



## Certificate of Analysis

**Product Description:** Polymyxin B Sulfate  
**Catalog Number:** 100565  
**Lot:** M4800

**Formula:** C<sub>55</sub>H<sub>96</sub>N<sub>16</sub>O<sub>13</sub>·2H<sub>2</sub>SO<sub>4</sub>  
**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	8083 u/mg (as is) 8190 u/mg (on dried basis)
FTIR	Conforms to Standard	Conforms to Standard
pH (1% aq soln)	5 - 7	6.2
Loss on Drying	≤8%	1.3%
Expiration Date	Month/Year	4/30/2017

Specific Optical Rotation: -86°

Related Substances (HPLC):

- Major Impurity: 2.1%
- Sum of Impurities: 15.6%

Phenylalanine: 11%

Sulfated Ash: 0.02%

Sulfate: 16.6%

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: 87.5%
- Polymyxin B3: 3.6%
- Polymyxin B1-I: 8.1%

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*

08/27/2012 - Christina Marotta  
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