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Certificate of Analysis

Product Description: Spectinomycin Dihydrochloride Pentahydrate
Catalog Number: 152067
Lot: M4520

Formula: $C_{14}H_{24}N_2O_7 \cdot 2HCl \cdot 5H_2O$
CAS #: 22189-32-8
Physical Description: White Powder

Formula Weight: 495.36
Storage: +4°C

Test	Specification	Result
Identity Test	Passes	Passes
Source	<i>Streptomyces</i> sp.	<i>Streptomyces</i> sp.
Potency	≥500 µg/mg	650 µg/mg
FTIR	Conforms to Standard	Conforms to Standard
Loss on Drying	<20%	17.6%
Optical Rotation	Positive	+18.0°
Heavy Metals	≤0.005%	<50 ppm
Expiration Date	Month/Year	6/15/2014

Solubility: Clear and Colorless

pH: 4.7

Sulfated Ash: 0.3%

Acetone: 0.04%

Microbial Limit:

-- Bacteria: <10 cfu/g

-- Fungi and Yeast: <10 cfu/g

-- E. coli: Not Detected

Related Substances:

-- Impurity D: 0.4%

-- Impurity E: 0.9%

-- Impurity A: 0.5%

-- Impurity C: Not Detected

-- Impurity F: 0.1%

-- Impurity G: Not Detected

-- Any Other Impurity: Not Detected

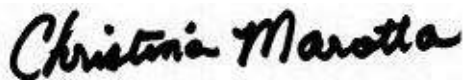
-- Total Impurities: 1.9%

Assay (based on anhydrous substance):

-- (4R) Dihydrospectinomycin Dihydrochloride: 1.7%

-- Sum of the Contents of Spectinomycin Dihydrochloride and (4R) Dihydrospectinomycin

Dihydrochloride: 96.3%



07/27/2012 - Christina Marotta

MP Biomedicals, LLC.

Technical Director

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