PREQUALIFICATION DOCUMENTS

MEDICAL DEVICES
(IN-VITRO DIAGNOSTIC KITS)

LOCAL MANUFACTURING UNITS AND SOLE AGENTS OF FOREIGN PRINCIPALS

(FINANCIAL YEAR 2019-2020)

Directorate General Health Services Punjab
24-Cooper Road Lahore.

Primary & Secondary Healthcare Department
Government of the Punjab
INVITATION FOR PREQUALIFICATION (2019-20)

MANUFACTURING UNITS AND SOLE AGENTS OF FOREIGN PRINCIPALS OF MEDICAL DEVICES (IVD)

1. Government of the Punjab is committed to procure quality Medical Devices (Hepatitis: B&C PCR & B&C RDTs Test Kits and Serum Separation Tubes 5 ml) for Hepatitis Control Program, working under the administrative control of Primary and Secondary Healthcare Department. To materialize this commitment Director General Health Services Punjab invites application for prequalification of Medical Devices (Hepatitis: B&C PCR & B&C RDTs Test Kits and Serum Separation Tubes 5 ml) for Financial Year 2019-20 from Local Manufactures/Sole Agents of Foreign Principals having established credentials in terms of technical, financial & managerial capabilities.

2. A complete set of Prequalification Documents can be downloaded from the following websites [www.ppra.punjab.gov.pk], [www.pshealth.punjab.gov.pk]/[www.dghs.punjab.gov.pk]. The firms are required to submit signed & stamped hard copy of prequalification documents.

3. The signed & stamped prequalification documents must reach at the Purchase Cell, Directorate General Health Services Punjab, 24 Cooper Road, Lahore on 17-10-2019 up till 11:00 A.M which shall be opened on the same date at 11:30 A.M.

4. The firms shall pay a non-refundable Prequalification Fee as mentioned in Pre-qualification documents at The Accounts Branch, Directorate General Health Services Punjab, 24-Cooper Road, Lahore.

5. The Request for Proposals (RFP) will be called only from the Prequalified Firms by the concerned procuring agencies.

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 printed applications accordingly. The time and venue shall remain the same.

Note: The process shall be governed by the Punjab Procurement Rules, 2014.
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</tr>
</tbody>
</table>
## 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 Local Manufacturing Units & Sole Agents of Foreign Principals for Medical Devices (IVD) against the list of items/sections contained in the Prequalification Documents. This prequalification will be concluded for Hepatitis Control Program, DGHS under administrative control of P & SHD.

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 2018.

Procuring agency may physically verify firm’s claim regarding submitted documents.

| 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
(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. In case of failure to participate, procuring agency may disqualify respective firm (fully or in partially) from pre-qualification 2019-20 and may initiate legal proceeding against the said firm.

3. Eligible Applicants

3.1 An Applicant can be a private or public entity registered with FBR having NTN & SRTN Registration.

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 any of the public sector organization in Pakistan 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 these 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 (IVD). 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 no later than Ten (10) days prior to the deadline for submission of applications. 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 Director General Health Services, 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 Payment Receipt may be collected from Accounts Branch, Directorate General of Health Services Punjab, 24 Cooper Road, Lahore after submitting fee of Rs: 5,000/- with providing
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:

a. Application Submission Form, in accordance with Information To Applicants (ITA);

b. Documentary evidence establishing the Applicant's eligibility to prequalify, in accordance with ITA & Prequalification Criteria;

c. Documentary evidence establishing the Applicant's qualifications, in accordance with ITA and Prequalification Criteria;

d. Any other document required as specified in the Prequalification Documents.

e. All information, statements and description contained in the Application 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

10.1  The Applicant must submit before date and time mentioned in invitation for prequalification. All blank fields are mandatory to fill/complete and submit hard copy of PQD and relevant required documents in tape binding with page number mentioned on each page.

11. Application Submission

11.1  The printed online application along with necessary documents shall be submitted (in tape binding) by hand in Purchase Cell Directorate General of Health Services Punjab, 24 Cooper Road, Lahore before 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 Applicants will submit their applications by hand. Applications shall be received by the Purchase Cell Directorate General of Health Services Punjab, 24 Cooper Road, Lahore at the address and no later than the deadline indicated in the Invitation for Prequalification.

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 application received by the Director General of Health Services Punjab, Primary & Secondary Healthcare Department after the deadline for submission of applications will not be entertained as indicated in the Invitation for Prequalification.

