (Attach report/ certificate) (if applicable)	
15.	**Free Sale Certificate of the items in the country of origin**	
16.	**Registration with MOH, Islamabad where applicable** Drugs/Surgical Disposable**,** attach separate sheet	
17.	List of Technical personnel with qualification (Attach List)	
18.	Total Employees (Including Technical staff)	
	Administration	
	Technical	
	Management	
	Sales / Marketing	
19.	**Market Availability** • Products routinely manufactured/imported Only occasionally / on request	
20.	**No of registered / items of the principals** (In case of drugs only)	
21.	**No of Thermo labile drugs** (if any)	
22.	**Storage Facilities** [For thermo labile drugs]	
23.	**Storage Facilities** [For the drugs to be stored at room temperature]	
24.	**Cold Chain Facility including cold room / storage and during transport**	
25.	GMP Certificate of the Principals, from the country of origin	
26.	**Export of the products to the countries other than Pakistan**	
27.	**Drug registration Certificate in the country of origin** (In case of drugs only)	
28.	**Emergency power supply arrangements** (For at least critical area)	

Signature_____
[With name and Designation]
Stamp of Company

BID EVALUATION CRITERIA
(PHARMACEUTICAL MANUFACTURER / IMPORTER)

Total Evaluation Marks allocated 100
Qualifying Marks. 70

1. Name of Firm : _____
   (Complete address)
   _____

2. Type of Firm : Manufacturer ☐ Importer ☐

S#	Evaluation Criteria		Marks Allocated		Marks obtained
Mandatory Requirement (if not fulfilled bid will straightaway be rejected					
1.	Conformity to the Purchaser's Specifications	Compliant with the required specifications and Terms & Conditions	20		
2.	Financial Soundness of the firm (Annual Turnover)	20 millions or above.	05		
3.	Non-Government Share %	More than 50% of annual turnover	05		
4.	Valid Manufacturing License & Drug Registration Certificates	Copy of Valid License	10	05	
		Drug Registration Certificates		05	
5.	Bio-Pharmaceutical Assessment.	Bio-Similar Studies of finished product.	20	10	
		IMS Ranking / Rating		05	
		Assay Procedure / Shelf Life / Stability Studies Data		05	
Other Requirements					
6.	Drug Regulator Reports for Last 3 Years.	Very Good	5	05	
		Good.		04	
		Satisfactory		03	
		Average		02	
		Poor		01	
		Not Supplied		00	
7.	Quality Control Department Assessment	PH.D	10	03	
		Pharmacist		02	
		Testing Facilities		03	
		GMP Compliance		02	
8.	Warehouse Department Assessment	Storage Facilities	10	04	
		Cold Chain Supply System (Where Appliance)		02	
		Warehouse Trained Staff.		04	
9.	Source of Raw Material	USA / Europe	10	10	
		Any other origin		00	
10.	Raw Material / Finished Material	Finished product / product processed and packed in finished form from USA / Europe	05	03	
		Registration in Country of origin		02	
		TOTAL	**100**		

Remarks:

BID EVALUATION CRITERIA
(DISTRIBUTOR / SUPPLIER FOR PHARMACEUTICAL TENDER)

Total Evaluation Marks allocate 100
Qualifying marks. 70

1. Name of Firm : _____
   (Complete address)
   _____

2. Type of Firm: Distributor ☐ Supplier ☐

		Specification	Marks Allocated		Marks of
Mandatory Requirement (if not fulfilled bid will straightaway be rejected					
1	Conformity to the Purchaser's Specifications	Compliant with the required specifications and Terms & Conditions	20		
2	Valid Authority letter from Manufacturer / Importer	M/s.	10		
3	Previous Performance with Government.	More than 3 years	10	10	
		2 years less than 3 years		05	
		Less than 1 year		02	
4	Financial Soundness of the bidder.	Bank Certificate that bidder can perform business up to Rs. 20.000 millions	05		
5	Original Tender Purchase receipt		05		
Other Requirements					
5	Certificates.	NTN Certificate	20	05	
		Professional Tax Certificate		05	
		Sales Tax Certificate		05	
		Whole Sale Drug License (for Pharmaceutical products only)		05	
6	Warehouse / Storage facility	Storage Facilities	10	05	
		Cold Chain Supply System (Where Appliance)		05	
7	Profile of Manufacturer / Importer (as per format attached)	Information upto 85%-100%	20	20	
		Information upto 70%-85%		15	
		Information upto 60%-70%		10	
		TOTAL	**100**		

Remarks: