

## **Gojira Fine Chemicals, LLC**

Quality Products & Services Meeting Customer Needs 5386 Majestic Parkway, Suite 7, Bedford Heights, OH 44146 www.gojirafc.com • sales@gojirafc.com

## **Specification**

## **Colistin Sulfate**

Catalog Number: CAS Number: Synonym(s): Molecular Formula: Molecular Weight: Storage: Retest Period: CS1005 1264-72-8 Polymyxin E sulfate  $C_{45}H_{85}N_{13}O_{10} \cdot H_2SO_4$ 820.61  $2^{\circ}C - 8^{\circ}C$ Three years from the date of manufacture

| Test                                | Specification                              |
|-------------------------------------|--|
| Appearance                          | White to off-white powder                  |
| Assay (Anhydrous)                   | ≥ 19000 IU/mg                              |
| Specific Rotation                   | -63° to -73°                               |
| Solubility                          | Freely soluble in water, insoluble in EtOH |
| рН                                  | 4.0 - 6.0                                  |
| Moisture (LOD)                      | ≤ 3.5%                                     |
| Sulfated Ash                        | ≤ 1.0%                                     |
| Sulfate                             | 16.0% - 18.0%                              |
| Related Substances                  |  |
| Total Impurities                    | ≤ 23%                                      |
| Any Single Impurity                 | ≤ 4.0%                                     |
| Impurity I                          | ≤ 3.0%                                     |
| Impurity II                         | ≤ 4.0%                                     |
| Impurity III                        | ≤ 3.0%                                     |
| Impurity IV                         | ≤ 3.0%                                     |
| Impurity V                          | ≤ 3.0%                                     |
| Impurity VI                         | ≤ 4.0%                                     |
| HPLC Composition (Anhydrous):       |  |
| Polymixins (E1,E2,E3,E1-1, E1-7MOA) | ≥ 77.0%                                    |
| Polymixin E3                        | ≤ 10.0%                                    |
| Polymixin E1-1                      | ≤ 10.0%                                    |
| Polymixin E1-7MOA                   | ≤ 10.0%                                    |

Approved:

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For research or further manufacturing. Not for drug, clinical or a food use in humans or animals.