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 which shall be submitted within a stated reasonable period of time. 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 Section/Item wise/firm wise for Medical Devices (IVD) 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 may physically verified by the department through inspection teams to inspect the premises of the firm for verification of firm’s claims. 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 item wise/section wise/firm wise, 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, Primary & Secondary Healthcare Department.
25. Notification of prequalification

25.1 Once the Director General of Health Services Punjab, Primary & Secondary Healthcare Department has completed the evaluation of the applications it shall notify all Applicants in writing through Official websites of DGHS & P&SHD indicating their Section/Item wise status as to prequalified or disqualified or ineligible.

26. Validity of Pre-Qualification

26.1 The Pre-Qualification shall be valid for FINANCIAL YEAR 2019-20
Annex-1

(On firm’s Original Letter Head)

Request Application for Prequalification Documents (FY 2019-20)
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 (FY 2019-20) Medical Devices

Dear Sir,

With reference to your advertisement regarding prequalification of Medical Devices (FY 2019-20) advertised on ------------ in the Daily ------------ Newspaper, it is requested to provide the Prequalification Documents against the following categories:

(Tick Appropriate Box)

1. Local Manufacturers (Medical Devices) □

2. Sole Agents (Medical Devices) □

M/s __________________________ hereby authorizes Mr./Ms. __________________________
Designation __________________________ CNIC No. __________________________

Official Email __________________________ 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 __________________________
PREQUALIFICATION CRITERIA OF MEDICAL DEVICES (IV DIAGNOSTIC KITS) FOR LOCAL MANUFACTURER/SOLE AGENTS

1-KNOCK DOWN CRITERIA (Firm Wise/Item Wise)

FOR CLASS-A (HBV & HCV RDT Kits/Devices)

<table>
<thead>
<tr>
<th>Sr. No.</th>
<th>Knock Down Clause</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>The firm shall submit original receipt of fee with prequalification application.</td>
<td>Yes/No</td>
</tr>
<tr>
<td>2</td>
<td>Valid DML/ License to Manufacture Medical Devices on form-3 /License to Import Medical Devices on form-4 issued by DRAP.</td>
<td>Yes/No</td>
</tr>
<tr>
<td>3</td>
<td>The firm must provide Drugs Sale License. (Where applicable)</td>
<td>Yes/No</td>
</tr>
<tr>
<td>4</td>
<td>The firm shall provide Valid Sole Agency Agreement issued from Foreign Manufacturer with indication of manufacturing site and its location. (For Sole agent)</td>
<td>Yes/No</td>
</tr>
<tr>
<td>5</td>
<td>The firm undertakes that currently it is not blacklisted/debarred by any procuring agency. The firm will provide undertaking in this regard on legalized and notarized Judicial stamp paper of Rs. 100/. Any false claim leads to disqualification of the firm.</td>
<td>Yes/No</td>
</tr>
<tr>
<td>6</td>
<td>Firm will provide valid GMP Certificate issued by DRAP (For local manufacturer only)</td>
<td>Yes /No</td>
</tr>
<tr>
<td>7</td>
<td>The firm shall provide/attach one of the following product’s valid certification /License/prequalification document</td>
<td>Yes/No</td>
</tr>
<tr>
<td>a.</td>
<td>United States Food &amp; Drug Administration-PMA letter or BLA license: Risk Class-III</td>
<td></td>
</tr>
<tr>
<td>b.</td>
<td>WHO-WHO Prequalification Public Report: Risk Class-All Classes</td>
<td></td>
</tr>
<tr>
<td>c.</td>
<td>JMHLW-JMHLW Minister’s Approval, JMHLW License for Manufacturer and JMHLW Recognized Foreign Manufacturer: Risk Class-III</td>
<td></td>
</tr>
<tr>
<td>d.</td>
<td>Health Canada-Medical Device License and summary report for a Class IV IVD and CMDCAS-issued ISO-13485 Certificate: Risk Class-IV</td>
<td></td>
</tr>
<tr>
<td>e.</td>
<td>Therapeutic Goods Administration (TGA)-Australia-TGA License for Manufacturer, TGA issued ISO-13485 Certificate, AUST R Number, TGA Full Quality Assurance Certificate, TGA Type-Examination Certificate and TGA Production Quality Assurance Certificate: Risk Class- IV</td>
<td></td>
</tr>
<tr>
<td>Note:</td>
<td>Certificates provided by the firm on its own letter head are not acceptable</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Applicant will provide cumulative Financial Turnover of last three consecutive financial years (i.e. 2016-17, 2017-18 &amp; 2018-19) must not be less than 300 Million Rupees. Firm will provide FBR sale tax return for three last financial years i.e. 2016-17/2017-18/2018-19 (total good or service supplied locally including reduced rates sales).</td>
<td>Yes/No</td>
</tr>
<tr>
<td>9</td>
<td>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 practices. Firm will provide undertaking on legally notarized judicial stamp paper of Rs. 100/- regarding it. Procuring Agency may physically verify firm’s claim. Firm must mention address of its storage facility on undertaking.</td>
<td>Yes/No</td>
</tr>
<tr>
<td>10</td>
<td>Declaration regarding Non-Conviction by any Court of law against applicant firm.</td>
<td>Yes/No</td>
</tr>
</tbody>
</table>
To establish its qualification, the firm shall provide the information requested in the respective annexures and requirements with documentary proof:

