Viral Therapeutics, Inc.

Certificate of Analysis

Reason for Submission: ☐ Release ☐ Corrected ☐ Amendment

LOT NUMBER:

PRODUCT NAME: Recombinant Creatine Kinase MB Isoenzyme Type II

DESCRIPTION: Recombinant full length Creatine Kinase MB Isoenzyme with amino acid sequence identical to native enzyme **produced in *Pichia pastoris***. Purified in the enzymatically active form. Reacts with monoclonal antibodies specific to MB Isoenzyme in ELISA.

STORAGE: Supplied frozen and should be stored at –70ºC or below. Aliquots should be dispensed to avoid multiple freeze thaws.

PACKAGING: Supplied in cryovials or other suitable container. Vials are filled to contain the exact amount of protein stated on the label. Losses will occur when aliquoting.

DATE OF MFG:

EXPIRY DATE: Greater than one year form date of receipt

I. BULK PRODUCT ANALYSIS

	Attribute	Specification	Result
1.	**Physical Characteristics**		
1.1	Appearance	Colorless clear to slightly hazy solution	
1.2	Formulation	50 v/v% Glycerol, 10 mM Tris-HCl, 0.5 mM DTT, 0.5 mM EDTA	
1.3	pH	6.8 ± 0.5	

	Attribute	Specification	Result
2	**Identity / Purity**		
2.1	Molecular Weight by SDS-PAGE	CKMB2 doublet band migrating about 47 kDa not resolved on most gels. Multiple impurity bands between 3 and 47 kDa visible with 2.5 ug loads not visible with 0.25 ug loads. 2 minor impurity bands at ~40-45 kDa visible with 0.25 ug loads. Comparable to reference lot.	
3	**Potency**		
3.1	Protein Concentration by Pierce BCA	1 – 5 mg/ml ± 20%	
3.2	Enzymatic Activity Sigma Diagnositics Creatine phospho-kinase (CPK) procedure No. 45-UV 1 IU = 1 micromole creatine phosphate formed per minute	Greater than or equal to 500 IU/mg @ 37ºC	

Comments: All tests reported as pass

Production Manager or Scientific Director _____ Date _____

NOT A FINISHED PRODUCT
INTENDED FOR FURTHER MANUFACTURING PROCESSING ONLY

BIOHAZARD INFORMATION
No physical or health hazards under OSHA definitions (NOT HAZARDOUS)