

Catalog Number: HZ-3001-GMP

Data Sheet



HumanKine® recombinant human HSA protein- GMP grade

Animal Component-Free Human co

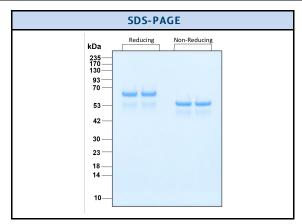
Human cell expressed

Tag-Free

Endotoxin Free

Product Description						
Serum albumin is the most abundant protein in blood plasma and has a vast number of roles including oncotic pressure and detoxification. It has important applications in medicine, including treatment of trauma and blood loss (PMID 7027277, 2574367). The use of bovine serum albumin is quite common but has the disadvantage of being animal origin and quite frequently increases the endotoxin level of the resulting solution. GMP grade Humankine® Recombinant HSA was expressed and purified tag free from HEK293 human cell line without the use of any animal components.						
Alternative Names	ALB, albumin, DKFZp779N1935, GIG42, HSA, PRO0883, PRO0903, PRO1341, PRO1708, PRO2044, PRO2619, PRO2675, Serum albumin, UNQ696/PRO1341					
Accession Number	P02768					
Source	Human Embryonic Kidney cells (HEK293). HEK293-derived HSA protein					
Species Reactivity	human					
Adventitious Virus	Ventitious Virus Master Cell Bank tested Negative for Adventitious Viruses					

Specifications					
Test Method		Specification			
Activity	N/A	N/A			
Molecular Mass	SDS-PAGE	62 kDa reduced, 53 kDa non-reduced, monomer, glycosylated			
Purity	SDS-PAGE	>95%			
Endotoxin	LAL	< 0.1 EU/µg by LAL Method			
Mycoplasma	PCR	Not Detected			



Purity of GMP-grade recombinant human HSA (HZ-3001-GMP) was determined by SDS- polyacrylamide gel electrophoresis. The protein was resolved in an SDS-polyacrylamide gel in reducing and non-reducing conditions and stained using Coomassie blue.

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Preparation				
Shipping Temperature	e ambient temperature			
Formulation	1x PBS, See Certificate of Analysis for details			
Reconstitution	Briefly centrifuge the vial before opening. It is recommended to reconstitute the protein to 0.2 mg/mL in sterile 1x PBS pH 7.4. Gently swirl or tap vial to mix.			

	Product Form	Temperature Conditions	Storage Time (From Date of Receipt)	
	Lyophilized	-20°C to -80°C	Until Expiry Date	
Stability and Storage	Lyophilized	Room Temperature	2 weeks	
_	Reconstituted as per CofA	-20°C to -80°C	6 months	
	Reconstituted as per CofA	4°C	1 week	
	Avoid repeated freeze-thaw cycles.			

Proteintech GMP Quality Policy HumanKine® GMP Proteins

Invitro recombinant protein production can be prone to variability due to various reasons ranging from quality of raw materials to inconsistency in the process. Therefore, HumanKine®, a proteintech brand's GMP proteins are produced and tested under an ISO 13485 certified quality management system in a clean room facility. Proteintech manufactures the GMP HumanKine® products according to the applicable sections in the following documents: USP Chapter 1043 (Ancillary Materials for Cell, Gene, and Tissue-Engineered Products, USP Chapter 92 (Growth Factors and Cytokines Used in Cell Therapy Manufacturing), WHO TRS, No. 822, 1992 Annex 1 (Good Manufacturing Practices for Biological Products), Ph. Eur. General Chapter 5.2.12, and EudraLex – Volume 4 – Part IV (Guidelines on GMP specific to ATMPs). Proteintech strives to achieve the utmost quality GMP raw material ensuring all applicable guidelines are taken into consideration.

The QMS is built to provide our customers with consistent and pure product delivered by documented processes, qualified personnel, validated processes, qualified equipment, qualified vendors, and a stringent final product release process. Although the final product release process is important, Proteintech performs in-process QC steps after each major manufacturing stage. Production records and facilities may be available for an inspection by approved personnel.

Our GMP policy covers all the aspects of production; from raw materials, facility, equipment, and Instruments to training and personal hygiene of staff. It also guarantees that the process is explicit, validated and well documented for transparency and traceability.

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