**PREQUALIFICATION CRITERIA OF MEDICAL DEVICES (IV DIAGNOSTIC KITS) FOR LOCAL MANUFACTURER/SOLE AGENTS**

**1-KNOCK DOWN CRITERIA (Firm Wise/Item Wise)**

**FOR CLASS-B (HBV, HCV PCR Kits/Devices and Serum Separating Tubes)**

<table>
<thead>
<tr>
<th>Sr. No.</th>
<th>Knock Down Clause</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>The firm shall submit original receipt of fee with prequalification application.</td>
<td>Yes/No</td>
</tr>
<tr>
<td>2</td>
<td>Valid DML/ License to Manufacture Medical Devices on form-3 /License to Import Medical Devices on form-4 issued by DRAP.</td>
<td>Yes/No</td>
</tr>
<tr>
<td>3</td>
<td>The firm must provide Drugs Sale License. (Where applicable)</td>
<td>Yes/No</td>
</tr>
<tr>
<td>4</td>
<td>The firm shall provide Valid Sole Agency Agreement issued from Foreign Manufacturer with indication of manufacturing site and its location. (For Sole agent)</td>
<td>Yes/No</td>
</tr>
<tr>
<td>5</td>
<td>The firm undertakes that currently it is not blacklisted/debarred by any procuring agency. The firm will provide undertaking in this regard on legalized and notarized Judicial stamp paper of Rs. 100/. Any false claim leads to disqualification of the firm.</td>
<td>Yes/No</td>
</tr>
<tr>
<td>6</td>
<td>Firm will provide valid GMP Certificate issued by DRAP (For local manufacturer only)</td>
<td>Yes/No</td>
</tr>
<tr>
<td>7</td>
<td>The firm shall provide/attach product's valid certification of United States Food &amp; Drug Administration (approved as per online published approval letter document available on official website of US FDA). Note: Certificates provided by the firm on its own letter head are not acceptable</td>
<td>Yes/No</td>
</tr>
<tr>
<td>8</td>
<td>Applicant will provide cumulative Financial Turnover of last three consecutive financial years (i.e. 2016-17, 2017-18 &amp; 2018-19) must not be less than 300 Million Rupees. Firm will provide FBR sale tax return for three last financial years i.e. 2016-17/2017-18/2018-19 (total good or service supplied locally including reduced rates sales).</td>
<td>Yes/No</td>
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<tr>
<td>9</td>
<td>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 practices. Firm will provide undertaking on legally notarized judicial stamp paper of Rs. 100/- regarding it. Procuring Agency may physically verify firm's claim. Firm must mention address of its storage facility on undertaking.</td>
<td>Yes/No</td>
</tr>
<tr>
<td>10</td>
<td>Declaration regarding Non-Conviction by any Court of law against applicant firm. The firm shall submit undertaking on Rs.100/- Judicial Stamp Paper legally notarized.</td>
<td>Yes/No</td>
</tr>
<tr>
<td>11</td>
<td>The firm shall undertake on Rs.100/- judicial stamp paper legally notarized that the Information provided by the firm at Annexure-A, B or C and any other information</td>
<td>Yes/No</td>
</tr>
</tbody>
</table>
provided by the firm are in accordance with terms & conditions of the prequalification documents.

