Viral Therapeutics, Inc.

# Certificate of Analysis

Reason for Submission: ☐ Release ☐ Corrected ☐ Amendment

LOT NUMBER:

PRODUCT NAME: Recombinant Creatine Kinase MB Isoenzyme Type I

DESCRIPTION: Recombinant full length Creatine Kinase MB Isoenzyme without C-terminal lysine on M chain **produced in *Pichia pastoris***. Purified under non-denaturing conditions. 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,<br>20 mM Sodium Phosphate,<br>1.0 mM DTT, 1.0 mM EDTA | |
| 1.3 | pH | 7.5 – 8.5 | |

| | 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. Comparable to reference lot. | |
| 3 | **Potency** | | |
| 3.1 | Protein Concentration by Coomassie Plus | 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)**