

DiaPharma Streptokinase

Data Sheet

Catalog #: B811111

Item Description: Streptokinase (Approximately 0.85 MIU)

Lot #: B-071601

Re-assay Date: 07/31/2019

All units of plasma have been tested for absence of HB_sAg (third generation test), anti-HIV (FDA licensed test) and found to be negative. This material should be handled as if capable of transmitting disease.

CAUTION:

**NOT SUITABLE OR INTENDED FOR USE IN HUMANS OR FOOD ANIMALS
NOT FOR STERILE USE OR INJECTION
FOR RESEARCH USE ONLY**

Product: Streptokinase (purified preparation of a bacterial protein elaborated by group C b-hemolytic streptococci). Supplied as white, water-soluble, lyophilized powder (non-sterile)

Material contains 11 mg sodium L-glutamate and 13.0 mg albumin (human) per 1,000,000 IU (1 MIU) of Streptokinase.

Contains no preservatives.

Amount:

per vial: Approximately **846,000 IU** (0.85 MIU) per vial

Prepared By: Jennifer Kiblinger **Date:** 07/13/2016

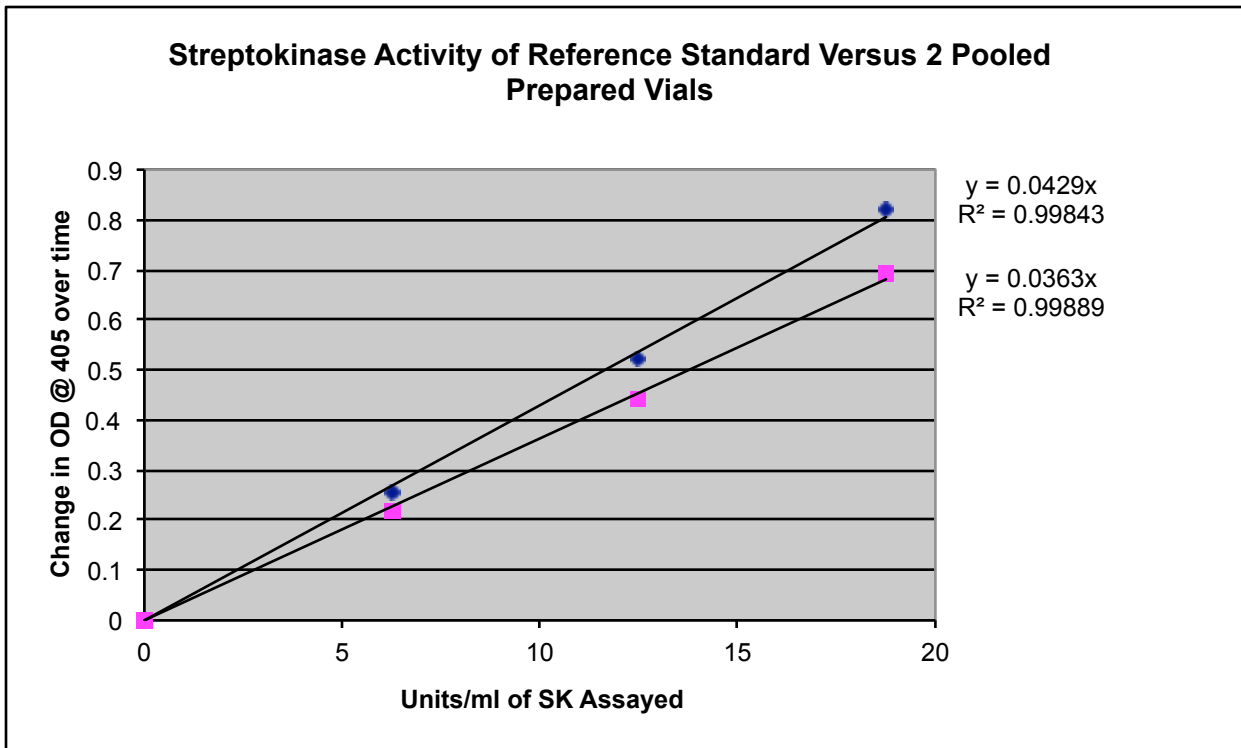
Printed Name: Jennifer J. Kiblinger
Title: Scientific Affairs Manager

Assay of DPG Streptokinase vs. 3rd Int. Reference Standard (06 July 2016)

Experimental: Bulk streptokinase (51.75 grams) was dissolved in 750 ml of purified water and 5 ml portions distributed to 144 vials (nominal vial size = 20 ml). Fluted stoppers were placed on top of each vial to allow vapors to evolve and the vials freeze-dried over 48 hours with a cycle that consisted of 4 hours freezing at -40°C, 12 hours under vacuum at -10°C, 24 hours under vacuum at +10°C, then the final 6 hours the shelf temperature was elevated to +15°C to drive off residual moisture. Vials were stoppered prior to vacuum release. All vials were then capped and labeled as containing "1 MIU" of Streptokinase. Two separate vials of prepared SK were assayed versus the 3rd International SK reference standard using previously described procedures.

Results of Assay:

IU/ml	Change in OD @ 405 nm over 14 minutes				
	Ref. Std	Avg. of 2 Vials	Vial 1	Vial 2	
0	0	0	0	0	0
6.25	0.257	0.217	0.173	0.175	
12.5	0.521	0.444	0.360	0.351	
18.75	0.820	0.691	0.555	0.551	



Calculations: Based upon the above assay slope comparison, as well as the slopes of the vials from above, we determined that the average number of Units contained in these vials was 846,000 or about 85% of the labeled potency.