

File No.GEM/TP/ Anti-D Grouping Sera/2019 (Version 3.0)									DRAFT T/P		
LEVEL 1 CATEGORY: Laboratory and Measuring and Observing and Testing Equipment - UNSPS Code 41000000											
LEVEL 2 CATEGORY: Serological and specimen preparation test systems, components and supplies - UNSPS Code 41200000											
LEVEL 3 CATEGORY : Blood Grouping Reagents - UNSPS Code 41209900											
Level 4 Category : Anti-D Grouping Sera - UNSPS Code 41209904									GEM Version 3.0		
S.NO	PARAMETER	HINT	TYPE OF FIELD	VALUES					UNIT	CATEGORY OF FIELD	REMARKS
GENERAL FEATURES											
1	Type of Blood Grouping Sera/Reagent	--	ENUMERABLE	Anti-D Grouping Sera IgM	Anti-D Grouping Sera IgG	Anti-D Grouping Sera (IgM + IgG)			--	GOLDEN	
2	Clinical Purpose	--	ENUMERABLE	For Rh Blood Typing					--	MANDATORY	
3	Antibody Type	--	ENUMERABLE	Monoclonal					--	MANDATORY	
4	Suitable for	--	ENUMERABLE	Tube Method	Slide Method	Microplate method			--	GOLDEN	Multi Select
5	Anti-D reagent should be capable of detecting all weak and partial D	--	ENUMERABLE	Yes					--	MANDATORY	
6	Titre should be $\geq 1:32$ with D positive cell in immediate spin and $\geq 1:128$ after 30-40 minutes incubation	--	ENUMERABLE	Yes					--	MANDATORY	
7	Ready to use reagent containing antibodies specific to the 'D' antigen on RBC	--	ENUMERABLE	Yes					--	MANDATORY	
8	Dropper Provided	--	ENUMERABLE	Yes					--	MANDATORY	
9	Reagent should have avidity less than 10 seconds	--	ENUMERABLE	Yes					--	MANDATORY	
10	Should not hemolyze cells or produce rouleux	--	ENUMERABLE	Yes					--	MANDATORY	
11	Storage Temperature	--	ENUMERABLE	2°C to 8°C					--	MANDATORY	
12	It should give easily observable agglutination reaction with antigen positive cells and clear absence of agglutination reaction in antigen negative cells	--	ENUMERABLE	Yes					--	MANDATORY	
13	Reagent should meet the standards approved by USFDA/CDSCO/NIB for blood bank reagents with respect to appearance, color, sensitivity, specificity, avidity, affinity and titer strength	--	ENUMERABLE	Yes					--	MANDATORY	
14	Reagent should meet the standards mentioned in the technical manual for blood banks approved by the MOHFW, GOI	--	ENUMERABLE	Yes					--	MANDATORY	
15	All Provisions of Drugs and Cosmetics Act, 1940 as amended till Date and rules made there under will always be applicable	--	ENUMERABLE	Yes					--	MANDATORY	
PACKAGING AND LABELING											
1	Packing Type	--	ENUMERABLE	Vial					--	MANDATORY	
2	Pack size	--	ENUMERABLE	5 ml	10 ml				--	GOLDEN	

3	Number of Vials in one pack	--	NUMERIC	1-10					--	MANDATORY	
4	Packaging insert provided	--	ENUMERABLE	Yes					--	MANDATORY	
5	Price unit	--	ENUMERABLE	Each Vial					--	MANDATORY	
6	Each vial should be labeled as per provisions given for labeling in Drugs and cosmetics act 1940 and rules made there under	--	ENUMERABLE	Yes					--	MANDATORY	
CERTIFICATIONS & REPORTS											
1	Availability of valid drug license issued from competent authority defined under Drugs and Cosmetics Act, 1940 (copy of the same to be submitted to buyer on demand)	--	ENUMERABLE	For Manufacture	For Sale				--	MANDATORY, FILTER	Multi Select
2	Drug License Number	Must Declare	TEXT						--	MANDATORY	AKBNV
3	Drug License Date	Must Declare	TEXT						--	MANDATORY	AKBNV
4	Manufacturer certifications (copy of the same to be submitted to the buyer on demand)	--	ENUMERABLE	ISO 13485	GMP	WHO GMP			--	MANDATORY, FILTER	Multi Select
5	Certification Number	Must Declare	TEXT						--	MANDATORY	AKBNV
6	Certification Date	Must Declare	TEXT						--	MANDATORY	AKBNV
7	Product Certification (copy of the same to be submitted to buyer on demand if certification is available)	--	ENUMERABLE	EU-CE (IVD)	US-FDA				--	MANDATORY, FILTER	Multi Select
8	Four digit number of notified body If product is EU-CE certified	Write '0' if not applicable	NUMERIC						--	MANDATORY	AKBNV
9	Product Certification Number	Must Declare	TEXT						--	MANDATORY	AKBNV
10	Product Certification Date	Must Declare	TEXT						--	MANDATORY	AKBNV
11	Certificate issuing Authority	Must Declare	TEXT						--	MANDATORY	AKBNV
12	Availability of Test report from Central GOVT/NABL/ILAC accredited Lab to prove the conformity to the declared specifications(copy of the same to be submitted to the buyer on demand)	--	ENUMERABLE	Yes					--	MANDATORY	
13	Evaluated and approved by National Institute of Biologicals (NIB) (copy of the same to be submitted to the buyer on demand)	--	ENUMERABLE	Yes	No				--	MANDATORY, FILTER	
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