DATED: 11.07.2022

TECHNICAL EVALUATION REPORT

NAME OF THE MEDICINE: TENOFOVIR 300 MG	
(A) BID / RFP TECHNICAL EVALUATION CRITERIA FOR DRUGS/MEDICINES (FOR LOCAL MANUFACTURER)	
COMPULSORY PARAMETERS	**NAME OF THE FIRMS**
	M/s Getz Pharma
Quoted Brand Name:	**Tenofo-B 300 mg**
MRP (PKR)	**3450**
DRUG REGISTRATION NUMBER (DRN)	**057803**
DRUG MANUFACTURING LICENSE NUMBER (DML)	**000284**
SHELF LIFE	**24 Months**
Bid Security Submitted	**Yes**
i. Original Tender Purchase Receipt obtained by Depositing Rs. 5000/- (Non- Refundable) to Cashier, Accounts Branch, against whole set of RFP/bidding documents at the office of PM PHCP, DGHS.	Yes
ii. Eligibility of Bidder as per Letter of invitation and Section II Clause 3.	Yes
iii. The bidder must be prequalified with Directorate General Health Services, Punjab. (In case of open tender this clause is not applicable).	Yes
iv. The bidder must possess valid Drug Manufacturing License issued by DRAP (in case of manufacturers) and valid Drug sale License (in case of sole agents).	Yes
v. The bidder will provide valid Drug Registration Certificate on the name of bidder of the quoted product (DRC must have quoted pack size). The product having less than one-year experience will be ineligible.	Yes
vi. The bidder must possess valid Good Manufacturing Certificate (GMP) issued by DRAP.	Yes
vii. Specifications quoted in the technical offer will be verified from samples provided with the bid. Product that complies 100% with the required specifications and fulfill the requirements as per rules shall be considered.	Yes

viii. The bidder must submit bio similarity studies data of quoted item (for biologicals and biotech products). The biosimilar study must be from DRAP notified labs or WHO/JPMHLW/EMA/US FDA approved/accredited labs only OR quoted product must have status of reference product for biosimilar studies on USA FDA/EMA official websites.	N/A
ix. Undertaking regarding "Non-Declaration of any Spurious/Adulterated Batch manufactured by firm by DTLs of the Punjab/any Competent Lab" on valid Rs.100 stamp paper duly verified by notary public.	Yes
x. The firm undertakes that currently it is not Blacklisted/Debarred by any procuring agency on valid Rs.100 stamp paper duly verified by notary public.	Yes
xi. The firm will undertake on notarized stamp paper of Rs.100 that the firm will be bound to provide stocks in reefer container(s) (maintaining controlled temperature as per item specs) for delivery of goods to the procuring agencies. Physical assurance will be pre-requisite at the time of delivery of goods.	Yes
xii. Four packs of samples for evaluation by the technical committee. (Samples must be of commercial pack).	Yes
STATUS	**ELIGIBLE**

TECHNICAL EVALUATION REPORT (PART-II)

NAME OF THE MEDICINE: TENOFOVIR 300 MG

(A) BID / RFP TECHNICAL EVALUATION CRITERIA FOR DRUGS/MEDICINES (FOR LOCAL MANUFACTURER)

ORDINARY PARAMETERS			NAME OF THE FIRMS
SR #	**DESCRIPTION**	**CATEGORY POINTS**	**M/s Getz Pharma**
1	**SOURCE OF API OF QUOTED ITEM**	**Max 20**	**15**
	Source Licensed by Original or accredited by FDA/WHO/EMA	20	
	(Certificate).		
	Firm should provide import documents (Bill of Lading/Airway Bill/GD documents etc.) of quoted source from **1st January 2020 till 30th June 2021**		
	Other source of API with certificate of analysis	15	15
	Furthermore, bidder will undertake on Rs.100/- notarized stamp paper that it will provide supply manufactured from claimed source.		
2	**EXPERIENCE OF THE QUOTED PRODUCT (SINCE Ist January 2021 till 30th June 2022)**	**Max 05**	**3**

