PREQUALIFICATION DOCUMENTS

(DRUGS/ MEDICINES)

(PHARMACEUTICAL MANUFACTURING UNITS AND SOLE AGENTS OF FOREIGN PRINCIPALS)

(FINANCIAL YEAR 2018-2019)
(The Pre-Qualification shall be valid to 30th June 2019 extendable to next financial year)

PROVINCIAL HEPATITIS CONTROL PROGRAM PUNJAB
DIRECTORATE GENERAL HEALTH SERVICE
GOVERNMENT OF THE PUNJAB
INVITATION FOR PREQUALIFICATION

PHARMACEUTICAL MANUFACTURING UNITS AND SOLE AGENTS OF FOREIGN PRINCIPLES OF

HEPATITIS MEDICINE

Provincial Hepatitis Control Program Punjab, Director General Health Services, Government of the Punjab, intends to prequalify Pharmaceutical Manufacturing Units & Sole Agents of Foreign Principles for the procurement of Medicine having established credentials in terms of Technical, Financial & Managerial Capabilities during the Financial Year 2018-19.

Provincial Hepatitis Control Program Punjab, Director General Health Services, Government of the Punjab, invites applications from Pharmaceutical Manufacturing Units & Sole Agents of Foreign Principles of Medicine for pre-qualification. Pre-qualification is open to all Pharmaceutical Manufacturing Units & Sole Agents of Foreign Principles for Medicine in Pakistan against the medicine contained in the Prequalification Documents.

A complete set of the Prequalification Documents in English can be downloaded from the official websites of the Punjab Procurement Regulatory Authority [www.ppra.punjab.gov.pk] & Provincial Hepatitis Control Program Punjab, [www.pshealth.punjab.gov.pk]. Further information can be obtained from the office of the purchase cell of Director General Health Services, Punjab at the address mentioned below

Applications for prequalification should be submitted in sealed envelope, to the office of Purchase cell of DGHS on or before 05-04-2019 (Friday) till 10:00 A.M positively and be clearly marked “Prequalification of Pharmaceutical Manufacturing Units & Sole Agents of Foreign Principles for Hepatitis Medicine.” The applications received till the stipulated date & time shall be opened publically on the same day at 10:30 A.M in the presence of the applicants or their authorized representatives who choose to attend.

Technical and Financial Proposals will be called from the Prequalified Firms later on. Provision of false, fabricated or materially incorrect information if found at any stage will lead to disqualification of the applicant under Rule 19 of Punjab Procurement Rules 2014 (Amended).

All applications should be submitted in Tape Binding. All documents should contain proper page marking, attached in sequence as indicated in Prequalification Documents and signatures of authorized person. Moreover, signing and stamping of each page of Prequalification documents/form is mandatory.

In case the date of opening is declared as a public holiday by the government 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:

1) The process shall be governed by the Punjab Procurement Rules, 2014 (Amended).

Provincial Hepatitis Control Program Punjab,
Directorate General Health Services
Government of Punjab
24-Cooper Road, Lahore, Pakistan
Phone: +92-42-99201145
Contents

Section I: Instructions to Applicants (ITA) ................................................................................. 5

A. General ........................................................................................................................................ 5

   1. Scope of Application .................................................................................................................. 5
   2. Fraud and Corruption ................................................................................................................ 5
   3. Eligible Applicants ...................................................................................................................... 6

B. Contents of the Prequalification Document ............................................................................. 6

   4. Sections of Prequalification Document .................................................................................... 6
   5. Clarification of Prequalification Document ................................................................................ 6
   6. Amendment of Prequalification Document ................................................................................ 7

C. Preparation of Applications ......................................................................................................... 7

   7. Cost of Applications ................................................................................................................... 7
   8. Language of Application ............................................................................................................ 7
   9. Documents Comprising the Application (Hard Copy) ................................................................ 7
  10. Application Submission Form (Online) ...................................................................................... 8
  11. Applicant Submission ............................................................................................................... 11
  12. Documents Establishing the Qualifications of the Applicant .................................................... 12
  13. Signing of the Application ........................................................................................................ 12

