

## CERTIFICATE OF ANALYSIS

<b>Generic Name</b>	Human Normal Immunoglobulin for Intravenous use BP	<b>Stage</b>	Finished Product (5%)
		<b>Analysis Started on</b>	10/01/2021
<b>Product Batch No.*</b>	96M222	<b>Analysis Completed on</b>	26/01/2021
<b>Mfg:</b>	JAN 2021	<b>A.R. No.</b>	GF/QP/TP/20/0553
<b>Exp.</b>	FEB 2023	<b>Mfg. Lic No.</b>	1181
<b>Spec. Ref. No.</b>	QC-Spec-IGG FP/01	<b>Page No.</b>	Page 1 of 3

S.No.	Test	Specification	Results	
Description				
1	Appearance	Clear or slightly opalescent and colorless or pale yellow, liquid	Clear, Colorless liquid	
2	pH	4.0 to 7.4 (1% w/v of protein in Normal saline)	4.96	
3	Osmolality	Minimum 240 mOsmol per kg.	376 mOsmol per kg	
Identification				
4	Precipitation	Should show precipitation band onl with anti human Antisera.	Complied	
5	Electrophoresis	The main component of preparation under examination corresponds to the IgG component of normal human serum.	Complies	
Quantity				
6	Total Protein	50.0mg/mL (90%-110% of Label claim i.e. NLT 45.0 mg/mL and NMT 55.0 mg/mL	49.9 mg/mL	
7	Protein composition	NMT 5% of the protein has mobility different from that of the principal band.	2.20 %	
Molecular Size Distribution				
8	Liquid Chromatography	Monomers, Dimer	Monomer: The relative retention to the corresponding peak in the chromatogram obtained with the reference solution is 1 ± 0.02.	Complies
			Dimer: The peak with relative retention time of about 0.85	Complies

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			Corresponding to the principal peak.	
			Sum of peak areas of monomer and dimer should not be less than 90% of total area of the chromatogram.	98.06 %
		Polymers, Aggregates	Sum of peak areas of Polymers and aggregates should not be more than 3% of total area of the chromatogram.	1.94 %
Viral Safety Analysis				
9	HIV I/II Ab	Should be negative for Viral marker test by ELISA method.		Negative
10	HBs Ag			Negative
11	HCV Ab			Negative
Other Tests:				
12	Anticomplementary activity	The consumption of complement is not greater than 50 percent (1 CH50 per milligram of immunoglobulin).		Complies
13	Prekallikrein activator	NMT 35 IU/mL		3.7 IU/mL
14	Antibody to hepatitis B surface antigen	Minimum 0.5 IU per gram of Immunoglobulin.		12.9 IU per gram
15	Immunoglobulin A	NMT 2mg/ml		Complies
16	Estimation of Maltose Content	The amount of Maltose should be NLT 90% and NMT 110% of label claim.		106.0%
		The amount of Maltose should be NLT 90 and		106.0 g/L

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		NMT 110 g/L	
17	Anti-A and Anti-B Haemagglutinins	The 1 to 64 dilutions do not show agglutination	Complies
18	Anti-D antibodies	It complies with the test for anti-D antibodies in human immunoglobulin for intravenous use.	Complies
<b>Microbial Tests</b>			
19	Sterility	No evidence of growth should be observed after 14 days of incubation.	Complies
<b>Safety Test</b>			
20	Pyrogen	Should pass the test for Pyrogen	Complies

**Remarks:** The above batch complies with the pre-established specifications.

Note: \* 96M222 to 5% IVIG with a fill volume of 100mL.

	<b>Analysed by</b>	<b>Approved By</b>	<b>Checked By</b>	<b>Released by</b>
<b>Name</b>	Olga Petrova	Taylor Bush	Margaret McCombes	Patrick Dogget
<b>Designation</b>	Asst. Manager-QP	Asst. Manager-QP	Executive-QA	Asst. Manager-QA
<b>Sign and Date</b>	<i>O. Petrova</i>	<i>Taylor B.</i>	<i>Maggie McCombes</i>	<i>Patrick</i>