

PREQUALIFICATION DOCUMENTS

(SURGICAL DRESSINGS)

**(MANUFACTURING UNITS AND SOLE AGENTS OF FOREIGN
PRINCIPALS)**



(FINANCIAL YEAR 2024-2025)

**Primary & Secondary Healthcare Department
Government of the Punjab**

Table of Contents

Section I: Instructions to Applicants (ITA)

A. General.....

 1. Scope of Application.....

 2. Fraud and Corruption

 3. Eligible Applicants.....

B. Contents of the Prequalification Document.....

 4. Sections of Prequalification Document.....

 5. Clarification of Prequalification Document

 6. Amendment of Prequalification Document

C. Preparation of Applications.....

 7. Cost of Applications

 8. Language of Application

 9. Documents Comprising the Application.....

 10. Application Submission Form

 11. Documents Establishing the Eligibility of the Applicant.....

 12. Documents Establishing the Qualifications of the Applicant

 13. Signing of the Application and Number of Copies.....

D. Submission of Applications

 14. Sealing and Identification of Applications

 15. Deadline for Submission of Applications.....

 16. Late Applications

 17. Opening of Applications

E. Procedures for Evaluation of Applications

 18. Confidentiality

 19. Clarification of Applications

 20. Responsiveness of Applications

 21. Domestic Bidder Price Preference.....

F. Evaluation of Applications and Prequalification of Applicants.....



 22. Evaluation of Applications

- 23. Right to Accept or Reject Applications.....
- 24. Prequalification of Applicants.....
- 25. Notification of Prequalification
- 26. Validity of Prequalification

Section II: Prequalification Criteria Surgical Dressings

Section III:

- A: List of Surgical Dressings
- C: Application Submission Form.....
- D: Application Affidavit.....

 <p>PURCHASE CELL DIRECTORATE GENERAL HEALTH SERVICES PUNJAB 24-COOPER ROAD, LAHORE Phone No. +924299201145 Purchase Cell E-mail- pcdghs@gmail.com</p>	<p>Primary & Secondary Healthcare Department</p> 
INVITATION FOR PREQUALIFICATION (Financial Year 2024-25)	
<ol style="list-style-type: none">1. Government of the Punjab is committed to procure and supply quality Medical Devices and Surgical Dressings to patients. Directorate General Health Services (DGHS) Punjab invited applications for prequalification of firms (Manufacturers and Sole Agents of Foreign Principals - more specifically described in the prequalification documents) concerning procurement & supply of Medical Devices and Surgical Dressings items for Financial Year 2024-25. This prequalification shall also be applicable for various procuring agencies likely District Health Authorities (DHAs), Vertical Programs, Punjab Health Facilities Management Company (PHFMC), Specialized Healthcare & Medical Education Department (SHC&MED), Governor House Medical Center, Punjab Emergency Services Rescue 1122, Prison Hospital of Punjab etc. (detail of procuring agencies in documents) who assigned DGHS Punjab to conclude their prequalification process under rule 64-A of Punjab Procurement Rules (PPR), 2014.2. A complete set of Prequalification Documents in English can be downloaded from the websites [www.ppra.punjab.gov.pk], [www.pshealthpunjab.gov.pk] [www.dghs.punjab.gov.pk]. Pre-application meeting is scheduled to be held on 23-01-2024 at 11:00 A.M in the committee room of this DGHS Punjab. The minutes of Pre-application meeting shall be construed as part of prequalification documents and same shall be uploaded on the official website of procuring agency on or before 26-01-2024. Any amendment shall be made as prescribed in PPR-2014.3. The firms are required to submit prequalification documents online on following Department's link [http://pqod.pshealthpunjab.gov.pk] or official website of P&SHD. [http://www.pshealthpunjab.gov.pk] related to prequalification application. The last date and time for online submission of Pre-Qualification documents is 15-02-2024 till 11:00 A.M via department's online portal and the signed computerized print of the same online submitted Pre-Qualification documents in hard copy of prequalification application must reach The Purchase Cell, Directorate General Health Services Punjab, 24 Cooper Road, Lahore on 15-02-2024 till 11:00 A.M which shall be opened on the same date at 11:30 AM. In case of any discrepancy & conflict in submitted online prequalification application and hard copy of application, the prequalification application submitted in hard form will prevail.4. The firms shall pay a non-refundable Prequalification Fee on Challan Form 32-A as mentioned in Pre-qualification documents.5. Prequalified firm(s) shall be entitled to participate in the subsequent procurement proceedings as per requirement of the procuring agency(s).6. In case the date of opening or last date of submission is declared as a public holiday or non-working day due to any reason, the next official working day shall be deemed to be the date of submission and opening of applications accordingly. The time and venue shall remain the same.	
Note: The process shall be governed by the Punjab Procurement Rules, 2014.	
Director General Health Services Punjab	
DIRECTORATE GENERAL HEALTH SERVICES PUNJAB Primary & Secondary Healthcare Department, Government of The Punjab E-mail: pedghsalahore@gmail.com Contact No: +92 (42)99201145	
IPL-520	

Section I: Instructions to Applicants (ITA)

A. General

1. Scope of Application

1.1 In connection with the Invitation for Prequalification “as per PPR 2014” the Director General Health Services Punjab, Primary & Secondary Healthcare Department Government of the Punjab, issues this Prequalification Document (PQD) to applicants interested to prequalify Surgical Dressings Manufacturing Units & Sole Agents of Foreign Principals for Surgical Dressings against the list of items contained in the Prequalification Documents. This prequalification will be concluded for DGHS and shall also be applicable for various procuring agencies likely District Health Authorities (DHAs), Vertical Programs, Punjab Health Facilities Management Company (PHFMC), Specialized Healthcare & Medical Education Department (SH&MED), Governor House Medical Center, Punjab Emergency Services Rescue 1122, Prison Hospital of Punjab etc. who assigned DGHS Punjab to conclude their prequalification process under rule 64-A of Punjab Procurement Rules (PPR), 2014. Prequalification will be carried only for the items which comes under the definition of drugs under Drugs Act 1976/DRAP Act 2012/Punjab Drugs Rules 2007/ Punjab Drugs Amendment Act 2017 for Drug items & Medical Devices Rules 2017. DGHS may through their physical inspection committee(s)/inspector(s) shall verify the facts/claims submitted by the applicant(s). Any forged document(s)/claim(s) shall be dealt under PPR-2014.

2. Fraud and Corruption

2.1 Director General Health Services Punjab, Primary & Secondary Healthcare Department Government of the Punjab requires that applicant observe the highest standard of ethics during the submission of application for prequalification and further documents required for prequalification.

(a) In pursuance to this, the following terms are defined:

(i) “corrupt practice” is the offering, giving, receiving or soliciting, directly or indirectly, of anything of value to influence improperly the actions of another party;

(ii) “fraudulent practice” is any act or omission, including a misrepresentation, that knowingly or recklessly misleads, or attempts to mislead, a party to obtain a financial or other benefit or to avoid an obligation;

(iii) “collusive practice” is an arrangement between two or more parties designed to achieve an improper purpose, including to influence improperly the actions of another party;

(iv) “coercive practice” is impairing or harming, or threatening to impair or harm, directly or indirectly, any party or the property of the party to influence improperly the actions of a party;

- (v) “obstructive practice” is deliberately destroying, falsifying, altering or concealing of evidence material to the investigation or making false statements to investigators in order to materially impede a Bank investigation into allegations of a corrupt, fraudulent, coercive or collusive practice; and/or threatening, harassing or intimidating any party to prevent it from disclosing its knowledge of matters relevant to the investigation or from pursuing the investigation; or
- (b) Director General Health Services Punjab, Primary & Secondary Healthcare Department Government of the Punjab will reject a proposal for prequalification if it determines that the applicant has directly or through an agent, engaged in corrupt, fraudulent, collusive, coercive or obstructive practices in competing for the prequalification in question;
- (c) Director General Health Services Punjab, Primary & Secondary Healthcare Department Government of the Punjab will declare ineligible, either indefinitely or for a stated period of time, if it, at any time, determines that the firm has, directly or through an agent, engaged in corrupt, fraudulent, collusive, coercive or obstructive practices in competing for prequalification.
- (d) The prequalified firms are required to participate in RFP/bidding process announced by any procuring agency under administrative control of Primary & Secondary Healthcare Department. All prequalified firms shall participate in subsequent bidding process (RFP) of all the procuring agency(s) who assigned DGHS Punjab to conclude their prequalification process under rule 64-A of Punjab Procurement Rules (PPR), 2014. In case of non-participation, DGHS may suspend/cancel the prequalification status of Firm/Product at any stage as well as debar the firm for future procurement processes.

3. Eligible Applicants

- 3.1 Local manufacturer or Sole agent of foreign manufacturer can be a private or public entity registered with DRAP and FBR having NTN & SRTN Registration in its own name. Any authorized agent of Local manufacturer and authorized agent of Sole agent of foreign manufacturer shall be ineligible.
- 3.2 If Government of Pakistan prohibits commercial relations with any Country, the firms dealing with such countries are ineligible to apply.
- 3.3 A firm declared disqualified / blacklisted / debarred by Directorate General Health Services (DGHS) Punjab shall be ineligible for prequalification

B. Contents of the Prequalification Documents

4. Sections of Prequalification Documents

- 4.1 The documents for the prequalification of Applicants (hereinafter - “prequalification documents”) consists of all the sections indicated

below, and should be read in conjunction with any Addendum if issued.

Section I. Instructions to Applicants (ITA)

Section II. Prequalification criteria

Section III. A: Application Form

B: Application affidavit

4.2 The “Invitation for Prequalification Applications” (IPA) issued by the Procuring Agency is part of the prequalification documents.

4.3 Director General Health Services Punjab, Primary & Secondary Healthcare Department Government of The Punjab accepts no responsibility for the completeness of the prequalification documents and its addenda unless the original receipt of the fee deposit slip is attached with the documents.

4.4 The Applicant is expected to examine all instructions, forms, and terms in the Prequalification Documents and to furnish all information or documentation required by the Prequalification Documents.

5. Clarification of Prequalification Document

5.1 A prospective Applicant requiring any clarification of the Prequalification Documents shall contact the Director General Health Services Punjab, Primary & Secondary Healthcare Department Government of the Punjab in writing at the address indicated in the **Invitation for Pre-Qualification of Surgical Dressings**. The Director General Health Services Punjab, Primary & Secondary Healthcare Department Government of the Punjab will respond in writing to any request for clarification provided that such request is received preferably before submission of PQ application. The Director General Health Services Punjab, Primary & Secondary Healthcare Department Government of the Punjab shall forward copies of its response to all applicants who have acquired the prequalification documents through its official website including a description of the inquiry but without identifying its source. Director General Health Services Punjab, Primary & Secondary Healthcare Department Government of the Punjab deemed it necessary to amend the prequalification documents as a result of a clarification it shall do under intimation to all the applicants who have obtained the prequalification documents through its official website.

6. Amendment of Prequalification Document

6.1 At any time prior to the deadline for submission of applications, the Director General Health Services Punjab, Primary & Secondary Healthcare Department Government of the Punjab may amend the Prequalification Documents by issuing addenda/Corrigendum.

6.2 Any addendum/corrigendum/minutes of pre-application conference issued shall be part of the Prequalification Documents and shall be communicated in writing to all who have obtained the prequalification documents from the Primary & Secondary Healthcare Department. The minutes shall also be uploaded on the official websites of Director General Health Services Punjab and Primary & Secondary Healthcare Department Government of the Punjab

6.3 To give prospective Applicants reasonable time to take an addendum/corrigendum into account in preparing their applications, the Director General Health Services Punjab, Primary & Secondary Healthcare

Department Government of the Punjab may, at its discretion, extend the deadline for the submission of applications

C. Preparation of Applications

- 7. Cost of Applications**
- 7.1 The Applicant shall bear all costs associated with the preparation and submission of its application. Director General Health Services Punjab, Primary & Secondary Healthcare Department Government of the Punjab will in no case be responsible or liable for those costs, regardless of the conduct or outcome of the prequalification process.
- 7.2 A non-refundable Prequalification Fee of Rs. 10,000/- on Challan Form 32-A shall be paid in **Account No. C 02871** to defray the cost of documents and physical inspection.
- 8. Language of Application**
- 8.1 The application as well as all correspondence and documents relating to the prequalification exchanged by the Applicant and Director General Health Services Punjab, Primary & Secondary Healthcare Department Government of the Punjab, shall be written in the language specified in the **Prequalification Documents**. Supporting documents and printed literature that are part of the application may be in another language, provided they are accompanied by an accurate translation of the relevant passages in the language specified in the **Prequalification Documents**, in which case, for purposes of interpretation of the application, the translation shall govern.
- 9. Documents Comprising the Application (Hard copy)**
- 9.1 The application shall comprise the following:
- Application Submission Form, in accordance with Information To Applicants (ITA);
 - Documentary evidence establishing the Applicant's eligibility to prequalify, in accordance with ITA & Prequalification Criteria;
 - Documentary evidence establishing the Applicant's qualifications, in accordance with ITA and & Prequalification Criteria
 - Any other document required as specified in the Prequalification Documents.
 - All information, statements and description contained in the Application (online and hard copy) are in all respect true, correct and complete to the best of our knowledge and belief and there is no difference in information provided online and submitted in hard copy.**
- 10. Application Submission Form (Online)**
- 10.1 The Applicant must submit Application via online portal through "**pqod.pshealthpunjab.gov.pk**" or "**www.pshealthpunjab.gov.pk**" before date and time mentioned in invitation for prequalification. All blank fields are mandatory to fill/complete and submit online printed forms along with hard copy of PQD and relevant required documents (Hardcopy) in tape binding with page number mentioned on each page(All the activities related to time period will be calculated from the date of submission of hard copy of PQD documents including all type of applications/Requests to the DGHS as per PPR-2014 and online process is a parallel activity).Uploading of documents (Scan Copy) in relevant fields will be in PDF format only, except Payment Receipt.

