# POLYMYXIN B SULFATE USP (MICRONIZED)

<table>
<thead>
<tr>
<th>Code No.</th>
<th>SCN No.</th>
<th>CAS No.</th>
<th>Effective Date</th>
<th>Product Manager</th>
<th>Rev. No.</th>
<th>Approved By</th>
</tr>
</thead>
<tbody>
<tr>
<td>PBSNCM</td>
<td>2570</td>
<td>1405-20-5</td>
<td>September 29, 2017</td>
<td>TA</td>
<td>Original</td>
<td>CJB</td>
</tr>
</tbody>
</table>

**CHARACTERISTICS:** White or almost white hygroscopic powder

**TEST:**

<table>
<thead>
<tr>
<th>Identification test</th>
<th>SPECIFICATIONS:</th>
<th>TEST METHOD:</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. The retention times of the major peaks of the sample solution correspond to those of the standard solution, as obtained in the test for Composition of Polymyxins.</td>
<td>To pass test</td>
<td>USP</td>
</tr>
</tbody>
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| B. A reddish-violet color is produced | To pass test | USP |
| C. A 50-mg/ml solution of Polymyxin B Sulfate meets the requirements | To pass test | General <191> Sulfate |

- **Assay:** 6000 Polymyxin B Units/mg min
- **Residue on ignition:** 5.0% max (where used for prescription compounding)
- **Organic impurities (related substance):**
  - Any individual impurity: 3.0% max
  - Total impurity: 17.0% max
- **pH:** 5.0-7.5
- **Loss on drying:** 7.0% max

**Composition of polymyxins**

1) Polymyxin B3: 6.0% max
2) Polymyxin B1-1: 15.0% max
3) Sum of Polymyxins: 80.0% min

**Residual solvents**

- Ethanol: 5000 ppm max

**PACKAGING:** 0.5 kg tin

**SHELF LIFE:** 2 years from the date of manufacture

**OTHER:** May be used as an API (Active Pharmaceutical Ingredient). Please note: Government agency fees may apply to specific uses/applications.