D. Submission of Applications .......................................................................................................... 12

   14. Sealing and Identification of Applications ............................................................................... 12
   15. Deadline for Submission of Applications .............................................................................. 12
   16. Late Applications ...................................................................................................................... 12
   17. Opening of Applications .......................................................................................................... 12

E. Procedures for Evaluation of Applications .................................................................................. 12

   18. Confidentiality ......................................................................................................................... 12
   19. Clarification of Applications .................................................................................................... 13
   20. Responsiveness of Applications .............................................................................................. 13

F. Evaluation of Applications and Prequalification of Applicants ................................................ 13

   22. Evaluation of Applications ..................................................................................................... 13
23. Right to Accept or Reject Applications.......................................................... 13
24. Prequalification of Applicants........................................................................ 13
25. Notification of Prequalification ..................................................................... 13
26. Validity of Prequalification ............................................................................ 13

Section II: Prequalification Criteria Drugs /Medicines 14

Section II(A): ........................................................................................................ 14-15
Section II(B): ........................................................................................................ 16-17
Section II(C): ........................................................................................................ 18-19
Section II(Annex-A): Drugs/Medicines (Local manufacturers) ...................... 20
Section II(Annex-B): Drugs/Medicines (Sole Agents)......................................... 21

Section III: ........................................................................................................... 35-36

Section III(A): Application Submission Form......................................................... 36
Section III(B): Application Affidavit....................................................................... 37

Section IV: ........................................................................................................... 38-56

Section IV(Annex-1): ........................................................................................... 38
Section IV(Annex-2): ........................................................................................... 39
Section IV(Annex-3): ........................................................................................... 40-56

**************************************************
## A. General

### 1. Scope of Application

1.1 In connection with the Invitation for Prequalification “as per PPR 2014” the PHCP Director General Health Service, Government of the Punjab issues this Prequalification Document (PQD) to applicants interested to prequalify Pharmaceutical Manufacturing Units & Sole Agents of Foreign Principals for Drugs/Medicines against the list of items/sections contained in the Prequalification Documents. Prequalification will be carried only for the items contained in this document.

### 2. Fraud and Corruption

2.1 Government of the PHCP Director General Health Service 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) Government of the Punjab, PHCP 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...
3. Eligible Applicants

3.1 An Applicant can be a private or public entity.

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
   - Section IV: Annexures.

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

4.3 The PHCP Director General Health Service accepts no responsibility for the completeness of the prequalification documents and its addenda unless the original receipt of the 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 PHCP Director General Health Service in writing at the address indicated in the Invitation for Pre-Qualification of Drugs/Medicines / . The Director General Health Service will respond in writing to any request for clarification provided that such request is received no later than fifteen (03) days prior to the deadline for submission of applications. The PHCP Director General Health Service 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. If the PHCP Director General Health Service 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.
6. Amendment of Prequalification Document

6.1 At any time prior to the deadline for submission of applications, the PHCP Director General Health Service may amend the Prequalification Documents by issuing addenda.

6.2 Any addendum/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 PHCP Director general health Service, Government of the Punjab. The minutes shall also be uploaded on the official website of Director General Health Service.

6.3 To give prospective Applicants reasonable time to take an addendum into account in preparing their applications, the PHCP Director General Health Service 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. PHCP Director General Health Service will in no case be responsible or liable for those costs, regardless of the conduct or outcome of the prequalification process.

8. Language of Application

8.1 The application as well as all correspondence and documents relating to the prequalification exchanged by the Applicant and PHCP Director General Health Service, 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

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 and submitted in hard copy.