	Supply of the quoted product Equivalent or Higher than the advertised quantity in Private Sector.	5	
	Supply of the quoted product at least 70% or above of total of advertised quantity in Private Sector.	4	
	Supply of the quoted product at least 50% to below 70% of advertised quantity in Private Sector.	3	3
	Supply of the quoted product at least 25% to below 50% of advertised quantity in Private Sector.	2	
	The bidder shall provide (attach) summary of market/private sale. (This summary must be on stamp paper of Rs.100 duly legalized/notarized which may be verified. Any false claim lead to disqualification/blacklisting of firm)		
3	**EXPERIENCE OF THE QUOTED PRODUCT (SINCE Ist January 2021 till 30th June 2022)**	**Max 05**	**4**
	Supply of the quoted product Equivalent or higher than advertised quantity in Public sector.	5	
	Supply of the quoted product at least 70% or above of total of advertised quantity in Public Sector.	4	4
	Supply of the quoted product at least 50% to below 70% of advertised quantity in Public Sector.	3	
	Supply of the quoted product at least 25% to below 50% of advertised quantity in Public Sector.	2	
	The bidder shall provide (attach) summary of purchase orders of institutional sale along with delivery challan (DC)of subsequent Purchase Orders. (This summary must be on stamp paper of Rs.100 duly legalized/notarized along with Purchase Orders (from Ist January 2020 till 30th June 2021) & relevant DC. The Purchase Orders /DC may be verified, and any false claim shall lead to disqualification/blacklisting of firm. Purchase order along with relevant delivery Challan of the respective government institution will be considered only (alone purchase order will not be considered.)		
4	**CREDIBILITY & CERTIFICATION OF MANUFACTURER**	**Max 15**	**9**
I.	Valid ISO 17025 Certification for competence of Testing and Calibration of Labs.	3	0
II.	Valid ISO 14001 (certificate)	3	3
III.	Valid International reputed certification (WHO/UNICEF/JPMHLW/UNFPA/WFP/US-FDA/ PICS)	3	0
IV.	Waste Water Treatment Plant (attach copy of layout plan and SOPs)	3	3
V.	Registration of firm with IQVIA Solutions (formerly IMS) for each quoted item.	3	3
5	**QUALITY OF PRODUCT**	**Max 10**	**10**
	If samples of quoted product declared sub-standard by DTL are less than 1% during last Financial Year.	10	10
	If samples of quoted product declared sub-standard by DTL are 1-2% during last Financial Year.	7	
	If samples of quoted product declared sub-standard by DTL are 2-3% during last Financial Year.	5	
The *bidder will provide undertaking on Rs.100/- notarized stamp paper. Data of substandard batches may be verified from Drug Testing Laboratories.*			
6	**NUMBER OF FUNCTIONAL STABILITY CHAMBER**	**Max 6**	**6**
	No. of functional stability chamber 2-3 or	2	

	No. of functional stability chamber 4-6 or	4	
	No. of functional stability chamber 7 or above	6	6
The firm must submit undertaking on notarized stamp paper of worth Rs.100/- . The Firm will also submit valid calibration/validation report.			
7	**STABILITY STUDIES**	**Max 02**	**2**
	Accelerated Stability Study data of quoted item	1	1
	Real Time Stability Study data of quoted item (Jan 2019 to onward)	1	1
8	**Primary Reference Standard with Valid Shelf Life used for Quality Control Testing/Analysis of Quoted Item**	**Max 02**	**0**
	(The firm shall submit Import/Shipping Documents/Import trail and Certificate of Analysis (COA).		0
9	**TECHNICAL STAFF OF MANUFACTURING UNIT**	**Max 05**	**5**
	Total Number of pharmacist (Minimum number of employed pharmacists must be 10)	5	5
	The bidder shall provide the attested copies of degrees & appointment issued by firm to employees.		
MARKS OBTAINED (QUALIFING MARKS 42 OUT OF 70 (60%)		**Max 70**	**54**
STATUS OF THE FIRM			**RESPONSIVE**

Note: Any Bidder Aggrieved by the decision of Technical Evaluation Committee may submit a written grievance in the Office of Program Manager, Hepatitis Control Program Punjab, till 20th November, 2022 05:00 P.M.