Purchase Cell will explain procedure for online submission of application in pre-application conference mentioned in invitation for prequalification.

Note: The application form can be viewed and checked, if any error and can be edited before final submission date and time, however you can edit your filled application till last date and time of submission of application online. After final submission date and time, system will not allow to submit/edit application online and it can neither be submitted manually nor by any other methods of submission. Once Application is submitted online (upto last date and time of submission) then cannot be edited/changed or corrected and any mistake from online submission by the firm will be wholly responsibility of that firm.

So it is advised that read carefully and make sure that your application is completed and corrected for each and every aspect before final submission of date and time. (incomplete/Ambiguous/Incorrect) applications and any misleading information provided by the firm may lead to rejection of application either partially (Item wise) or completely.

After completing application, you can print the filled application after the last date and time of submission online mentioned in advertisement by click on the print tab and submitted this print with hardcopy (Tape binding) upto last date and time as per advertisement.

Step.1 Firm will submit request letter (with prequalification category as per requirement for prequalification on firm's original letter head (as per specimen in Annex-1) and copy of Prequalification fee deposited on form 32-A .

Step.2 Firm can go to web online portal "https://pqod.pshealthpunjab.gov.pk/" and click on sign up tab and a registration form will be opened. Enter the required fields as per request letter submitted by the firm i.e. (Company Complete name, Official Email address, NTN, STN, Payment slip (upload), Mobile No must be as per request letter submitted). Then create password and confirm password then enter register tab and wait. A message on system screen will be appeared as:

"PQOD, CONFIRM EMAIL ADDRESS SENT.

Please check your Email Inbox, a confirm Email is sent to given official email address"

Step.3 For account confirmation an email will be received at your given email address as:

"Thank you for your registration, please click on the below link to complete your registration:

"<http://pqod.pshealthpunjab.gov.pk/Account/ConfirmEmail?Token=4fc624f9-c34a-446f-9ed2-75726cea6e60&Email=abc@gmail.com>"

So click this link for confirmation from your given email inbox.

Step.4 Purchase Cell will verify particulars given for registration/Login ID from your request letter and allow for each category in which the firm has to be applied for prequalification.

Login ID will be remained same for future correspondence in Purchase Cell DATA Base and No duplicate Login ID is allowed to be created by any firm. Same login ID can be used for Local Manufacturer

(Drugs/Medicines), Sole agent (Drugs/Medicines) and Non-Drugs/Medical Devices as per category applied for prequalification.

Step.5 After verification the firm can sign in by entering official email and password and click sign in tab. PQOD application will be opened.

Step.6 Dashboard with progress bar will be appeared along with category in which firm has applied as:

1. Local Manufacturers (Drugs/Medicines)

2. Sole Agents (Drugs/Medicines)

3. Sole Agents (Non-Drugs/Medical Devices)

4.Surgical Dressings

Step.7 For local manufacturers (Drugs/Medicines)

Click on section A. local manufacturers (Drugs/Medicines)

Step (A-1) General Information (fill the blank fields)

Manufacturing site information (in-house manufacturing or third-party manufacturing-select one category) and add blank fields (however incase if manufacturing units or third-party units are more than one then fill separately for each manufacturing unit DATA and also upload documents as per given number of manufacturing units. Click the save tab. for editing you can select the manufacturing unit and with help of editing tab you can edit manufacturing units DATA.

Then add focal person information and click on the save tab. In case of editing saved tab is disabled and after editing firm will click on update tab always whenever one will be done editing.

Step (A-2) Fill the detail of employees, category wise mentioned in portal. For addition click + tab and for deletion click x Tab.

Step (A-3) Firm's knock down criteria (Fill Yes/No/NA tab). Detail is also mentioned in prequalification documents in Evaluation Criteria for Local Manufacturers (Drugs).

Step (A-4) In attachment section upload files in pdf format only, (Firm's documents and Manufacturing unit wise documents upload).Once file is uploaded the download button will be enabled/showed. You can add multiple pages if pages are more than one.

Step (A-5) Quality Control equipment - One can add equipment name with model number, manufacturer and last date of validation/calibration. Then click save tab. You can edit via editing tab or can delete via x tab. You can add more equipment (if any) that are not mentioned in portal and then add "Others (Specify)" and below this tab you can enter new equipment that is not present in list.

Step (A-6) Drugs/Medicines list with item wise generic is present in system. Fill the blank/unfilled/empty fields appropriately. First item's knock down clauses are mentioned. Then provide information related to quoted item. Fill all the required field and click save tab. You can edit via editing tab or can delete via x tab

Step.8 For Sole Agents (Drugs/Medicines)

Click on section B, Sole Agents (Drugs/Medicines)

Step (B-1) General Information (fill the blank fields)

Manufacturing site information (Direct "Principal's in-house manufacturing" or Indirect "third party manufacturing"-select one category) and add blank fields (however incase if manufacturing units

or third-party units are more than one then fill separately for each manufacturing unit DATA and also upload documents as per given number of manufacturing units. Click the save tab. for editing you can select the manufacturing unit and with help of editing tab you can edit manufacturing units DATA.

Then add focal person information and click on the save tab. In case of editing saved tab is disabled and after editing always click on update tab whenever editing is completed.

Step (B-2) Fill the detail of employees, category wise mentioned in portal. For addition click + tab and for deletion click x Tab.

Step (B-3) Firm's knock down criteria (Fill Yes/No/NA tab). Detail is also mentioned in prequalification documents in Evaluation Criteria for Sole Agents (Drugs/Medicines).

Step (B-4) In attachment section upload files in pdf format only, (Firm's documents and Manufacturing unit wise documents upload).Once file is uploaded the download button will be enabled/showed. You can add multiple pages if pages are more than one.

Step (B-5) Drugs/Medicines list with item wise generic is present in system. Fill the blank/unfilled/empty fields appropriately. First item's knock down clauses are mentioned. Then provide information related to quoted item. Fill all the required field and click save tab. You can edit via editing tab or can delete via x tab.

Step.9 For Sole Agents/Local Manufacturers (Medical Devices(C) /Surgical Dressings(D)).

Click on section C/D, Sole Agents/Local Manufacturers (Medical Devices/surgical Dressings)

Step (C-1/D-1) General Information (fill the blank fields)

Manufacturing site information (Direct "Principal's in-house manufacturing" or Indirect "third party manufacturing"-select one category) and add blank fields (however incase if manufacturing units or third-party units are more than one then fills separately for each manufacturing unit DATA and also upload documents as per given number of manufacturing units. Click the save tab. for editing you can select the manufacturing unit and with help of editing tab you can edit manufacturing units DATA.

Then add focal person information and click on the save tab. In case of editing saved tab is disabled and after editing you will click on update tab always whenever you will be done editing.

Step (C-2/D-2) Fill the detail of employees, category wise mentioned in portal. For addition click + tab and for deletion click x Tab.

Step (C-3/D-3) Firm's knock down criteria (Fill Yes/No/NA tab). Detail is also mentioned in prequalification documents in Evaluation Criteria for Sole Agents (Drugs/Medicines).

Step (C-4/D-4) In attachment section upload files in pdf format only, (Firm's documents and Manufacturing unit wise documents upload).Once file is uploaded the download button will be enabled/showed. You can add multiple pages if pages are more than one.

Step (C-5/D-5) Non-Drugs/Medical Devices/Surgical Dressings list with item wise generic is present in system. Fill the blank/unfilled/empty fields appropriately. First item's knock down clauses are mentioned. Then provide information related to quoted

item. Fill all the required field and click save tab. You can edit via editing tab or can delete via x tab.

Note: Incase if category of any item is changed from Non-Drug to drug in case of medical devices then the said prequalification category will be considered as per Drugs Act 1976/DRAP Act 2012/Punjab Drugs Rules 2007/ Punjab Drugs Amendment Act 2017/Medical Devices Rules 2017 classification regarding registration of any item and will be amended accordingly as per law.

In case of any discrepancy & conflict in submitted online data of application and hard copy of application, the data submitted in hard form will prevail.

- | | | |
|-----------------------------------------------------------------------|------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 11.Application Submission | 11.1 | The signed hard copy of online submitted prequalification application must reach The Purchase Cell, Directorate General Health Services Punjab, 24 Cooper Road before closing date and time mentioned in the advertisement. |
| 12. Documents Establishing the Qualifications of the Applicant | 12.1 | To establish its qualifications the Applicant shall provide the information requested in the corresponding Information Sheets included in Section III, Prequalification Criteria |
| 13. Signing of the Application | 13.1 | The Applicant shall prepare and submit the application for prequalification as described in ITA & Prequalification Documents. The application shall be typed or written in indelible ink and shall be signed by a person duly authorized to sign on behalf of the Applicant. |

D. Submission of Applications

- | | | |
|-------------------------------------------------------|------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 14. Sealing and Identification of Applications | 14.1 | The Applicant shall enclose the application in a sealed envelope that shall: <ol style="list-style-type: none"> a. bear the name and address of the Applicant; b. be addressed to the Director General Health Services Punjab, Primary & Secondary Healthcare Department in accordance with ITA; and c. bear the specific identification of this prequalification process indicated in the Prequalification Documents |
| | 14.2 | The Procuring Agency will accept no responsibility for not processing any envelope that was not identified as required. |
| 15. Deadline for Submission of Applications | 15.1 | The signed hard copy of online submitted prequalification application must reach The Purchase Cell, Directorate General Health Services Punjab, 24 Cooper Road before closing date and time mentioned in the advertisement. |
| | 15.2 | The Director General of Health Services Punjab Primary & Secondary Healthcare Department may, at its discretion, extend the deadline for the submission of applications by amending the Prequalification Documents in which case all rights and obligations of the Director General of Health Services Punjab, Primary & Secondary Healthcare Department and the Applicants subject to the previous deadline shall thereafter be subject to the deadline as extended. |

- 16. Late Applications**
- 16.1 Any hard copy of application submitted at the Director General of Health Services Punjab, Primary & Secondary Healthcare Department after the deadline for submission of applications as indicated in the **Invitation for Prequalification** will not be entertained and shall be declared as late submission.
- 17. Opening of Applications**
- 17.1 The Director General of Health Services Punjab, Primary & Secondary Healthcare Department shall open all Applications at the date, time and place specified in the **Invitation for Prequalification**. Late Applications shall be treated in accordance with ITA.
- 17.2 Director General of Health Services Punjab, Primary & Secondary Healthcare Department shall prepare a record of the opening of applications that shall include the name and other details of the Applicant. A copy of the record shall be distributed to all Applicants.

E. Procedures for Evaluation of Applications

- 18. Confidentiality**
- 18.1 Information relating to the evaluation of applications, and recommendation for prequalification, shall not be disclosed to Applicants or any other persons not officially concerned with such process until the notification of prequalification is made to all Applicants.
- 18.2 From the deadline for submission of applications to the time of notification of the results of the prequalification, any Applicant that wishes to contact the Director General of Health Services Punjab, Primary & Secondary Healthcare Department on any matter related to the prequalification process, may do so but only in writing.
- 19. Clarification of Applications**
- 19.1 To assist in the evaluation of applications, the Director General of Health Services Punjab, Primary & Secondary Healthcare Department may, at its discretion, ask any Applicant for a clarification of its application (both online and hard copy) which shall be submitted within 7 days. Any request for clarification and all clarifications shall be in writing.
- 19.2 If an Applicant does not provide clarifications of the information requested by the deadline, the application shall be evaluated based on the information and documents available at the time of evaluation of the application.
- 20. Responsiveness of Applications**
- 20.1 All applications not responsive to the requirements of the prequalification document shall be rejected.
- 21. Domestic Bidder Preference**
- 21.1 A margin of preference for domestic bidders shall not apply in the bidding process resulting from this prequalification.

