



Certificate of Analysis

Product Description: Polymyxin B Sulfate
Catalog Number: 100565
Lot: M3297

Formula: C₅₅H₉₆N₁₆O₁₃·2H₂SO₄
CAS #: 1405-20-5
Physical Description: White Powder

Formula Weight: 1385.63
Storage: +4°C, desiccate

Test	Specification	Result
Identity Test	Passes	Passes
Potency	≥6,000 u/mg	8041 u/mg (as is) 8194 u/mg (on dried basis)
FTIR	Conforms to Standard	Conforms to Standard
pH (1% aq soln)	5 - 7	6.4
Loss on Drying	≤8%	1.9%
Expiration Date	Month/Year	6/30/2016

Specific Optical Rotation: -87°

Related Substances (HPLC):

- Major Impurity: 2.1%
- Sum of Impurities: 13.5%

Phenylalanine: 11%

Sulfated Ash: 0.00%

Sulfate: 16.3%

Heavy Metals: ≤20 ppm

TAMC: ≤10 cfu/g

TYMC: ≤10 cfu/g

Assay (microbiological): 804 µg/mg (as is); 819 µg/mg (on dried basis)

Assay (HPLC, on dried basis):

- Sum of polymyxins B1,B2,B3,B1-I: 88.7%
- Polymyxin B3: 3.3%
- Polymyxin B1-I: 8.9%

Particle Size:

- ≥99.0% ≤20 µm by vol.
- ≥90.0% ≤15 µm by vol.
- ≥75.0% ≤10 µm by vol.
- ≥35.0% ≤5 µm by vol.

Christina Marotta

01/31/2012 - Christina Marotta
MP Biomedicals, LLC.
Technical Director

This is an electronically generated document
<mailto:biotech@mpbio.com>
<http://www.mpbio.com>

Online Ordering, MSDSs, certificates of analysis and data sheets now available on our web site
Technical Service: 1-800-279-5490 (440-337-1200) Customer Service: 1-800-854-0530 (440-337-1200)