10. Application Submission Form

10.1 The Applicant shall prepare an Application Submission Sheet using the form provided in Section III, Application Forms. This Form must be completed without any alteration to its format.
### 11. Documents Establishing the Qualifications of the Applicant

11.1 To establish its eligibility in accordance with ITA, the Applicant shall complete the eligibility declarations in the Application.

### 12. Signing of the Application

12.1 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, PHCP Director General Health Service 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 PHCP Director General Health Service at the address and no later than the deadline indicated in the Invitation for Prequalification.

15.2 The PHCP Director General Health Service 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 PHCP Director General Health Service 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 PHCP Director General Health Service 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 PHCP Director General Health Service 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 Health Service 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 PHCP Director General Health Service 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 PHCP Director General Health Service 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 Drugs/Medicines & which the Applicant meets the appropriate requirements of this prequalification document. The information provided in response to the invitation for prequalification shall be evaluated as per Prequalification Documents and May also be physically verified by the DGHS.

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 PHCP Director General Health Service 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 the PHCP Director General Health Services.

#### 25. Notification of prequalification

25.1 Once the Director General Health Service has completed the evaluation of the applications it shall notify all Applicants in writing 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 to 30th June 2019 extendable to next financial year.
**Section II (A): PREQUALIFICATION CRITERIA (Drug Items)**

**FOR LOCAL MANUFACTURERS**

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

<table>
<thead>
<tr>
<th>Sr. No.</th>
<th>Knock Down Clause</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>The firm provide/attach valid Drugs Manufacturing License issued by DRAP.</td>
</tr>
<tr>
<td>2</td>
<td>The firm provide/attach all valid Drugs Registration Certificates issued by DRAP against all quoted items.</td>
</tr>
<tr>
<td>3</td>
<td>The Annual Sales turnover of the firm for the period 1st July 2017 to 30 June 2018. The bidder shall provide Income Tax Returns issued by FBR and/or Audited balance sheet.</td>
</tr>
<tr>
<td>4</td>
<td>The firm undertakes that currently it is not blacklisted/debarred by any procuring agency.</td>
</tr>
</tbody>
</table>
| 5       | The firm undertakes that it has provided/attached valid GMP Certificate issued by DRAP.  
(Only those Sections & Pharmaceutical Category will be considered for prequalification whose GMP Inspection Report declared satisfactory and/or which are mentioned in the GMP Certificate) |
| 6       | The firm undertakes that it has provided valid ISO/Quality Management System/another International Certificate of the manufacturer  
(Valid ISO 9001:2008 & Certificate/Quality Management System/Other International certificate of the manufacturer (e.g., WHO/ UNFPA/ UNICEF/ WFP/ US FDA Prequalification/Approval & ISO 14001 and ISO 18001 etc.) |
| 7       | The firm undertakes on 100 rupees judicial stamp paper duly notarized legalized that the equipment’s installed in quality control, quality assurance & microbiological laboratories and of relevant section are functional calibrated & validated. Procuring agency may physically verify the claim (In case of non-compliance none of the section(s) of the firm will be prequalified. Furthermore, in case if any equipment found deficient to perform official tests of the product (quoted) or equipment is missing, none of specific section/item of the firm will be prequalified) |
| 8       | The firm undertakes on 100 rupees judicial stamp paper duly notarized legalized that Facility having functional Heating, Ventilation & Air Conditioning System (HVAC). Procuring agency may physically verify the claim |
| 9       | The firm undertakes on 100 rupees judicial stamp paper duly notarized legalized that it has R.O Water/De-ionized water Plant with the minimum capacity of 500L available and functional. Procuring agency may physically verify the claim |
| 10      | The firm undertakes on 100 rupees judicial stamp paper duly notarized legalized that the firm has minimum two functional stability chambers. Procuring agency may physically verify the claim |
| 11      | The firm undertakes on 100 rupees judicial stamp paper duly notarized legalized that Information provided by the firm at Annexure-A,C& E or any other information provided by the firm in accordance with terms & conditions of the prequalification documents |
2-KNOCK DOWN CRITERIA (Quoted Product/Item Wise)-Drug Items