F. Evaluation of Applications and Prequalification of Applicants

- 22. Evaluation of application**
- 22.1 Prequalification shall be done firm wise and its subsequent item for Drugs/Medicines which the Applicant meets the appropriate requirements of this prequalification document. The information

- provided in response to the invitation for prequalification will be evaluated as per Prequalification Documents and will also be physically verified by the DGHS through inspection team(s) to inspect the premises of the firm for verification of requirements. Good manufacturing practices and good storage practices as defined under Drugs Act 1976/DRAP Act 2012/ Punjab Drugs Amendment Act 2017 and Punjab Drugs Rules 2007/Medical Devices Rules respectively.
- 22.2 The Prequalification will be firm wise and its subsequent item, however in case of any addition in the formulary, the qualification against prequalification section will be considered and in certain cases where any principal of procurement will going to be violated, the procuring agency may invite open competitive bidding in best public interests.
- 23. Right to accept or reject the applications** 23.1 The Director General of Health Services Punjab, Primary & Secondary Healthcare Department reserves the right to accept or reject all the applications, and to annul the prequalification process, without thereby incurring any liability to Applicants.
- 24. prequalification of applicants** 24.1 All Applicants whose applications have met the specified requirements will, to the exclusion of all others, be prequalified by DGHS the Primary & Secondary Healthcare Department.
- 25. Notification of prequalification** 25.1 Director General of Health Services Punjab, after completion of evaluation process of submitted PQ applications shall notify all qualified applicants in writing/through PQOD online Portal and Official websites of DGHS & P&SHD indicating their Item wise status as prequalified.
- 26. Validity of Pre-Qualification** 26.1 The Pre-Qualification shall be valid for Financial Year 2024-25 and may be extendable for next financial year (FY 2025-26) for pre-qualified firms. But it is mandatory that the prequalification process shall be conducted for enhancement of prequalified pool.

Annex-1-(On firm's Original Letter Head)

**Request Application for Prequalification Documents (2024-25)
Drugs & Non-Drugs/Medical Devices**

Ref.No/

Dated:

The Director General Health Services Punjab,
Primary & Secondary Health Care Department
Govt. of The Punjab.

Subject: **Request Application for Prequalification Documents (2024-25) Drugs & Non-Drugs/Medical Devices**

Dear Sir,

With reference to your advertisement regarding prequalification of Drugs & Non-Drugs/Medical Devices (2024-25) advertised on ----- in the Daily Newspaper, it is requested to provide the Prequalification Documents against the following categories.

(Tick Appropriate Box)

- 1. Local Manufacturers (Drugs/Medicines)
- 2. Sole Agents (Drugs/Medicines)
- 3. Local Manufacturers (Non-Drugs/Medical Devices)
- 4. Sole Agents (Non-Drugs/Medical Devices)
- 5. Local Manufacturers /Sole Agents (Surgical Dressings Only)

M/s _____ hereby authorizes Mr./Ms. _____

Designation _____ CNIC No. _____

Official Email _____ (For Login I.D), Mobile No. _____ (for sms alerts) to fill/complete/submit the prequalification application via online portal "pqod.pshealth.punjab.gov.pk".

Firm's NTN: _____

Firm's STN: _____

Authorized By

Name _____

Signature _____

Designation _____

Contact No. _____

Stamp _____

Section II-A: PREQUALIFICATION CRITERIA (Surgical Dressing Only) FOR LOCAL MANUFACTURER/SOLE AGENTS OF FOREIGN PRINCIPAL

1-KNOCK DOWN CRITERIA (Firm Wise)

Sr. No.	Knock Down Clause	Status
1	Valid DML/ License to Manufacture Medical Devices on form-3 /License to Import Medical Devices on form-4 issued by DRAP.	Yes/No
2	Valid Drugs Sale License. (Where applicable)	Yes/No
3	Valid Sole Agency Agreement. (For Sole agent).	Yes/No
4	The firm undertakes that currently it is not blacklisted/debarred by Directorate General Health Services (DGHS) Punjab. The firm shall provide undertaking in this regard on legalized and notarized e-stamp paper of Rs 100. Any false claim leads to disqualification of the firm.	Yes/No
5	Valid ISO 13485 of the manufacturer.	Yes /No
6	Valid GMP Certificate OR Valid Satisfactory GMP Inspection Report issued by DRAP (For local manufacturer only. Only those Sections & Pharmaceutical Category shall be considered for prequalification whose GMP Inspection Report declared satisfactory and/or which are mentioned in the GMP Certificate.	Yes /No
7	The firm undertakes that has proper warehouse and storage facility as per recommendation of the manufacturer and at required temperature and follows good storage and distribution practice. Firm shall provide undertaking on legally notarized e-stamp paper of rupees 100. Firm must mention address of its storage facility on undertaking.	Yes/No
8	Firm undertake that the Information provided by the firm is in accordance with the terms & conditions of the prequalification documents on e-stamp paper of Rs.100 dully legalized/notarized.	Yes/No
9	Minimum Annual financial turnover for any of single financial year (i.e. 2020-21/2021-22/2022-23)/calendar year (i.e. 2021/2022/2023) must be 300 Million Rupees or above for surgical dressings of local manufacturer/Sole Agent of Foreign manufacturer. Firm shall provide FBR income tax return/sales Tax return for the financial year 2020-21, 2021-22 and 2022-23 or in case of calendar year 2021, 2022, and 2023. Note: Income Tax/Sales Tax return for the FY 2022-23 shall be supported with bank statement (FY-2022-23) of the title account of the applicant firm only. Both Tax return and Bank statement must be above 300 Million Rupees. (Firm shall attach bank statement signed and stamped from concerned bank along with FBR income tax/sales tax return) and same for calendar year-2023. (Joint venture, consortium and subsidiary shall not be accepted.)	Yes/No
10	The applicant shall submit proof of manufacturing from the chamber of commerce/equivalent body from the country of origin. (For foreign manufacturer only)	Yes/No
11	The firm shall submit undertaking on Rs.100 e-stamp paper that the firm follows the labor laws (Including child free labor and minimum wages as per Government policy). (For manufacturer only)	Yes/No
12	The firm shall submit undertaking on Rs.100 e-stamp paper that none of its supplied batch in Public Sector Institutions has been declared Spurious/Adulterated since 01-01-2021 till the closing date of Prequalification Document submission.	Yes/No

13	The firm (in case of limited company) shall provide form-A (latest) and certificate of incorporation duly verified by SECP. (Memorandum and article of association of companies). Firm will provide Form C (Registered from registrar of firms) / sole proprietorship.	Yes/No
14	The firm shall submit undertaking on Rs.100 e-stamp paper legalized/notarized that Firm has not been prosecuted by Provincial Quality Control Board (PQCB) on the offense of Spurious/Adulterated surgical dressings since 01-01-2021 till the closing date of Prequalification Document submission.	Yes/No
15	The firm shall submit original receipt of fee with prequalification application.	Yes/No
16	The applicant shall submit an affidavit on Rs. 100/- e-stamp paper (Notarized) stating the applicant accepts all the terms and conditions of the Prequalification Documents.	Yes/No
17	The firm shall submit prequalification application along with all relevant documents on online portal (PQOD) of P&SHD.	Yes/No
2-KNOCK DOWN CRITERIA (Quoted Product/Item Wise)-Local Manufacturer/Sole Agents of Foreign Principal-Surgical Dressing.		
	<p>1. Valid DRC/ Device Enlistment certificate as per Medical Devices Rules 2017, issued by DRAP to the applicant (exemption wherever applicable under rules).</p> <p>2. Quoted products must be tried and tested in local environment for at least three years (Financial year) since July 2018 onward till closing date of submission of PQD application. (Firm Must attach Purchase Orders of quoted items of Public Sector Institution anywhere in Pakistan).</p> <p>3. Tested samples of the quoted item declared Substandard by the DTLs of Punjab (Not over 10%) from (01-01-2023) if any.</p> <p>4. Substandard Batch Recall History since (01-01-2023) if any.</p> <p>5. Any Punitive Action Taken by DRAP since (01-01-2023). (Punitive means, suspension/cancelation of Manufacturing License or Drug Registration by DRAP since (01-01-2023) till the closing date of Prequalification Document submission.)</p> <p>6. Any Punitive Action Taken by PQCB since (01-01-2023). (Punitive means, Prosecuted by PQCB).</p> <p>7. The firm submit copies of Goods Declaration certificates of quoted items for at least three years since July 2018 onward till closing date of submission of PQD application along with all relevant documents such as bill of lading/airway bill, commercial invoice and packing list (For Importers only). These documents must be verifiable from WeBOC/PSW.</p> <p>NOTE: Firm shall provide undertaking for knock down clause 3,4,5, and 6 on legally notarized e-stamp paper of rupees 100/-</p>	

Note:

- DGHS shall through their physical inspection committee(s)/inspector(s) shall verify the facts/claims submitted by the applicant(s). Any forged document(s)/claim(s) shall be dealt under PPR-2014.**
- To establish its qualification, the firm shall provide the information requested in the respective annexures and requirements with documentary proof:
- The firm will be prequalified for the particular item/ brand.
- In order to avoid internet connectivity and load shedding issue, applicants are advised to apply online as early as possible without waiting for the due date.
- In case of any issue during online application submission at PQOD, immediately send email at **pcdghslahore@gmail.com** along with screen short of issue faced by applicant.

GENERAL FIRM’S INFORMATION
(Surgical Dressings Manufacturer)

I. Company Profile.

1. Name of company : _____
 Year established : _____
 Form of company : Individual
 Partnership
 Corporation
 Other (specify) _____

 Legal status : _____
 Trade registers number : _____
 NTN & Sales Tax number (If applicable): : _____
 Mfg. License Number : _____
 (attach valid copy)
 2. Address : _____
 Telephone : _____ Telefax: _____
 E-mail: : _____
 3. Employees:

S.No.	Category	Quantity
1	Management	
2	R &D	
3	Sales	
4	Administrative	
5	Production and quality control	
6	Others (specify)	
	Total	

Please attach the company organizational chart

II. Product Information

Please provide the information as per Annexure-C

1. Are all manufacturing operations (processing, packaging, labeling) carried out internally?
 YES NO

If “No,” attach a list of Surgical Dressings and/or raw materials manufactured by other companies and marketed by you. Please give the names of the companies, for each item.

S.No.	Product Name	Manufacturer	Address
1.			
2.			
3.			

If any products are repackaged, attach a list of such products with the name and address of the manufacturer for each product:

S.No.	Product Name	Manufacturer	Address
1.			
2.			
3.			

III. QUALITY DEPARTMENT

1. Do you maintain your own quality control laboratory?

YES NO (if NO please provide details of alternate arrangements)

2. Number of specialized personnel working in your quality control, quality assurance and microbiological laboratory/ies (excluding administrative personnel). Provide their academic and professional details on a separate sheet.

Pharmacists : _____

Chemists : _____

Others : _____

3. List of Equipment installed in quality control, quality assurance and microbiological laboratory/ies for quality assurance as per BP/USP.

4. Are these equipment calibrated & validated.

YES

NO

5. Are all raw materials completely tested prior to use or is a Certificate of Analysis accepted?
 YES NO Certificate of Analysis

6. Are control samples of each batch retained?
 YES NO

7. Name and title of the authorized person (s) responsible for batch release:
Name: _____
Title: _____
Experience in Surgical Dressings: _____ years

8. Name and qualification of the head of the Quality Control department:
Name: _____
Qualification: _____
Experience in Surgical Dressings: _____ years

9. Describe your storage facilities:

The firm will provide logistics/distribution network in Punjab.
The firm will provide human resource regarding logistics/distribution network in Punjab.

**Authorized Sole agent for Foreign Principal’s Qualification
(Surgical Dressings)**

I. Company Profile.

1. Name of company : _____

Year established : _____

Form of company : Individual
 Partnership
 Corporation
 Other (specify)

Legal status : _____

Trade registers number : _____

NTN & Sales Tax number (If applicable):

Valid sole agency
agreement
(attach valid copy)

2. Address : _____

Telephone : _____ Telefax: _____

E-mail & Web : _____

Please attach the company organizational chart

3. Type of activity carried out by the company (tick the appropriate category/ies)

- Manufacturer
- Branded products
- Generic products
- Medical supplies
- Laboratory reagents
- Other products (specify below)

4. Names and addresses of international Surgical Dressings companies, parent companies and/or subsidiaries and associated companies with whom there is collaboration or joint venture, if any:

S.No.	Product Name	Company	Address
1.			
2.			
3.			

