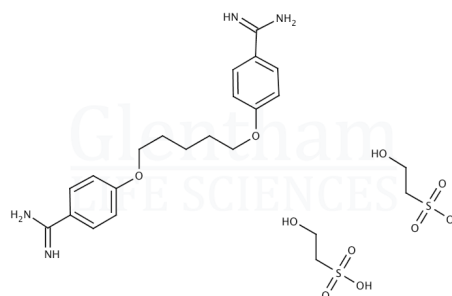


## Product Specification

|                   |                                             |
|-------------------|---------------------------------------------|
| Product Name      | Pentamidine isethionate salt, EP, USP grade |
| Glentham Code     | GK1903                                      |
| CAS Number        | 140-64-7                                    |
| EINECS            | 205-424-1                                   |
| MDL-Nummer        | MFCD00079213                                |
| Molecular Weight  | 592.68                                      |
| Molecular Formula | $C_{19}H_{24}N_4O_2 \cdot 2C_2H_6O_4S$      |
| Storage Temp.     | +20°C                                       |



| Property                       | Specification                                                    |
|--------------------------------|------------------------------------------------------------------|
| Physical Description           | White or almost white crystalline powder, or colourless crystals |
| Identification (IR)            | To conform to standard                                           |
| Identification                 | O2 combustion (USP Test B); Tests B and C (EP)                   |
| Identification (HPLC)          | Retention time to conform                                        |
| Solubility (10% in water)      | Clear ( $\leq$ ref. sus. II); colourless solution ( $\leq$ 6)    |
| pH (5% in water)               | 4.5 - 6.5                                                        |
| Heavy Metals                   | $\leq$ 20ppm                                                     |
| Residue on Ignition            | $\leq$ 0.1%                                                      |
| Melting Point                  | 187 - 191 °C                                                     |
| Ammonium Isethionate           | $\leq$ 0.2%                                                      |
| 1,5-Dibromopentane             | $\leq$ 0.1%                                                      |
| Monoamide Impurity             | $\leq$ 0.2% (HPLC)                                               |
| Bisamide Impurity              | $\leq$ 0.2% (HPLC)                                               |
| Any Other Individual Impurity  | $\leq$ 0.05% (HPLC)                                              |
| Total Impurities               | $\leq$ 0.4% (HPLC)                                               |
| Loss on Drying                 | $\leq$ 4.0% (105°C)                                              |
| Assay (Titration)              | 98.5 - 101.5 % (dried substance)                                 |
| Pharmacopoeia Specification(s) | EP, USP                                                          |

|                       |              |
|-----------------------|--------------|
| