

CERTIFICATE OF ANALYSIS

Recombinant Human albumin

Storage: 2 °C to 8°C

Name of Product: RECOMBINANT HUMAN ALBUMIN		Revision No.:	00
Batch No.	FBB300423	Date of Release	09-12-2023
Mfg. Date	11-2023	STP Number	STP003-00
Retest Date	05-2024	Page No.	1 of 1

S. No.	Test	Specification	Results
1	Appearance	Clear, slightly viscous and colorless to yellow amber colour solution practically free from any visible contamination.	Complies
2	Identification: Peptide Mapping	The peptide map chromatographic profiles of the sample solution are similar to those of the standard solution.	Complies
3	pH	6.4 to 7.4.	6.95
4	Assay total Protein by HPLC-GPC	19.0% to 21.0%	20.1%
5	Assay: Albumin content Purity by HPLC-GPC	≥ 99.0%.	>99.0 %
6	Impurities : High Molecular weight proteins	≤ 1.0 %.	0.60 %
7	Host Cell Proteins	≤ 100 ppm/g of protein.	< 100 ppm/g of protein
8	Host Cell DNA	≤ 10 ppm/g of protein.	< 10 ppm/g of protein
9	Bacterial Endotoxin	≤ 0.5 USP Endotoxin Unit/ mL of Recombinant Albumin Human	Complies
10	Sterility Test	Sample should be sterile	Complies

REMARKS: The Product Complies / Does Not Comply as per specification No. SPEC003-00.

	Prepared by	Reviewed by	Approved by
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Department	Quality Assurance	Quality Assurance	Quality Assurance
Designation	Senior Executive	Assistant Manager	Head Quality
Sign & Date	KM 09-12-2023	Sri 09-12-2023	Sri 09-12-2023