5. Employees:

S.No.	Category	Quantity
1	Management	
2	R &D	
3	Sales	
4	Administrative	
5	Production and quality control	
6	Others (specify)	
	Total	

6. Capital value of the company (specify currency)

(a) Authorized capital: _____

(b) Paid up capital: _____

(c) Administration: _____

7. Annual sales turnover in the previous one year. Mention Private Sector and Public Sector sales separately (in Pak Rupees)

(In Million)

Annual turnover	Open market sales	Public Sector Sale	Year

Arbitration History (if any): _____

Authorized Sole agent for Foreign Manufacturer
(Surgical Dressings)

Product applied for:

S.No. of the item	Name of Item	Name of Manufacturer	Country of Origin	Quality Compliance standards

Name of firm _____

Address _____

Phone _____ Fax _____

E-mail _____ URL http://www. _____

Type of firm: Sole Proprietor Partner Ship Limited

Other _____ Date of establishment _____

List of Board of Directors, Partners, Key Management Personnel (both Technical, Sales & Management - include position, professional qualification, experience).

Total area of the firm premises _____ Owned Rented

Total Area of ware house _____

Facilities in ware house _____

Total no. of Employees: Technical _____ Non – Technical _____

National Tax Number _____ Date _____

General Tax Number _____ Date _____

Registrations / Prequalification with other departments: _____

Detail of Head / Branch Office / Workshop (s):

Address: _____

Phone _____ Fax _____

Address _____

Phone _____ Fax _____

Sales / Marketing Staff:

Name	Designation / Responsibility	Qualification	Total Experience	Experience with Current Firm	Training Detail (Local &abroad)

Technical Staff:

Name	Designation / Responsibility	Qualification	Total Experience	Experience with Current Firm

Name & Capacity of the Authorized Contact Person: _____

Signature of the Authorized Contact Person: _____

Date: _____ Stamp of the Firm: _____

DOCUMENTS TO BE ATTACHED (COPIES)

The firm must attach relevant documents

NAME OF APPLICANT FIRM (Local Manufacturer/Sole Agents-Surgical Dressings-Draft) _____

Item Code	Generic Name	copies of Goods Declaration (for importers only)	Quoted Brand	Experience of Product	Valid Sole Agency Agreement (for importer only)	Quoted strength	Pack Size	Mfg By	Mfg for	MRP fixed by DRAP	Valid DR C/ Device Enlistment certificate	Drug Reg. Date	Mfg Capacity/day (quoted item in finished units)	Section (Validation/calibration)	Required Storage temp(quoted item)	Spurious sample	DTL Substandard (Not over 10%) From(01-01-2023)	Substandard Batch Recall History (01-01-2023)	Punitive Action by DRAP from (01-01-2023)	Punitive Action by PQCB from (01-01-2023)	Convicted by Drug Court from (01-01-2023)
1																					
2																					

Annexure-D

Sr.	Generic Name
1	Absorbable gelatin sponge
2	Absorbent Cotton Wool Pack 500gm
3	Bandage Plaster of Paris, Dozen Pack. 10cm x2.7Metre
4	Bandage Plaster of Paris, Dozen Pack. 15cmx2.7Metre
5	Cotton Bandage Dozen Pack. 15cmx6m
6	Cotton Bandage Dozen Pack. 10cmx6m
7	Cotton Bandage Dozen Pack. 6.5cmx6m
8	Cotton Crepe Bandage Dozen Pack or less. 7.5 cmx4.5m
9	Cotton Crepe Bandages, Dozen pack or less. 10cm x 4.5m,
10	Gauze Roll Surgical 1x30 m
11	Sterile Gauze Dressing 10x10x8ply
12	Sterile Gauze Pad 12Ply/Layer 3" x 3"
13	Sterile Gauze Piece
14	Surgical Hypoallergenic Latex Free Breathable Paper Tape 2.5 cm X 5 yards or above
15	Surgical Hypoallergenic Latex Free Breathable Paper Tape 5cm X 5 yards or above
16	Surgical Paper Tape rolls (Fixomal or equivalent) all sizes
17	Surgical Transparent Dressing all sizes
18	Zinc oxide adhesive plaster all sizes

NOTE: Detailed specification of items will be advertised at the time of bidding.

Section III: Application Forms

Application Submission Form

Date: __ / __ / 2024

To

**Director General Health Services Punjab
Government of the Punjab
Primary & Secondary Healthcare Department.**

I/we, the undersigned, apply to be prequalified for the referenced Pre-qualification and declare that:

- (a) I/we have examined and have no reservations to the Prequalification Documents, including Addendum(s). (if any) issued in accordance with Instructions to Applicants (ITA) *[insert the number and issuing date of each addendum]*.
- (b) I/we, have nationalities from eligible countries, in accordance with ITA *[insert the nationality of the Applicant, including that of all partners in case of a Joint Venture /Consortium if applicable]*;
- (c) I/we, for any part of the application resulting from this prequalification, do not have any conflict of interest;
- (d) I/we for any part of the contract resulting from this prequalification, currently have not been declared disqualified / blacklisted by Directorate General Health Services (DGHS) Punjab
- (e) I/we understand that you may cancel the prequalification process at any time, the prequalification does not bound the procuring agency to call for the bids from the prequalified firms.
- (f) All information, statements and description contained in the Application (online and hard copy) are in all respect true, correct and complete to the best of our knowledge and belief and there is no difference in information provided online and submitted in hard copy.

Signed *[insert signature(s) of an authorized representative(s) of the*

Applicant] Name *[insert full name of person signing the application]*

In the Capacity of *[insert capacity of person signing the application]*

Duly authorized to sign the application for and on behalf
of: Applicant's Name *[insert full name of Applicant]*

Address [insert street number/town or city/country/ address]

Dated on _ -/_ -_/2024.

Affidavit

(Pak Rs.100/-)

Applicants signed affidavit on PKR 100 paper confirming not having been declared ineligible by any of the public sector organization in Pakistan, as described in the documents.

Signed *[insert signature(s) of an authorized representative(s) of the Applicant]* Name *[insert full name of person signing the application]*

In the Capacity of *[insert capacity of person signing the application]*

Duly authorized to sign the application for and on behalf of: Applicant's Name *[insert full name of Applicant]*

Address *[insert street number/town or city/country/ address]*

Dated on _ -/_ -_/2024

Physical Inspection of Applicants

Part A:

As per evaluation criteria, eligibility of applicants and other terms and conditions specified in PQ Documents.

Part B:

To inspect/evaluate any violation or critical/major non-compliance of cGMP.

Note: Non-compliances/violations of any parameter(s) of Part A or Part B will lead to “Non-prequalification” of the applicant

PREQUALIFICATION DOCUMENTS

(MEDICAL DEVICES)

**(MANUFACTURING UNITS AND SOLE AGENTS OF FOREIGN
PRINCIPALS)**



(FINANCIAL YEAR 2024-2025)

**Primary & Secondary Healthcare Department
Government of the Punjab**

Table of Contents

Section I: Instructions to Applicants (ITA)	
A. General.....	
1. Scope of Application.....	
2. Fraud and Corruption	
3. Eligible Applicants.....	
B. Contents of the Prequalification Document.....	
4. Sections of Prequalification Document	
5. Clarification of Prequalification Document	
6. Amendment of Prequalification Document	
C. Preparation of Applications.....	
7. Cost of Applications.....	
8. Language of Application	
9. Documents Comprising the Application.....	
10. Application Submission Form.....	
11. Documents Establishing the Eligibility of the Applicant.....	
12. Documents Establishing the Qualifications of the Applicant	
13. Signing of the Application and Number of Copies.....	
D. Submission of Applications	
14. Sealing and Identification of Applications	
15. Deadline for Submission of Applications.....	
16. Late Applications	
17. Opening of Applications	
E. Procedures for Evaluation of Applications	
18. Confidentiality	
19. Clarification of Applications	
20. Responsiveness of Applications	
21. Domestic Bidder Price Preference.....	
F. Evaluation of Applications and Prequalification of Applicants.....	
22. Evaluation of Applications.....	

23. Right to Accept or Reject Applications.....

24. Prequalification of Applicants.....

25. Notification of Prequalification

26. Validity of Prequalification



Section II: Prequalification Criteria Medical Devices

Section III:

A: List of Medical Devices.....

C: Application Submission Form.....

D: Application Affidavit.....

 <p>PURCHASE CELL DIRECTORATE GENERAL HEALTH SERVICES PUNJAB 24-COOPER ROAD, LAHORE Phone No. +924299201145 Purchase Cell E-mail- pcdghs@gmail.com</p>	<p>Primary & Secondary Healthcare Department</p> 
INVITATION FOR PREQUALIFICATION (Financial Year 2024-25)	
<ol style="list-style-type: none">1. Government of the Punjab is committed to procure and supply quality Medical Devices and Surgical Dressings to patients. Directorate General Health Services (DGHS) Punjab invited applications for prequalification of firms (Manufacturers and Sole Agents of Foreign Principals - more specifically described in the prequalification documents) concerning procurement & supply of Medical Devices and Surgical Dressings items for Financial Year 2024-25. This prequalification shall also be applicable for various procuring agencies likely District Health Authorities (DHAs), Vertical Programs, Punjab Health Facilities Management Company (PHFMC), Specialized Healthcare & Medical Education Department (SHC&MED), Governor House Medical Center, Punjab Emergency Services Rescue 1122, Prison Hospital of Punjab etc. (detail of procuring agencies in documents) who assigned DGHS Punjab to conclude their prequalification process under rule 64-A of Punjab Procurement Rules (PPR), 2014.2. A complete set of Prequalification Documents in English can be downloaded from the websites [www.ppra.punjab.gov.pk], [www.pshealthpunjab.gov.pk] [www.dghs.punjab.gov.pk]. Pre-application meeting is scheduled to be held on 23-01-2024 at 11:00 A.M in the committee room of this DGHS Punjab. The minutes of Pre-application meeting shall be construed as part of prequalification documents and same shall be uploaded on the official website of procuring agency on or before 26-01-2024. Any amendment shall be made as prescribed in PPR-2014.3. The firms are required to submit prequalification documents online on following Department's link [http://pqod.pshealthpunjab.gov.pk] or official website of P&SHD. [http://www.pshealthpunjab.gov.pk] related to prequalification application. The last date and time for online submission of Pre-Qualification documents is 15-02-2024 till 11:00 A.M via department's online portal and the signed computerized print of the same online submitted Pre-Qualification documents in hard copy of prequalification application must reach The Purchase Cell, Directorate General Health Services Punjab, 24 Cooper Road, Lahore on 15-02-2024 till 11:00 A.M which shall be opened on the same date at 11:30 AM. In case of any discrepancy & conflict in submitted online prequalification application and hard copy of application, the prequalification application submitted in hard form will prevail.4. The firms shall pay a non-refundable Prequalification Fee on Challan Form 32-A as mentioned in Pre-qualification documents.5. Prequalified firm(s) shall be entitled to participate in the subsequent procurement proceedings as per requirement of the procuring agency(s).6. In case the date of opening or last date of submission is declared as a public holiday or non-working day due to any reason, the next official working day shall be deemed to be the date of submission and opening of applications accordingly. The time and venue shall remain the same.	
Note: The process shall be governed by the Punjab Procurement Rules, 2014.	
Director General Health Services Punjab	
DIRECTORATE GENERAL HEALTH SERVICES PUNJAB Primary & Secondary Healthcare Department, Government of The Punjab E-mail: pedghsalahore@gmail.com Contact No: +92 (42)99201145	
IPL-520	

Section I: Instructions to Applicants (ITA)

A. General

1. Scope of Application

1.1 In connection with the Invitation for Prequalification “as per PPR 2014” the Director General Health Services Punjab, Primary & Secondary Healthcare Department Government of the Punjab, issues this Prequalification Document (PQD) to applicants interested to prequalify Pharmaceutical Manufacturing Units & Sole Agents of Foreign Principals for Medical Devices against the list of items contained in the Prequalification Documents. This prequalification will be concluded for DGHS and shall also be applicable for various procuring agencies likely District Health Authorities (DHAs), Vertical Programs, Punjab Health Facilities Management Company (PHFMC), Specialized Healthcare & Medical Education Department (SH&MED), Governor House Medical Center, Punjab Emergency Services Rescue 1122, Prison Hospital of Punjab etc. who assigned DGHS Punjab to conclude their prequalification process under rule 64-A of Punjab Procurement Rules (PPR), 2014. Prequalification will be carried only for the items which comes under the definition of drugs under Drugs Act 1976/DRAP Act 2012/Punjab Drugs Rules 2007/ Punjab Drugs Amendment Act 2017 for Drug items & Medical Devices Rules 2017. DGHS may through their physical inspection committee(s)/inspector(s) shall verify the facts/claims submitted by the applicant(s). Any forged document(s)/claim(s) shall be dealt under PPR-2014.

