DiaPharma Streptokinase

Data Sheet

Catalog #: B811111
Item Description: Streptokinase (Approximately 1.34 MIU)
Lot #: B-101301
Expiration Date: 10/31/2018

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 1,340,000 IU (1.34 MIU) per vial

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Assay of DiaPharma Streptokinase

vs. 3rd Int. Reference Standard (**Assay Date:** 15 October 2013)

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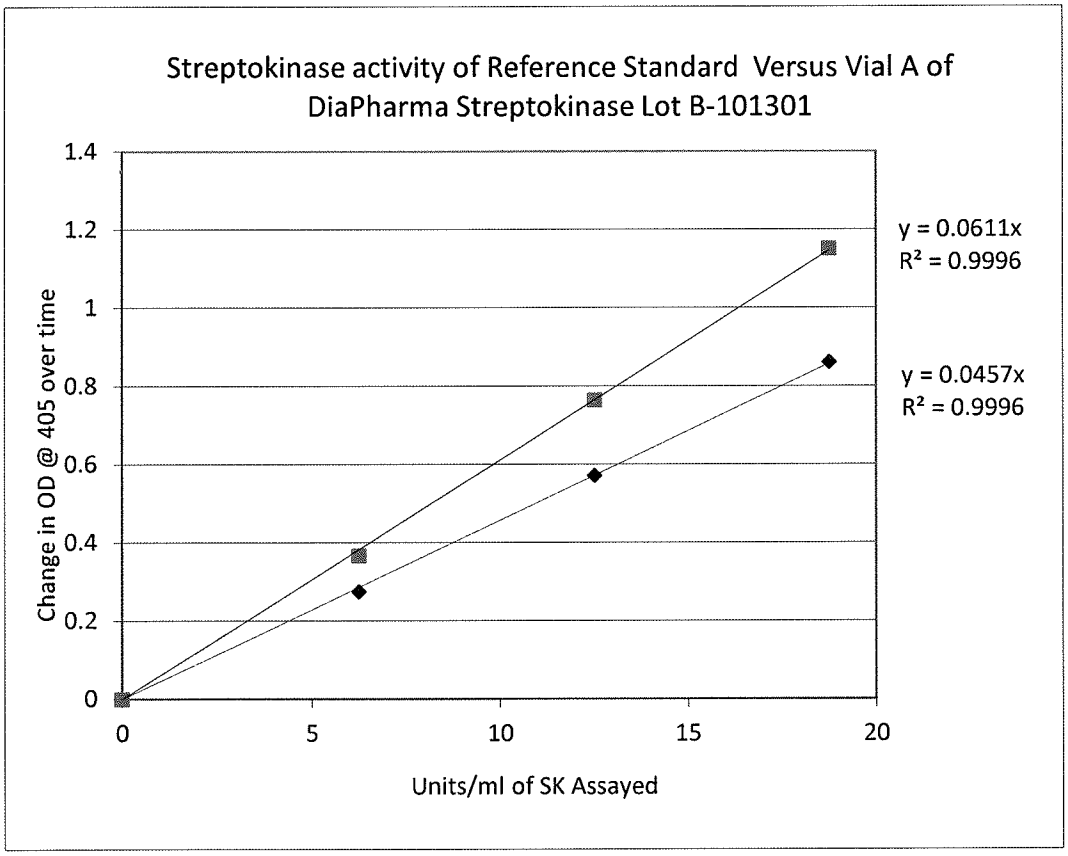
Experimental: Bulk streptokinase (43.5 grams) was dissolved in 1 620 ml of purified water and 5 ml portions distributed to 135 vials (nominal vial size = 20 ml). Fluted stoppers were placed on top of each vial to allow vapors to evolve and the vials freeze-dried over 48 hours with a cycle that was 4 hours freezing at -40, 12 hours under vacuum at -10, 24 hours under vacuum at +10, then the final 6 hours the shelf temperature was elevated to +15 to drive off residual moisture. The stoppers were then pressed in place and the vacuum released on the dryer. All vials were then capped and labeled as containing "1 MIU" of Streptokinase. We then assayed three separate vials of the SK versus the 3rd International SK reference standard using previously described procedures.

Assay Results:

	Change in OD @ 405 nm over 14 minutes	
IU/ml	Ref. Std	Dup. Avg.
0	0	0
6.25	0.274	0.3665
12.5	0.571	0.764
18.75	0.8605	1.1515



Conclusion: Based upon the above assay slope comparison, as well as the slopes of the vials above, it was determined that the average number of Units contained in these vials was 1,340,000 or **1.34 MIU**.