12 The applicant will submit an affidavit on Rs. 100/- judicial stamp paper (Notarized) stating the applicant accepts all the terms and conditions as mentioned in Prequalification Documents.  Yes/No

To establish its qualification, the firm shall provide the information requested in the respective annexures and requirements with documentary proof:
GENERAL FIRM’S INFORMATION
(Medical Device Local 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:

<table>
<thead>
<tr>
<th>S.No.</th>
<th>Category</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Management</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>R &amp;D</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Sales</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Administrative</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Production and quality control</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Others (specify)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td></td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>S.No.</th>
<th>Product Name</th>
<th>Manufacturer</th>
<th>Address</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td></td>
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<td>3.</td>
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</tbody>
</table>

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

<table>
<thead>
<tr>
<th>S.No.</th>
<th>Product Name</th>
<th>Manufacturer</th>
<th>Address</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
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<td>2.</td>
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<td>3.</td>
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</tr>
</tbody>
</table>

### 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?
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.
Annexure “B”

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

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:

<table>
<thead>
<tr>
<th>S.No.</th>
<th>Product Name</th>
<th>Company</th>
<th>Address</th>
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<tbody>
<tr>
<td>1.</td>
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</tbody>
</table>
5. Employees: (Where applicable)

<table>
<thead>
<tr>
<th>S.No.</th>
<th>Category</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Management</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>R &amp; D</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Sales</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Administrative</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Production and quality control</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Others (specify)</td>
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<td></td>
<td><strong>Total</strong></td>
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</tbody>
</table>

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)

<table>
<thead>
<tr>
<th>Annual turnover</th>
<th>Open market sales</th>
<th>Public Sector Sale</th>
<th>Year</th>
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Arbitration History (if any): ________________________________
Authorized Sole agent for Foreign Manufacturer
(Medical Devices)

Product applied for:

<table>
<thead>
<tr>
<th>S.No. of the item</th>
<th>Name of Item</th>
<th>Name of Manufacturer</th>
<th>Country of Origin</th>
<th>Quality Compliance standards</th>
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</table>

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:

<table>
<thead>
<tr>
<th>Name</th>
<th>Designation / Responsibility</th>
<th>Qualification</th>
<th>Total Experience</th>
<th>Experience with Current Firm</th>
<th>Training Detail (Local &amp; abroad)</th>
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</table>

Technical Staff:

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<thead>
<tr>
<th>Name</th>
<th>Designation / Responsibility</th>
<th>Qualification</th>
<th>Total Experience</th>
<th>Experience with Current Firm</th>
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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 (Medical Devices) ____________________________

<table>
<thead>
<tr>
<th>Item Code</th>
<th>Generic Name</th>
<th>Quoted Brand</th>
<th>Quoted strength/size</th>
<th>pack Size</th>
<th>Country of Origin</th>
<th>Mfg By</th>
<th>MRP (Rs)</th>
<th>Quality Compliance Standards</th>
<th>Required Storage tempt (quoted item)</th>
<th>Valid Sole Agency Agreement</th>
<th>Date of Sole agency agreement</th>
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Section III: Application Forms

Application Submission Form

Date: __/__/2019

To

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

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, have not been declared disqualified / blacklisted by any of the public organization of the Procuring Agency's country

(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 __-__/__/2019
Affidavit
(Pak Rs.100/-)

a) Applicants signed affidavit on PKR 100.00 judicial paper confirming not having been declared ineligible by any of the public sector organization in Pakistan, as on during last three years. Described in the documents.

b) Applicants confirming not having been involved in any litigation

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 _ -./. _./2019
### Annexure-E

<table>
<thead>
<tr>
<th>Inquiry No.</th>
<th>Generic Name</th>
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<tbody>
<tr>
<td>1</td>
<td>Hepatitis B Surface Antigen (HBsAg) Rapid Diagnostic Testing Kits/Devices</td>
</tr>
<tr>
<td>2</td>
<td>Anti HCV Antibodies (HBsAg) Rapid Diagnostic Testing Kits/Devices</td>
</tr>
<tr>
<td>3</td>
<td>HBV PCR Kits, US FDA (United States Food &amp; Drug Administration) approved as per online published approval letter document available on official website of US FDA.</td>
</tr>
<tr>
<td>4</td>
<td>HCV PCR Kits, US FDA (United States Food &amp; Drug Administration) approved as per online published approval letter document available on official website of US FDA.</td>
</tr>
<tr>
<td>5</td>
<td>Serum Separating Tube- Gel Tube 5ml, US FDA (United States Food &amp; Drug Administration) approved as per online published approval letter document available on official website of US FDA.</td>
</tr>
</tbody>
</table>