2. Fraud and Corruption

2.1 Director General Health Services Punjab, Primary & Secondary Healthcare Department Government of the Punjab requires that applicant observe the highest standard of ethics during the submission of application for prequalification and further documents required for prequalification.

(a) In pursuance to this, the following terms are defined:

(i) “corrupt practice” is the offering, giving, receiving or soliciting, directly or indirectly, of anything of value to influence improperly the actions of another party;

(ii) “fraudulent practice” is any act or omission, including a misrepresentation, that knowingly or recklessly misleads, or attempts to mislead, a party to obtain a financial or other benefit or to avoid an obligation;

(iii) “collusive practice” is an arrangement between two or more parties designed to achieve an improper purpose, including to influence improperly the actions of another party;

(iv) “coercive practice” is impairing or harming, or threatening to impair or harm, directly or indirectly, any party or the property of the party to influence improperly the actions of a party;

(v) “obstructive practice” is deliberately destroying, falsifying, altering or concealing of evidence material to the investigation or making false statements to investigators in order to materially impede a Bank investigation into allegations of a corrupt, fraudulent, coercive or collusive practice; and/or threatening, harassing or intimidating any party to prevent it from disclosing its knowledge of matters relevant to the investigation or from pursuing the investigation; or

(b) Director General Health Services Punjab, Primary & Secondary Healthcare Department Government of the Punjab will reject a proposal for prequalification if it determines that the applicant has directly or through an agent, engaged in corrupt, fraudulent, collusive, coercive or obstructive practices in competing for the prequalification in question;

(c) Director General Health Services Punjab, Primary & Secondary Healthcare Department Government of the Punjab will declare ineligible, either indefinitely or for a stated period of time, if it, at any time, determines that the firm has, directly or through an agent, engaged in corrupt, fraudulent, collusive, coercive or obstructive practices in competing for prequalification.

(d) The prequalified firms are required to participate in RFP/bidding process announced by any procuring agency under administrative control of Primary & Secondary Healthcare Department. All prequalified firms shall participate in subsequent bidding process (RFP) of all the procuring agency(s) who assigned DGHS Punjab to conclude their prequalification process under rule 64-A of Punjab Procurement Rules (PPR), 2014. In case of non-participation, DGHS may suspend/cancel the prequalification status of Firm/Product at any stage as well as debar the firm for future procurement processes.

3. Eligible Applicants

- 3.1 Local manufacturer or Sole agent of foreign manufacturer can be a private or public entity registered with DRAP and FBR having NTN & SRTN Registration in its own name. Any authorized agent of Local manufacturer and authorized agent of Sole agent of foreign manufacturer shall be ineligible.
- 3.2 If Government of Pakistan prohibits commercial relations with any Country, the firms dealing with such countries are ineligible to apply.
- 3.3 A firm declared disqualified / blacklisted / debarred by Directorate General Health Services (DGHS) Punjab shall be ineligible for prequalification

B. Contents of the Prequalification Documents

4. Sections of Prequalification

- 4.1 The documents for the prequalification of Applicants (hereinafter - “prequalification documents”) consists of all the sections indicated

Documents

below, and should be read in conjunction with any Addendum if issued.

Section I. Instructions to Applicants (ITA)

Section II. Prequalification criteria

Section III. A: Application Form

B: Application affidavit

4.2 The “Invitation for Prequalification Applications” (IPA) issued by the Procuring Agency is part of the prequalification documents.

4.3 Director General Health Services Punjab, Primary & Secondary Healthcare Department Government of The Punjab accepts no responsibility for the completeness of the prequalification documents and its addenda unless the original receipt of the fee deposit slip is attached with the documents.

4.4 The Applicant is expected to examine all instructions, forms, and terms in the Prequalification Documents and to furnish all information or documentation required by the Prequalification Documents.

5. Clarification of Prequalification Document

5.1 A prospective Applicant requiring any clarification of the Prequalification Documents shall contact the Director General Health Services Punjab, Primary & Secondary Healthcare Department Government of the Punjab in writing at the address indicated in the **Invitation for Pre-Qualification of Medical Devices**. The Director General Health Services Punjab, Primary & Secondary Healthcare Department Government of the Punjab will respond in writing to any request for clarification provided that such request is received preferably before submission of PQ application. The Director General Health Services Punjab, Primary & Secondary Healthcare Department Government of the Punjab shall forward copies of its response to all applicants who have acquired the prequalification documents through its official website including a description of the inquiry but without identifying its source. Director General Health Services Punjab, Primary & Secondary Healthcare Department Government of the Punjab deemed it necessary to amend the prequalification documents as a result of a clarification it shall do under intimation to all the applicants who have obtained the prequalification documents through its official website.

6. Amendment of Prequalification Document

6.1 At any time prior to the deadline for submission of applications, the Director General Health Services Punjab, Primary & Secondary Healthcare Department Government of the Punjab may amend the Prequalification Documents by issuing addenda/Corrigendum.

6.2 Any addendum/corrigendum/minutes of pre-application conference issued shall be part of the Prequalification Documents and shall be communicated in writing to all who have obtained the prequalification documents from the Primary & Secondary Healthcare Department. The minutes shall also be uploaded on the official websites of Director General Health Services Punjab and Primary & Secondary Healthcare Department Government of the Punjab

6.3 To give prospective Applicants reasonable time to take an addendum/corrigendum into account in preparing their applications, the Director General Health Services Punjab, Primary & Secondary Healthcare

Department Government of the Punjab may, at its discretion, extend the deadline for the submission of applications

C. Preparation of Applications

- 7. Cost of Applications**
- 7.1 The Applicant shall bear all costs associated with the preparation and submission of its application. Director General Health Services Punjab, Primary & Secondary Healthcare Department Government of the Punjab will in no case be responsible or liable for those costs, regardless of the conduct or outcome of the prequalification process.
- 7.2 A non-refundable Prequalification Fee of Rs. 10,000/- on Challan Form 32-A shall be paid in **Account No. C 02871** to defray the cost of documents and physical inspection.
- 8. Language of Application**
- 8.1 The application as well as all correspondence and documents relating to the prequalification exchanged by the Applicant and Director General Health Services Punjab, Primary & Secondary Healthcare Department Government of the Punjab, shall be written in the language specified in the **Prequalification Documents**. Supporting documents and printed literature that are part of the application may be in another language, provided they are accompanied by an accurate translation of the relevant passages in the language specified in the **Prequalification Documents**, in which case, for purposes of interpretation of the application, the translation shall govern.
- 9. Documents Comprising the Application (Hard copy)**
- 9.1 The application shall comprise the following:
- Application Submission Form, in accordance with Information To Applicants (ITA);
 - Documentary evidence establishing the Applicant's eligibility to prequalify, in accordance with ITA & Prequalification Criteria;
 - Documentary evidence establishing the Applicant's qualifications, in accordance with ITA and & Prequalification Criteria
 - Any other document required as specified in the Prequalification Documents.
 - All information, statements and description contained in the Application (online and hard copy) are in all respect true, correct and complete to the best of our knowledge and belief and there is no difference in information provided online and submitted in hard copy.**
- 10. Application Submission Form (Online)**
- 10.1 The Applicant must submit Application via online portal through "**pqod.pshealthpunjab.gov.pk**" or "**www.pshealthpunjab.gov.pk**" before date and time mentioned in invitation for prequalification. All blank fields are mandatory to fill/complete and submit online printed forms along with hard copy of PQD and relevant required documents (Hardcopy) in tape binding with page number mentioned on each page(All the activities related to time period will be calculated from the date of submission of hard copy of PQD documents including all type of applications/Requests to the DGHS as per PPR-2014 and online process is a parallel activity).Uploading of documents (Scan Copy) in relevant fields will be in PDF format only, except Payment Receipt.

Purchase Cell will explain procedure for online submission of application in pre-application conference mentioned in invitation for prequalification.

Note: The application form can be viewed and checked, if any error and can be edited before final submission date and time, however you can edit your filled application till last date and time of submission of application online. After final submission date and time, system will not allow to submit/edit application online and it can neither be submitted manually nor by any other methods of submission. Once Application is submitted online (upto last date and time of submission) then cannot be edited/changed or corrected and any mistake from online submission by the firm will be wholly responsibility of that firm.

So it is advised that read carefully and make sure that your application is completed and corrected for each and every aspect before final submission of date and time. (incomplete/Ambiguous/Incorrect) applications and any misleading information provided by the firm may lead to rejection of application either partially (Item wise) or completely.

After completing application, you can print the filled application after the last date and time of submission online mentioned in advertisement by click on the print tab and submitted this print with hardcopy (Tape binding) upto last date and time as per advertisement.

Step.1 Firm will submit request letter (with prequalification category as per requirement for prequalification on firm's original letter head (as per specimen in Annex-1) and copy of Prequalification fee deposited on form 32-A.

Step.2 Firm can go to web online portal "https://pqod.pshealthpunjab.gov.pk/" and click on sign up tab and a registration form will be opened. Enter the required fields as per request letter submitted by the firm i.e. (Company Complete name, Official Email address, NTN, STN, Payment slip (upload), Mobile No must be as per request letter submitted). Then create password and confirm password then enter register tab and wait. A message on system screen will be appeared as:

"PQOD, CONFIRM EMAIL ADDRESS SENT.

Please check your Email Inbox, a confirm Email is sent to given official email address"

Step.3 For account confirmation an email will be received at your given email address as:

"Thank you for your registration, please click on the below link to complete your registration:

["http://pqod.pshealthpunjab.gov.pk/Account/ConfirmEmail?Token=4fc624f9-c34a-446f-9ed2-75726cea6e60&Email=abc@gmail.com"](http://pqod.pshealthpunjab.gov.pk/Account/ConfirmEmail?Token=4fc624f9-c34a-446f-9ed2-75726cea6e60&Email=abc@gmail.com)

So click this link for confirmation from your given email inbox.

Step.4 Purchase Cell will verify particulars given for registration/Login ID from your request letter and allow for each category in which the firm has to be applied for prequalification.

Login ID will be remained same for future correspondence in Purchase Cell DATA Base and No duplicate Login ID is allowed to be created by any firm. Same login ID can be used for Local Manufacturer

(Drugs/Medicines), Sole agent (Drugs/Medicines) and Non-Drugs/Medical Devices as per category applied for prequalification.

Step.5 After verification the firm can sign in by entering official email and password and click sign in tab. PQOD application will be opened.

Step.6 Dashboard with progress bar will be appeared along with category in which firm has applied as:

1. Local Manufacturers (Drugs/Medicines)

2. Sole Agents (Drugs/Medicines)

3. Sole Agents (Non-Drugs/Medical Devices)

Step.7 For local manufacturers (Drugs/Medicines)

Click on section A. local manufacturers (Drugs/Medicines)

Step (A-1) General Information (fill the blank fields)

Manufacturing site information (in-house manufacturing or third-party manufacturing-select one category) and add blank fields (however incase if manufacturing units or third-party units are more than one then fill separately for each manufacturing unit DATA and also upload documents as per given number of manufacturing units. Click the save tab. for editing you can select the manufacturing unit and with help of editing tab you can edit manufacturing units DATA.

Then add focal person information and click on the save tab. In case of editing saved tab is disabled and after editing firm will click on update tab always whenever one will be done editing.

Step (A-2) Fill the detail of employees, category wise mentioned in portal. For addition click + tab and for deletion click x Tab.

Step (A-3) Firm's knock down criteria (Fill Yes/No/NA tab). Detail is also mentioned in prequalification documents in Evaluation Criteria for Local Manufacturers (Drugs).

Step (A-4) In attachment section upload files in pdf format only, (Firm's documents and Manufacturing unit wise documents upload).Once file is uploaded the download button will be enabled/showed. You can add multiple pages if pages are more than one.

Step (A-5) Quality Control equipment - One can add equipment name with model number, manufacturer and last date of validation/calibration. Then click save tab. You can edit via editing tab or can delete via x tab. You can add more equipment (if any) that are not mentioned in portal and then add "Others (Specify)" and below this tab you can enter new equipment that is not present in list.