<table>
<thead>
<tr>
<th>Sr. No.</th>
<th>Knock Down Clause</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>The firm must provide Valid Drugs Sale License issued by Competent Authority for Sole Agents of Foreign Principal.</td>
</tr>
<tr>
<td>2</td>
<td>The firm must provide/attached all valid Drugs Registration Certificates issued by DRAP against all quoted items.</td>
</tr>
<tr>
<td>3</td>
<td>The firm must provide/attach Valid Sole Agency Agreement.</td>
</tr>
<tr>
<td>4</td>
<td>The firm undertakes that currently it is not blacklisted/debarred by any procuring agency.</td>
</tr>
</tbody>
</table>
5. The firm undertakes that it has provided/attached valid GMP Certificate issued by Drug Regulatory Authority of Country of Manufacturer (notarized translation) or COPP (certificate of Pharmaceutical Product).

6. The Sole agent undertakes on 100 rupees judicial stamp paper duly notarized legalized that that he has warehouse and storage facility as per required temperature as per Drug Rules and follows Good Distribution and Storage Practices.

7. The firm undertakes that the Information provided by the firm at Annexure-B,D & E and any other information provided by the firm in accordance with terms & conditions of the prequalification documents.

---

**2-KNOCK DOWN CRITERIA (Quoted Product/Item Wise)-Sole Agents-Drug Items**

1. Drug Registration Number (DRN).
2. Firm maintains Required storage temperature as per quoted product’s requirement Firm undertakes on 100 rupees judicial stamp paper duly notarized legalized.
3. No item of the firm should be declared Spurious samples firm undertakes on 100 rupees judicial stamp paper duly notarized legalized.
4. Samples Substandard (Not more than 2 samples) from (01-01-2017 onwards). Firm undertakes on 100 rupees judicial stamp paper duly notarized legalized.
5. Substandard Batch Recall History from (01-01-2017 onwards) if any
6. No Punitive Action should be Taken by DRAP against firm. Firm undertakes on 100 rupees judicial stamp paper duly notarized legalized if any
7. No Punitive Action should be Taken by PQCB against firm. Firm undertakes on 100 rupees judicial stamp paper duly notarized legalized.
8. Firm should not Convicted by Drug Court(s) firm undertakes on 100 rupees judicial stamp paper duly notarized legalized
9. Valid Sole agency agreement.

To establish its qualification, the firm shall provide the information requested in the respective annexures and requirements with documentary proof.

Note: The firm will be prequalified for the particular item/brand.
Annex-“A”

GENERAL FIRM’S INFORMATION

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 medicine 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>
<td></td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td></td>
<td></td>
<td></td>
</tr>
</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>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

III. QUALITY DEPARTMENT

1. Do you maintain your own quality control laboratory? If NO please provide details alternate arrangements.
   [ ] YES [ ] NO

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. Indicate if you perform quality tests conducted routinely:

   [ ] Active starting materials
   [ ] non-active starting materials
   [ ] packaging materials
   [ ] intermediate products
   [ ] bulk products
   [ ] finished products

10. Explain process of approving sources for starting materials and describe basis for approving specifications of starting materials.

    __________________________________________________________
    __________________________________________________________

11. Do you conduct tests on each container of the active starting material?

    [ ] YES  [ ] NO

    If not, explain your way of sampling:

    ___________________________________________________________
    ___________________________________________________________

12. Do you test each container of non-active starting materials?

    [ ] YES  [ ] NO

    If “No,” describe method of sampling:

    __________________________________________________________
    __________________________________________________________
13. Are stability tests routinely conducted for every product?

