File No.GEM/TP/HCV ELISA Test Kits /2019 (Version 3.0)										DRAFT T/P	
Level 1 Category : Laboratory and Measuring and Observing and Testing Equipment - UNSPS Code 41000000											
Level 2 Category : Measuring and Observing and Testing Instruments - UNSPS Code 41110000											
Level 3 Category : Manual Test Kits and Quality Controls and Calibrators and Standards - UNSPS Code 41116100											
Level 4 Category : HCV ELISA Test Kits - UNSPS Code 41116197										GEM Version 3.0	
S.NO	PARAMETER	HINT	TYPE OF FIELD	VALUES					UNIT	CATEGORY OF FIELD	REMARKS
GENERAL FEATURES											
1	Product Description	--	ENUMERABLE	HCV ELISA Test Kit					--	MANDATORY	
2	Clinical Purpose	--	ENUMERABLE	To provide diagnosis of Hepatitis C virus infection					--	MANDATORY	
PRODUCT INFORMATION											
1	Type of Kit	--	ENUMERABLE	3 rd generation	4 th generation				--	MANDATORY, FILTER	
2	Detects	--	ENUMERABLE	Antibodies specific to Hepatitis C Virus					--	MANDATORY	
3	Detection Type	--	ENUMERABLE	Qualitative	Quantitative				--	MANDATORY, FILTER	
4	Microplate ELISA Coated with recombinant and/or synthetic peptide antigens for core NS3, NS4 and NS5	--	ENUMERABLE	Yes					--	MANDATORY	
5	Test can be performed on	--	ENUMERABLE	Whole Blood	Serum	Plasma			--	MANDATORY, FILTER	Multi Select
6	Assay Procedure Time (minutes)	--	ENUMERABLE	90	120				min	MANDATORY, FILTER	
7	The Assay should have sensitivity of ≥ 99 % and specificity of ≥ 98%	--	ENUMERABLE	Yes						MANDATORY	
8	The assay component should include reactive and non reactive control with each kit	--	ENUMERABLE	Yes					--	MANDATORY	
9	Storage temperature	--	ENUMERABLE	2^0C to 8^0C					--	MANDATORY	
10	The supplier should ensure maintenance of cold chain during storage and transportation of Kits at 2°C to 8°C.	--	ENUMERABLE	Yes					--	MANDATORY	
11	Cold Chain indicator provided with the kits	--	ENUMERABLE	Yes					--	MANDATORY	
12	A cumulative time/temperature indicator should indicate the exposure to temperature in the range of 2°C to 8°C								--	MANDATORY	
13	The cumulative time temperature indicator technology used should be pre qualified by WHO	--	ENUMERABLE	Yes					--	MANDATORY	
14	Adequate documents in english detailing the principle, components, methodologies, validity criteria, performance characteristics,bio-safety, limitations of assay, storage condition, manufacturing and expiry dates and methods of disposal provided with each kit	--	ENUMERABLE	Yes					--	MANDATORY	
15	The assay component should include reactive and non reactive control with each kit	--	ENUMERABLE	Yes					--	MANDATORY	
16	The Kit Should be compatible to both semi automated and fully automated Elisa analyzers.	--	ENUMERABLE	Yes					--	MANDATORY	
17	The volume of all the chemicals used should be adequate enough for automated Elisa analyze	--	ENUMERABLE	Yes					--	MANDATORY	
18	The volume should cover the dead volume for automated ELISA system	--	ENUMERABLE	Yes					--	MANDATORY	

19	The kit should comply with all provisions of Drugs and cosmentics Act, 1940 and applicable rules there under	--	ENUMERABLE	Yes					--	MANDATORY	
PACKAGING											
1	Pack Size	--	ENUMERABLE	48 tests / kit	96 tests / kit				--	GOLDEN	
2	The packing and labelling should be as per Drugs and Cosmetics Act, 1940 and applicable rules there under	--	ENUMERABLE	Yes					--	MANDATORY	
CERTIFICATIONS & REPORTS											
1	The kit should have approval of the statutory authority in its country of origin	--	ENUMERABLE	Yes					--	MANDATORY	
2	The Kit should be registered and licensed in India by DCGI in case of imported kits (Proof of the same to be submitted to buyer on demand)	--	ENUMERABLE	Yes	NA for domestically manufactured kits				--	MANDATORY	
3	Indigenous manufacturers should be licensed by the competent authority defined under Drugs and Cosmetics act 1940	--	ENUMERABLE	Yes	NA for imported kits				--	MANDATORY	
4	Availability of valid drug license from competent authority defined under Drugs and Cosmetics Act, 1940 (Proof of the same to be submitted to buyer on demand)	--	ENUMERABLE	For Manufacture to sale	For sale or distribution				--	MANDATORY, FILTER	Multi Select
5	Drug License Number	Must Declare	TEXT						--	MANDATORY	AKBNV
6	Drug License Date	Must Declare	TEXT						--	MANDATORY	AKBNV
7	Manufacturer certifications (Proof of the same to be submitted to the buyer on demand)	--	ENUMERABLE	GMP	WHO GMP				--	MANDATORY, FILTER	Multi Select
8	GMP/ WHO GMP Certification Number	Must Declare	TEXT						--	MANDATORY	AKBNV
9	GMP/ WHO GMP Certification Date	Must Declare	TEXT						--	MANDATORY	AKBNV
10	ISO 13485 Certified Manufacturer (Proof of the same to be submitted to buyer on demand)	--	ENUMERABLE	Yes					--	MANDATORY	
11	Product Certifications (Proof of the same to be submitted to buyer on demand)	--	ENUMERABLE	EU-CE (IVD)	US-FDA				--	MANDATORY, FILTER	Multi Select
12	Four digit number of notified body If product is EU-CE certified	Write '0' if not applicable	NUMERIC						--	MANDATORY	AKBNV
13	Certificatiion Number	Must Declare	TEXT						--	MANDATORY	AKBNV
14	Certificatiion Date	Must Declare	TEXT						--	MANDATORY	AKBNV
15	Certification Issuing Authority	Must Declare	TEXT						--	MANDATORY	AKBNV
16	Availability of Test report from Central GOVT/NABL/ILAC accredited Lab to prove the conformity to the declared specification(proof of the same to be submitted to the buyer on demand)	--	ENUMERABLE	Yes					--	MANDATORY	
17	Availability of Performance Evaluation Report (Proof of the same to be submitted to the buyer on demand)	--	ENUMERABLE	Yes					--	MANDATORY	
18	Performance Evaluation Report issuing body	--	ENUMERABLE	National Insitute of Biological Sciences	Other					MANDATORY, FILTER	
19	Name of the Performance Evaluation Report issuing body if other than specified institute	Must Declare	TEXT						--	MANDATORY	AKBNV
SHELF LIFE											
1	Shelf Life from the date of manufacture (in months)	--	NUMERIC	12	18	24	30	36	Months	GOLDEN	
2	The product should have atleast 3/4 of the total shelf life at the time of dispatch to the consignee	--	ENUMERABLE	Yes					--	MANDATORY	

(A. KESAVA RAO)
AD, GEM-SPV

(MANJU SHARMA)
DY.CEO

ACEO