Step (A-6) Drugs/Medicines list with item wise generic is present in system. Fill the blank/unfilled/empty fields appropriately. First item's knock down clauses are mentioned. Then provide information related to quoted item. Fill all the required field and click save tab. You can edit via editing tab or can delete via x tab

Step.8 For Sole Agents (Drugs/Medicines)

Click on section B, Sole Agents (Drugs/Medicines)

Step (B-1) General Information (fill the blank fields)

Manufacturing site information (Direct "Principal's in-house manufacturing" or Indirect "third party manufacturing"-select one category) and add blank fields (however incase if manufacturing units

or third-party units are more than one then fill separately for each manufacturing unit DATA and also upload documents as per given number of manufacturing units. Click the save tab. for editing you can select the manufacturing unit and with help of editing tab you can edit manufacturing units DATA.

Then add focal person information and click on the save tab. In case of editing saved tab is disabled and after editing always click on update tab whenever editing is completed.

Step (B-2) Fill the detail of employees, category wise mentioned in portal. For addition click + tab and for deletion click x Tab.

Step (B-3) Firm's knock down criteria (Fill Yes/No/NA tab). Detail is also mentioned in prequalification documents in Evaluation Criteria for Sole Agents (Drugs/Medicines).

Step (B-4) In attachment section upload files in pdf format only, (Firm's documents and Manufacturing unit wise documents upload).Once file is uploaded the download button will be enabled/showed. You can add multiple pages if pages are more than one.

Step (B-5) Drugs/Medicines list with item wise generic is present in system. Fill the blank/unfilled/empty fields appropriately. First item's knock down clauses are mentioned. Then provide information related to quoted item. Fill all the required field and click save tab. You can edit via editing tab or can delete via x tab.

Step.9 For Sole Agents/Local Manufacturers (Medical Devices(C) /Surgical Dressings(D).

Click on section C/D, Sole Agents/Local Manufacturers (Medical Devices/surgical Dressings)

Step (C-1/D-1) General Information (fill the blank fields)

Manufacturing site information (Direct "Principal's in-house manufacturing" or Indirect "third party manufacturing"-select one category) and add blank fields (however incase if manufacturing units or third-party units are more than one then fills separately for each manufacturing unit DATA and also upload documents as per given number of manufacturing units. Click the save tab. for editing you can select the manufacturing unit and with help of editing tab you can edit manufacturing units DATA.

Then add focal person information and click on the save tab. In case of editing saved tab is disabled and after editing you will click on update tab always whenever you will be done editing.

Step (C-2/D-2) Fill the detail of employees, category wise mentioned in portal. For addition click + tab and for deletion click x Tab.

Step (C-3/D-3) Firm's knock down criteria (Fill Yes/No/NA tab). Detail is also mentioned in prequalification documents in Evaluation Criteria for Sole Agents (Drugs/Medicines).

Step (C-4/D-4) In attachment section upload files in pdf format only, (Firm's documents and Manufacturing unit wise documents upload).Once file is uploaded the download button will be enabled/showed. You can add multiple pages if pages are more than one.

Step (C-5/D-5) Non-Drugs/Medical Devices/Surgical Dressings list with item wise generic is present in system. Fill the blank/unfilled/empty fields appropriately. First item's knock down clauses are mentioned. Then provide information related to quoted

item. Fill all the required field and click save tab. You can edit via editing tab or can delete via x tab.

Note: Incase if category of any item is changed from Non-Drug to drug in case of medical devices then the said prequalification category will be considered as per Drugs Act 1976/DRAP Act 2012/Punjab Drugs Rules 2007/ Punjab Drugs Amendment Act 2017/Medical Devices Rules 2018 classification regarding registration of any item and will be amended accordingly as per law.

In case of any discrepancy & conflict in submitted online data of application and hard copy of application, the data submitted in hard form will prevail.

11.Application Submission

11.1 The signed hard copy of online submitted prequalification application must reach The Purchase Cell, Directorate General Health Services Punjab, 24 Cooper Road before closing date and time mentioned in the advertisement.

12. Documents Establishing the Qualifications of the Applicant

12.1 To establish its qualifications the Applicant shall provide the information requested in the corresponding Information Sheets included in Section III, Prequalification Criteria

13. Signing of the Application

13.1 The Applicant shall prepare and submit the application for prequalification as described in ITA & Prequalification Documents. The application shall be typed or written in indelible ink and shall be signed by a person duly authorized to sign on behalf of the Applicant.

D. Submission of Applications

14. Sealing and Identification of Applications

14.1 The Applicant shall enclose the application in a sealed envelope that shall:

- a. bear the name and address of the Applicant;
- b. be addressed to the Director General Health Services Punjab, Primary & Secondary Healthcare Department in accordance with ITA; and
- c. bear the specific identification of this prequalification process indicated in the Prequalification Documents

14.2 The Procuring Agency will accept no responsibility for not processing any envelope that was not identified as required.

15. Deadline for Submission of Applications

15.1 The signed hard copy of online submitted prequalification application must reach The Purchase Cell, Directorate General Health Services Punjab, 24 Cooper Road before closing date and time mentioned in the advertisement.

15.2 The Director General of Health Services Punjab Primary & Secondary Healthcare Department may, at its discretion, extend the deadline for the submission of applications by amending the Prequalification Documents in which case all rights and obligations of the Director General of Health Services Punjab, Primary & Secondary Healthcare Department and the Applicants subject to the previous deadline shall thereafter be subject to the deadline as extended.

- 16. Late Applications** 16.1 Any hard copy of application submitted at the Director General of Health Services Punjab, Primary & Secondary Healthcare Department after the deadline for submission of applications as indicated in the **Invitation for Prequalification** will not be entertained and shall be declared as late submission.
- 17. Opening of Applications** 17.1 The Director General of Health Services Punjab, Primary & Secondary Healthcare Department shall open all Applications at the date, time and place specified in the **Invitation for Prequalification**. Late Applications shall be treated in accordance with ITA.
- 17.2 Director General of Health Services Punjab, Primary & Secondary Healthcare Department shall prepare a record of the opening of applications that shall include the name and other details of the Applicant. A copy of the record shall be distributed to all Applicants.

E. Procedures for Evaluation of Applications

- 18. Confidentiality** 18.1 Information relating to the evaluation of applications, and recommendation for prequalification, shall not be disclosed to Applicants or any other persons not officially concerned with such process until the notification of prequalification is made to all Applicants.
- 18.2 From the deadline for submission of applications to the time of notification of the results of the prequalification, any Applicant that wishes to contact the Director General of Health Services Punjab, Primary & Secondary Healthcare Department on any matter related to the prequalification process, may do so but only in writing.
- 19. Clarification of Applications** 19.1 To assist in the evaluation of applications, the Director General of Health Services Punjab, Primary & Secondary Healthcare Department may, at its discretion, ask any Applicant for a clarification of its application (both online and hard copy) which shall be submitted within 7 days. Any request for clarification and all clarifications shall be in writing.
- 19.2 If an Applicant does not provide clarifications of the information requested by the deadline, the application shall be evaluated based on the information and documents available at the time of evaluation of the application.
- 20. Responsiveness of Applications** 20.1 All applications not responsive to the requirements of the prequalification document shall be rejected.
- 21. Domestic Bidder Preference** 21.1 A margin of preference for domestic bidders shall not apply in the bidding process resulting from this prequalification.

F. Evaluation of Applications and Prequalification of Applicants

- 22. Evaluation of application** 22.1 Prequalification shall be done firm wise and its subsequent item for Drugs/Medicines which the Applicant meets the appropriate requirements of this prequalification document. The information provided in response to the invitation for prequalification will be evaluated as per Prequalification Documents and will also be

- physically verified by the DGHS through inspection team(s) to inspect the premises of the firm for verification of requirements. Good manufacturing practices and good storage practices as defined under Drugs Act 1976/DRAP Act 2012/ Punjab Drugs Amendment Act 2017 and Punjab Drugs Rules 2007/Medical Devices Rules respectively. Good manufacturing practices and good storage practices as defined under Drugs Act 1976/DRAP Act 2012/ Punjab Drugs Amendment Act 2017 and Punjab Drugs Rules 2007/Medical Devices Rules respectively.
- 22.2 The Prequalification will be firm wise and its subsequent item, however in case of any addition in the formulary, the qualification against prequalification section will be considered and in certain cases where any principal of procurement will going to be violated, the procuring agency may invite open competitive bidding in best public interests.
- 23. Right to accept or reject the applications** 23.1 The Director General of Health Services Punjab, Primary & Secondary Healthcare Department reserves the right to accept or reject all the applications, and to annul the prequalification process, without thereby incurring any liability to Applicants.
- 24. prequalification of applicants** 24.1 All Applicants whose applications have met the specified requirements will, to the exclusion of all others, be prequalified by DGHS the Primary & Secondary Healthcare Department.
- 25. Notification of prequalification** 25.1 Director General of Health Services Punjab, after completion of evaluation process of submitted PQ applications shall notify all qualified applicants in writing/through PQOD online Portal and Official websites of DGHS & P&SHD indicating their Item wise status as prequalified.
- 26. Validity of Pre-Qualification** 26.1 The Pre-Qualification shall be valid for Financial Year 2024-25 and may be extendable for next financial year (FY 2025-26) for pre-qualified firms. But it is mandatory that the prequalification process shall be conducted for enhancement of prequalified pool.

Annex-1-(On firm’s Original Letter Head)

**Request Application for Prequalification Documents (2024-25)
Drugs & Non-Drugs/Medical Devices**

Ref.No/

Dated:

The Director General Health Services Punjab,
Primary & Secondary Health Care Department
Govt. of The Punjab.

Subject: **Request Application for Prequalification Documents (2024-25) Drugs & Non-Drugs/Medical Devices**

Dear Sir,

With reference to your advertisement regarding prequalification of Drugs & Non-Drugs/Medical Devices (2024-25) advertised on ----- in the Daily Newspaper, it is requested to provide the Prequalification Documents against the following categories.

(Tick Appropriate Box)

- 1. Local Manufacturers (Drugs/Medicines)**
- 2. Sole Agents (Drugs/Medicines)**
- 3. Local Manufacturers (Non-Drugs/Medical Devices)**
- 4. Sole Agents (Non-Drugs/Medical Devices)**
- 5. Local Manufacturers /Sole Agents (Surgical Dressings Only)**

M/s _____ hereby authorizes Mr./Ms. _____

Designation _____ CNIC No. _____

Official Email _____ (For Login I.D), Mobile No. _____ (for sms alerts) to fill/complete/submit the prequalification application via online portal “pqod.pshealth.punjab.gov.pk”.

Firm’s NTN: _____

Firm’s STN: _____

Authorized By

Name _____

Signature _____

Designation _____

Contact No. _____

Stamp _____

Section II-PREQUALIFICATION CRITERIA**A- (Medical Devices Other Than Auto disable (AD) / Re-use prevention (RUP) Syringes)****FOR LOCAL MANUFACTURER/SOLE AGENTS OF FOREIGN PRINCIPAL****1-KNOCK DOWN CRITERIA (Firm Wise)**

Sr. No.	Knock Down Clause	Status
1	Valid DML/ License to Manufacture Medical Devices on form-3 /License to Import Medical Devices on form-4 issued by DRAP.	Yes/No
2	Valid Drugs Sale License. (For Sole agent) – (where applicable)	Yes/No
3	Valid Sole Agency Agreement. (For Sole agent).	Yes/No
4	The firm undertakes that currently it is not blacklisted/debarred by Directorate General Health Services (DGHS) Punjab. The firm shall provide undertaking in this regard on legalized and notarized e-stamp paper of Rs. 100. Any false claim leads to disqualification of the firm.	Yes/No
5	Valid ISO 13485 of the manufacturer.	Yes /No
6	Valid GMP Certificate OR Valid Satisfactory GMP Inspection Report issued by DRAP (For local manufacturer only).Only those Sections & Pharmaceutical Category shall be considered for prequalification whose GMP Inspection Report declared satisfactory and/or which are mentioned in the GMP Certificate)	Yes /No
7	The firm has provided/attached the product's valid CE/UNFPA/JMHLW/US FDA approval certification or prequalification by WHO. Certificates provided by the firm on its own letter head are not acceptable, CE marked by conformity assessment bodies (CABs) notified in NANDO database under the relevant European directive for medical devices of European Union shall be accepted only.	Yes/No
8	The firm undertakes that it has proper warehouse and storage facility as per recommendation of the manufacturer and at required temperature and follows good storage and distribution practice. Firm shall provide undertaking on legally notarized e-stamp paper of rupees 100. Procuring Agency may physically verify firm's claim. Firm must mention address of its storage facility on undertaking.	Yes/No
9	Firm undertake that the Information provided by the firm is in accordance with the terms & conditions of the prequalification documents on e-stamp paper of Rs.100 dully legalized/notarized.	Yes/No
10	Minimum Annual financial turnover for any of single financial year (i.e. 2020-21/2021-22/2022-23)/calendar year (i.e. 2021/2022/2023) must be 330 Million Rupees or above for medical devices of local manufacturer/Sole Agent of Foreign manufacturer. Firm shall provide FBR income tax return/sales Tax return for the financial year 2020-21, 2021-22 and 2022-23 or in case of calendar year 2021, 2022, and 2023. Note: Income Tax/Sales Tax return for the FY 2022-23 shall be supported with bank statement (FY-2022-23) of the title account of the applicant firm only. Both Tax return and Bank statement must be above 330 Million Rupees. (Firm shall attach bank statement signed and stamped from concerned bank along with FBR income tax/sales tax return) and same for calendar year-2023. (Joint venture, consortium and subsidiary shall not be accepted.)	Yes/No