[ ] YES  [ ] NO

If not, state reason why not:
_______________________________________________________________________________________
_______________________________________________________________________________________

14. Do you keep samples of each batch?

[ ] YES  [ ] NO

Indicate how long do you keep the samples:__________ years

15. Describe your storage facilities:
_______________________________________________________________________________________
_______________________________________________________________________________________
_______________________________________________________________________________________
Annexure-"B"

Authorized Sole agent for Foreign Principal's Qualification

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):
                      : ________________________________
   Drugs Sale License Number : ________________________________
   (attach valid copy)
   Valid sole agency agreement
   (attach valid copy)
   2. Address : ________________________________
   Telephone : ________________________________ Telephone: ________________________________
   E-mail : ________________________________

   Please attach the company organizational chart
   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)
*Indicate % of annual turnover:

1. Pharmaceutical formulations : ________%
2. Bulk drugs : ________%
3. Medical Supplies : ________%

[ ] Products sold to Public Sector
[ ] Market Sale
[ ] Both

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>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

5. 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><strong>Total</strong></td>
<td></td>
</tr>
</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>
<th>(In Million)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
“Annex-C”

**NAME OF APPLICANT FIRM (Local Manufacturer) ____________________________**

| Item Code | Generic Name | Section | Quote Brand | D/ Form | Volume (ml) | Quote Strength | Pac Size | Mfg By | Mfg for | MRP fixed by DRAP | Drug Reg No | Drug Reg Date | Mfg Capacity/d | Storage 
|-----------|--------------|---------|-------------|---------|-------------|---------------|---------|-------|--------|----------------|-------------|---------------|---------------|---------
| 1         |              |         |             |         |             |               |         |       |        |                |             |               |               |         |
| 2         |              |         |             |         |             |               |         |       |        |                |             |               |               |         |
### “Annex-D”

**NAME OF APPLICANT FIRM (Sole Agent)-DRUGS**

| Item Code | Generic Name | Section | Quoted Brand | D/ Form | Volume (ml) | Quoted strength | pack Size | Country of Origin | Mfg By | Mfg for | MRP fixed by DRA/ P | Drug Reg. No | Drug Reg. Date | Quality Compliance Standards | Requir ed Storage tempt (quote d item) | Spurious sample | DTL Substandard (Not more than two sample s) From(01-01-2017) | Substandard Batch Recall History (01-01-2017) | Puniti ve Action by DRAP | Puniti ve Action by PQCB | Convi cted by Drug Court | Valid Sole Agenc y Agreement | Verifie d/Not Verifie d (Valid sole agenc y Autho rizatio n) |
|-----------|--------------|---------|--------------|---------|-------------|----------------|----------|------------------|--------|---------|---------------------|------------|--------------|-----------------------------|--------------------------------|----------------|------------------------------------------------|--------------------------------|-------------------|-------------------|----------------|----------------|------------------|----------------|
| 1         |              |         |              |         |             |                 |          |                  |        |         |                     |            |              |                             |                                |                |                                                              |                                |                   |                   |                |                  |                  |
| 2         |              |         |              |         |             |                 |          |                  |        |         |                     |            |              |                             |                                |                |                                                              |                                |                   |                   |                |                  |                  |
### Annexure-E

#### Pre-Qualification (Drugs/Medicines / Formulary (2018-2019))

<table>
<thead>
<tr>
<th>ITEM CODE</th>
<th>GENERIC NAME</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Sofosbuvir 400 mg Capsule/Tablet</td>
</tr>
<tr>
<td>2</td>
<td>Declatsavir 60 mg Tablets /Capsule</td>
</tr>
<tr>
<td>3</td>
<td>Declatsavir (60 mg Tablets /Capsule) + Sofosbuvir (400 mg Capsule/Tablet) (Combo Packs)</td>
</tr>
</tbody>
</table>
Section III (A): Application Forms

Application Submission Form

Date: __/__/2019

To

THE PHCP DIRECTOR GENERAL HEALTH SERVICES
Government of 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
Section III (B)

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 described in the documents.

b) Applicants confirming not having been involved in any litigation during last three years.

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