

Catalog Number: HZ-1011-GMP

Data Sheet

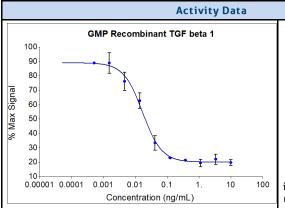


HumanKine® recombinant human TGF beta 1 protein-GMP grade

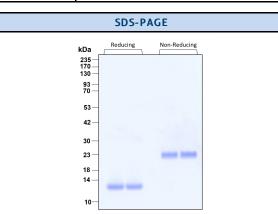
Animal Component-Free Human cell expressed Tag-Free Endotoxin Free
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Product Description					
Alternative Names	CED, DPD1, LAP, TGF?1, TGF beta 1, tgf beta1, TGFB, TGFB1, TGFbeta, tgf-beta1				
Accession Number	P01137				
Source	Human Embryonic Kidney cells (HEK293). HEK293-derived TGF beta 1 protein				
Species Reactivity	human, mouse				
Adventitious Virus	Master Cell Bank tested Negative for Adventitious Viruses				

Specifications					
Test	Method	Specification			
Activity	Dose-dependent inhibition of IL-4 induced proliferation of mouse HT-2 cells (BALB/c spleen activated by sheep erythrocytes in the presence of IL-2)	0.01-0.17 ng/mL			
Molecular Mass	SDS-PAGE	13 kDa reduced, 25 kDa non-reduced, homodimer, non-glycosylated			
Purity	SDS-PAGE	>95%			
Endotoxin	LAL	<0.1 EU/ug			
Mycoplasma	PCR	Not Detected			



Recombinant human GMP
TGF beta 1 (HZ-1011-GMP)
inhibits IL-4 induced
proliferation of the HT-2
mouse cell line. HT-2 cells
are Balb/c spleen cells
activated by sheep
erythrocytes in the
presence of IL-2. Cell
number was quantitatively
assessed by PrestoBlue®
cell viability reagent. HT-2
cells were treated with
increasing concentrations of
recombinant GMP TGF beta 1



Purity of GMP recombinant TGF beta 1 was determined by SDS-polyacrylamide gel electrophoresis. The protein was resolved in an SDS-polyacrylamide gel in reducing and non-reducing conditions followed by staining with Comassie blue.

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Document #: FR-QA118-101 Rev 0 Data Sheet Version #: Proteintech Group, Inc.

5500 Pearl Street, Suite 400 Rosemont, IL 60612 t: 1-888-478-4522; f: 1-312-455-8408 Email: proteintech@ptglab.com

Preparation				
Shipping Temperature ambient temperature				
Formulation	Formulation 50 mM NaOAc pH 3.7, 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 4 mM HCl containing 0.1% endotoxin-free recombinant human serum albumin (HSA). Gently swirl or tap vial to mix.			

Stability and Storage	Product Form	Temperature Conditions	Storage Time (From Date of Receipt)	
	Lyophilized	-20°C to -80°C	Until Expiry Date	
	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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