11	The applicant shall submit proof of manufacturing from the chamber of commerce/equivalent body from the country of origin. (For foreign manufacturer only)	Yes/No
12	The firm shall submit undertaking on Rs.100 e-stamp paper that the firm follows the labor laws (Including child free labor and minimum wages as per Government policy). (For local manufacturer only)	Yes/No
13	The firm shall submit undertaking on Rs.100 e-stamp paper that none of its manufactured/imported/supplied batch in Public Sector Institutions has been declared Spurious/Adulterated since 01-01-2021 till the closing date of Prequalification Document submission.	Yes/No
14	The firm (in case of limited company) shall provide form-A (latest) and certificate of incorporation duly verified by SECP. (Memorandum and article of association of companies). Firm will provide Form C (Registered from registrar of firms) / sole proprietorship.	Yes/No
15	The firm shall submit undertaking on Rs.100 e-stamp paper legalized/notarized that Firm has not been prosecuted by Provincial Quality Control Board (PQCB) on the offense of Spurious/Adulterated Medical Device since 01-01-2021 till the closing date of Prequalification Document submission.	Yes/No
16	The firm shall submit original receipt of fee with prequalification application.	Yes/No
17	The applicant shall submit an affidavit on Rs. 100/- e-stamp paper (Notarized) stating the applicant accepts all the terms and conditions of the Prequalification Documents.	Yes/No
18	The firm shall submit prequalification application along with all relevant documents on online portal (PQOD) of P&SHD.	Yes/No
2-KNOCK DOWN CRITERIA (Quoted Product/Item Wise)-Manufacturer/Sole Agents- Medical Devices (Other than Auto disable (AD) / Re-use prevention (RUP) Syringes)		
	<p>1. Quality Compliance Standards (CE/JMHLW/USFDA or prequalified by WHO (Certificate). Certificates provided by the firm on its own letter head are not acceptable. CE marked by conformity assessment bodies (CABs) notified in NANDO database under the relevant European directive for medical devices of European Union shall be accepted only.</p> <p>2. Device Enlistment Certificate of quoted item as per Medical Devices Rules 2017 issued by DRAP to the applicant (exemption wherever applicable under rules).</p> <p>3. Quoted products must be tried and tested in local environment for at least three years (Financial year) since July 2018 onward till closing date of submission of PQD application. (Firm Must attach Purchase Orders of quoted items of Public Sector Institution anywhere in Pakistan).</p> <p>4. Tested samples of the quoted item declared Substandard by the DTLs of Punjab (Not over 5%) from (01-01-2023) if any.</p> <p>5. Substandard Batch Recall History since (01-01-2023) if any.</p> <p>6. Any Punitive Action Taken by DRAP since (01-01-2023). (Punitive means, suspension/cancelation of Manufacturing License or Drug Registration by DRAP since (01-01-2023) till the closing date of Prequalification Document submission.)</p> <p>7. Any Punitive Action Taken by PQCB since (01-01-2023). (Punitive means, Prosecuted by PQCB).</p> <p>8. The firm submit copies of Goods Declaration certificates of quoted items for at least three years since July 2018 onward till closing date of submission of PQD application along with all relevant documents such as bill of lading/airway bill, commercial invoice and packing list (For Importers only). These documents must be verifiable from WeBOC/PSW.</p> <p>NOTE: Firm shall provide undertaking for knock down clause 4, 5, 6, and 7 legally notarized e-stamp paper of rupees 100/-</p>	

**B- (For Auto disable (AD) / Re-use prevention (RUP) Syringes)
FOR LOCAL MANUFACTURER/SOLE AGENTS OF FOREIGN PRINCIPAL
1-KNOCK DOWN CRITERIA (Firm Wise)**

S.No	Knock Down Clauses	Status
1	Valid DML/ License to Manufacture Medical Devices on form-3 /License to Import Medical Devices on form-4 issued by DRAP.	Yes/No
2	Valid Drugs Sale License. (For Sole agent) – (where applicable).	Yes/No
3	Valid Sole Agency Agreement. (For Sole agent).	Yes/No
4	The firm undertakes that currently it is not blacklisted/debarred by Directorate General Health Services (DGHS) Punjab. The firm shall provide undertaking in this regard on legalized and notarized e-stamp paper of Rs. 100. Any false claim leads to disqualification of the firm.	Yes/No
5	Valid ISO 13485 of the manufacturer.	Yes /No
6	Valid GMP Certificate OR Valid Satisfactory GMP Inspection Report issued by DRAP (For local manufacturer only).Only those Sections & Pharmaceutical Category shall be considered for prequalification whose GMP Inspection Report declared satisfactory and/or which are mentioned in the GMP Certificate)	Yes /No
7	The firm has provided/attached the product's valid JMHLW/US FDA approval certification or prequalification by WHO. Certificates provided by the firm on its own letter head are not acceptable, Certification status shall be verified from official website of the aforementioned Agencies.	Yes/No
8	The firm undertakes that has proper warehouse and storage facility as per recommendation of the manufacturer and at required temperature and follows good storage and distribution practice. Firm shall provide undertaking on legally notarized e-stamp paper of rupees 100. Procuring Agency may physically verify firm's claim. Firm must mention address of its storage facility on undertaking.	Yes/No
9	Firm undertake that the Information provided by the firm is in accordance with the terms & conditions of the prequalification documents on e-stamp paper of Rs.100 dully legalized/notarized.	Yes/No
10	Minimum Annual financial turnover for any of single financial year (i.e. 2020-21/2021-22/2022-23)/calendar year (i.e. 2021/2022/2023) must be 330 Million Rupees or above for medical devices of local manufacturer/Sole Agent of Foreign manufacturer. Firm shall provide FBR income tax return/sales Tax return for the financial year 2020-21, 2021-22 and 2022-23 or in case of calendar year 2021, 2022, and 2023. Note: Income Tax/Sales Tax return for the FY 2022-23 shall be supported with bank statement (FY-2022-23) of the title account of the applicant firm only. Both Tax return and Bank statement must be above 330 Million Rupees. (Firm shall attach bank statement signed and stamped from concerned bank along with FBR income tax/sales tax return) and same for calendar year-2023. (Joint venture, consortium and subsidiary shall not be accepted.)	Yes/No
11	The applicant shall submit proof of manufacturing from the chamber of commerce/equivalent body from the country of origin. (For foreign manufacturer only)	Yes/No
12	The firm shall submit undertaking on Rs.100 e-stamp paper that the firm follows the labor laws (Including child free labor and minimum wages as per Government policy). (For manufacturer only)	Yes/No

13	The firm shall submit undertaking on Rs.100 e-stamp paper that none of its supplied batch in Public Sector Institutions has been declared Spurious/Adulterated since 01-01-2021 till the closing date of Prequalification Document submission.	Yes/No
14	The firm (in case of limited company) shall provide form-A (latest) and certificate of incorporation duly verified by SECP. (Memorandum and article of association of companies). Firm will provide Form C (Registered from registrar of firms) / sole proprietorship.	Yes/No
15	The firm shall submit undertaking on Rs.100 e-stamp paper legalized/notarized that Firm has not been prosecuted by Provincial Quality Control Board (PQCB) on the offense of Spurious/Adulterated medical devices since 01-01-2021 till the closing date of Prequalification Document submission.	Yes/No
16	The firm shall submit original receipt of fee with prequalification application.	Yes/No
17	The applicant shall submit an affidavit on Rs. 100/- e-stamp paper (Notarized) stating the applicant accepts all the terms and conditions of the Prequalification Documents.	Yes/No
18	The firm shall submit prequalification application along with all relevant documents on online portal (PQOD) of P&SHD.	Yes/No
2-KNOCK DOWN CRITERIA (Quoted Product/Item Wise)- Manufacturer/Sole Agents-Medical Devices (For Auto Disable Syringes)		
	<p>1. Quality Compliance Standards (JMHLW/US FDA or prequalified by WHO (Certificate). Certificates provided by the firm on its own letter head are not acceptable. Certification status shall be verified from official website of the aforementioned Agencies.</p> <p>2. Device Enlistment Certificate as per Medical Devices Rules 2017 issued by DRAP to the applicant. (exemption wherever applicable under rules).</p> <p>3. Quoted products must be tried and tested in local environment for at least one year (Financial year) since July 2018 onward till closing date of submission of PQD application. (Firm Must attach Purchase Orders of quoted items of Public Sector Institution anywhere in Pakistan).</p> <p>4. Tested samples of the quoted item declared Substandard by the DTLs of Punjab (Not over 5%) from (01-01-2023) if any.</p> <p>5. Substandard Batch Recall History since (01-01-2023) if any.</p> <p>6. Any Punitive Action Taken by DRAP since (01-01-2023). (Punitive means, suspension/cancelation of Manufacturing License or Drug Registration by DRAP since (01-01-2023) till the closing date of Prequalification Document submission.)</p> <p>7. Any Punitive Action Taken by PQCB since (01-01-2023). (Punitive means, Prosecuted by PQCB).</p> <p>8. The firm submit copies of Goods Declaration certificates of quoted items for at least one year since July 2018 onward till closing date of submission of PQD application along with all relevant documents such as bill of lading/airway bill, commercial invoice and packing list (For Importers only). These documents must be verifiable from WeBOC/PSW.</p> <p>NOTE: Firm shall provide undertaking for knock down clause 4,5,6, and 7 on legally notarized e-stamp paper of rupees 100/-</p>	

Note:

- DGHS may through their physical inspection committee(s)/inspector(s) shall verify the facts/claims submitted by the applicant(s). Any forged document(s)/claim(s) shall be dealt under PPR-2014.**

2. To establish its qualification, the firm shall provide the information requested in the respective annexures and requirements with documentary proof:
3. The firm will be prequalified for the particular item/ brand.
4. In order to avoid internet connectivity and load shedding issue, applicants are advised to apply online as early as possible without waiting for the due date.
5. In case of any issue during online application submission at PQOD, immediately send email at **pcdghslahore@gmail.com** along with screen short of issue faced by applicant.

GENERAL FIRM’S INFORMATION

(Medical Devices Manufacturer)

I. Company Profile.

1. Name of company : _____

Year established : _____

Form of company : Individual
 Partnership
 Corporation
 Other (specify)

Legal status : _____

Trade registers number : _____

NTN & Sales Tax number (If applicable): : _____

Mfg. License Number : _____

(attach valid copy)

2. Address : _____

Telephone : _____ Telefax: _____

E-mail: : _____

3. Employees:

S.No.	Category	Quantity
1	Management	
2	R &D	
3	Sales	
4	Administrative	
5	Production and quality control	
6	Others (specify)	
	Total	

Please attach the company organizational chart

II. Product Information

Please provide the information as per Annexure-C

1. Are all manufacturing operations (processing, packaging, labeling) carried out internally?
 YES NO

If “No,” attach a list of pharmaceuticals and/or raw materials manufactured by other companies and marketed by you. Please give the names of the companies, for each item.

S.No.	Product Name	Manufacturer	Address
1.			
2.			
3.			

If any products are repackaged, attach a list of such products with the name and address of the manufacturer for each product:

S.No.	Product Name	Manufacturer	Address
1.			
2.			
3.			

III. QUALITY DEPARTMENT

1. Do you maintain your own quality control laboratory?
 YES NO (if NO please provide details of alternate arrangements)
2. Number of specialized personnel working in your quality control, quality assurance and microbiological laboratory/ies (excluding administrative personnel). Provide their academic and professional details on a separate sheet.
- Pharmacists : _____
- Chemists : _____
- Others : _____
3. List of Equipment installed in quality control, quality assurance and microbiological laboratory/ies for quality assurance as per BP/USP.
- _____
- _____
4. Are these equipment calibrated & validated.
 YES NO
5. Are all raw materials completely tested prior to use or is a Certificate of Analysis accepted?
 YES NO Certificate of Analysis

6. Are control samples of each batch retained?

YES

NO

7. Name and title of the authorized person (s) responsible for batch release:

Name: _____

Title: _____

Experience in pharmaceuticals: _____ years

8. Name and qualification of the head of the Quality Control department:

Name: _____

Qualification: _____

Experience in pharmaceuticals: _____ years

9. Describe your storage facilities:

The firm will provide logistics/distribution network in Punjab.

The firm will provide human resource regarding logistics/distribution network in Punjab.

**Authorized Sole agent for Foreign Principal’s Qualification
(Medical Devices Items)**

I. Company Profile.

1. Name of company : _____
 Year established : _____
 Form of company : Individual
 Partnership
 Corporation
 Other (specify)
 Legal status : _____
 Trade registers number : _____
 NTN & Sales Tax number (If applicable):

Valid sole agency agreement
(attach valid copy)

2. Address : _____
 Telephone : _____ Telefax: _____
 E-mail & Web : _____

Please attach the company organizational chart

3. Type of activity carried out by the company (tick the appropriate category/ies)

- Manufacturer
- Branded products
- Generic products
- Medical supplies
- Laboratory reagents
- Other products (specify below)

4. Names and addresses of international pharmaceutical companies, parent companies and/or subsidiaries and associated companies with whom there is collaboration or joint venture, if any:

S.No.	Product Name	Company	Address
1.			
2.			
3.			

5. Employees:

S.No.	Category	Quantity
1	Management	
2	R &D	
3	Sales	
4	Administrative	
5	Production and quality control	
6	Others (specify)	
	Total	

6. Capital value of the company (specify currency)

(a) Authorized capital: _____

(b) Paid up capital: _____

(c) Administration: _____

7. Annual sales turnover in the previous one year. Mention Private Sector and Public Sector sales separately (in Pak Rupees)

(In Million)

Annual turnover	Open market sales	Public Sector Sale	Year

Arbitration History (if any): _____

Authorized Sole agent for Foreign Manufacturer
(Medical Devices/Non-Drug items)

Product applied for:

S.No. of the item	Name of Item	Name of Manufacturer	Country of Origin	Quality Compliance standards

Name of firm _____

Address _____

Phone _____ Fax _____

E-mail _____ URL http://www. _____

Type of firm: Sole Proprietor Partner Ship Limited

Other _____ Date of establishment _____

List of Board of Directors, Partners, Key Management Personnel (both Technical, Sales & Management - include position, professional qualification, experience).

Total area of the firm premises _____ Owned Rented

Total Area of ware house _____

Facilities in ware house _____

Total no. of Employees: Technical _____ Non – Technical _____

National Tax Number _____ Date _____

General Tax Number _____ Date _____

Registrations / Prequalification with other departments: _____

Detail of Head / Branch Office / Workshop (s):

Address: _____

Phone _____ Fax _____

Address _____

Phone _____ Fax _____

Sales / Marketing Staff:

Name	Designation / Responsibility	Qualification	Total Experience	Experience with Current Firm	Training Detail (Local &abroad)

Technical Staff:

Name	Designation / Responsibility	Qualification	Total Experience	Experience with Current Firm

Name & Capacity of the Authorized Contact Person: _____

Signature of the Authorized Contact Person: _____

Date: _____ Stamp of the Firm: _____

DOCUMENTS TO BE ATTACHED (COPIES)

The firm must attached relevant documents

**NAME OF APPLICANT FIRM (Local Manufacturer/Sole Agent-Medical Devices (Other than Auto Disable (AD) / Re-use Prevention (RUP) Syringe)-
Draft Form) _____**

Item Code	Generic Name	Section	Quoted Brand	Quoted strength/size	pack Size	Country of Origin	Mfg By	Mfg for	MRP (Rs)	Quality Compliance Standards	Required Storage tempt (quoted item)	Valid Sole Agency Agreement	Date of Sole agency agreement	Product 3-years' experience in Pakistan	Verified/ Not Verified (Valid sole agency Authorization)
1															
2															

NAME OF APPLICANT FIRM (Local Manufacturer/Sole Agent-Medical Devices (For Auto Disable (AD) / Re-use Prevention (RUP) Syringe)-Draft Form)

Item Code	Generic Name	Section	Quoted Brand	Quoted strength/size	Pack Size	Country of Origin	Mfg. By	Mfg. for	MRP (Rs.)	Quality Compliance Standards	Required Storage tempt (quoted item)	Valid Sole Agency Agreement	Date of Sole agency agreement	Verified/ Not Verified (Valid sole agency Authorization)
1														
2														

Sr.	Generic Name
1	Adhesive Sticking Plaster
2	Auto Disable (AD)/Re-use prevention (RUP) Syringe 0.5ml with needle (Blister Pack)
3	Auto Disable (AD)/Re-use prevention (RUP) Syringe 10 ml with needle (Blister Pack)
4	Auto Disable (AD)/Re-use prevention (RUP) Syringe 1ml with needle (Blister Pack)
5	Auto Disable (AD)/Re-use prevention (RUP) Syringe 2ml with needle (Blister Pack)
6	Auto Disable (AD)/Re-use prevention (RUP) Syringe 3ml with needle (Blister Pack)
7	Auto Disable (AD)/Re-use prevention (RUP) Syringe 5 ml with needle (Blister Pack)
8	AV Fistula Needles (Arterial+ venous) with fixed wings. (Individually Sterile Packed) size 16/17G.
9	AV Set Blood Tubing Lining with one transducer protector (Fluid Barrier) & Pre-Pump Arterial Pressure Monitoring Line (Individually Sterile Packed).
10	Bicarbonate Solution of appropriate composition for hemodialysis
11	Biopsy Jar with formaline 240ml
12	Black Silk, Size 1, 30mm, 1/2 Circle round body needle
13	Black Silk, Size 2/0, 60mm straight cutting needle
14	Black Silk, Size 1, 40mm 3/8 Circle curve cutting (CC) needle
15	Black Silk, 2/0, 30mm 1/2 circle round body needle
17	Blood Bags Sterile Packs 250ml single
18	Blood Bags Sterile Packs 500ml single
19	Blood Transfusion Set Sterile Packs
20	Breathing Circuit (Adult / Peads)
21	Caps Surgical
22	Catgut Chromic size 2 1/2 circle RB
23	Catgut Chromic, Size 1, with 40mm Intestinal RB Needle
24	Catgut Chromic, Size 1, 30mm, 1/2 Circle RB Needle
25	Catgut Chromic, Size 1, 40mm, curved Needle
26	Catgut Chromic, Size 2/0, 30mm, 1/2 Circle Round Body needle
27	Chest Electrodes (Peads / Adults)
28	CVP Line (Double Lumen) (All Sizes)
29	CVP Line (Triple Lumen) (All Sizes)
30	Disposable Airways Sterile Blister Pack (All sizes)
31	Disposable Delivery Kit
32	Disposable Insulin Syringe 1ml with needle (Blister Pack)
33	Disposable syringe 10ml with needle. (Blister pack)
34	Disposable Syringe 20ml with needle. (Blister pack)
35	Disposable Syringe 50ml with needle. (Blister pack)
36	Disposable Syringe 60ml with Central Nozzle or Catheter Tip (Blister Pack)
37	Double Lumen catheter for Haemodialysis
38	Endotracheal tube (all sizes) Sterile Packs with cuff Set
39	Endotracheal tube (all sizes) Sterile Packs without cuff Set
40	Epidural Kit
41	Examination Gloves Latex (S.M.L)
42	Face Mask Surgical

Pre-Qualification Documents –Medical Devices - Year 2024-2025

Sr.	Generic Name
43	Face Mask Surgical with Tie
44	Foley's catheter (all sizes) Sterile Packs All sizes
45	HME Filter (Neonate / Peads / Adult)
46	Hollow Fiber Dialyzer (All Sizes) Individually Sterile Packed
47	I.V Cannula with Injection Port and Integrated Closing Cone Sterile Pack 18G
48	I.V Cannula with Injection Port and Integrated Closing Cone Sterile Pack 20G
49	I.V Cannula with Injection Port and Integrated Closing Cone Sterile Pack 22G
50	I.V Cannula with/without Injection Port with Integrated Closing Cone Sterile Pack 24G
51	I.V. Sets Sterile blister Pack
52	Instrumental Disinfectant Solution Of appropriate composition
53	IUCD (CU-T 380A) UNFPA/WHO Prequalified
54	Male Latex Condom (UNFPA/WHO prequalified)
55	Nasal Cannula (all sizes)
56	Nasogastric tube (all sizes)
57	Nebulizer Kit (Peads / Adult)
58	Nelton Catheter Sterile Packs
59	Oxygen Mask (Peads / Adult)
60	Poly propylene Size 1, 40mm 1/2 circle RB Needle
61	Poly propylene, Size 2/0, 30mm 1/2 circle RB Needle
62	Poly propylene, Size 2/0,60mm Straight Cutting needle (SCN)
63	Polydioxanone all sizes for paediatric surgery
64	Polyglactin / Polyglycolic Acid, 3/0, RB
65	Polyglactin/ Polyglycolic acid, Size 1,40mm.1/2 Circle Round Body needle
66	Polyglactin/ Polyglycolic acid, size 2/0,30mm, 1/2 Circle Round Body needle
67	Redvic drain with Bottle (all sizes)
68	Scalp Vein Set Sterile Packs (All Sizes)
69	Spinal Needle Sterile Packs All Sizes
70	Sterile Surgical Gloves Pairs 6 ½, 7, 7 ½ (Powdered)
71	Sterilized Cord Clamps Sterile Packs
72	Sterilized Surgical Blades Sterile Packs All Sizes
73	Suction Catheter (All Sizes)
74	Surface Disinfectant Solution Of appropriate composition
75	Three-way stopper with Tubing
76	Three-way stopper without Tubing
77	Urine Bags Sterile (2000ml) Packs
78	Volumetric Chamber (I.V Burette) Sterile Packs 100ml size

NOTE: Detailed specification of items will be advertised at the time of bidding.

Section III: Application Forms

Application Submission Form

Date: __ / __ / 2024

To

**Director General Health Services Punjab
Government of the Punjab
Primary & Secondary Healthcare Department.**

I/we, the undersigned, apply to be prequalified for the referenced Pre-qualification and declare that:

- (a) I/we have examined and have no reservations to the Prequalification Documents, including Addendum(s). (if any) issued in accordance with Instructions to Applicants (ITA) *[insert the number and issuing date of each addendum]*.
- (b) I/we, have nationalities from eligible countries, in accordance with ITA *[insert the nationality of the Applicant, including that of all partners in case of a Joint Venture /Consortium if applicable]*;
- (c) I/we, for any part of the application resulting from this prequalification, do not have any conflict of interest;
- (d) I/we for any part of the contract resulting from this prequalification, currently have not been declared disqualified / blacklisted Directorate General Health Services (DGHS) Punjab
- (e) I/we understand that you may cancel the prequalification process at any time, the prequalification does not bound the procuring agency to call for the bids from the prequalified firms.
- (f) All information, statements and description contained in the Application (online and hard copy) are in all respect true, correct and complete to the best of our knowledge and belief and there is no difference in information provided online and submitted in hard copy.

Signed *[insert signature(s) of an authorized representative(s) of the Applicant]* Name *[insert full name of person signing the application]*

In the Capacity of *[insert capacity of person signing the application]*

Duly authorized to sign the application for and on behalf of: Applicant's Name *[insert full name of Applicant]*

Address *[insert street number/town or city/country/ address]*

Dated on _ -/_ -_/2024

Affidavit

(Pak Rs.100/-)

Applicants signed affidavit on PKR 100.00 paper confirming not having been declared ineligible by any of the public sector organization in Pakistan, as described in the documents.

Signed *[insert signature(s) of an authorized representative(s) of the Applicant]* Name *[insert full name of person signing the application]*

In the Capacity of *[insert capacity of person signing the application]*

Duly authorized to sign the application for and on behalf of: Applicant's Name *[insert full name of Applicant]*

Address *[insert street number/town or city/country/ address]*

Dated on _ -/_ -_/2024

Physical Inspection of Applicants

Part A:

As per evaluation criteria, eligibility of applicants and other terms and conditions specified in PQ Documents.

Part B:

To inspect/evaluate any violation or critical/major non-compliance of cGMP.

Note: Non-compliances/violations of any parameter(s) of Part A or Part B will lead to “Non-prequalification” of the applicant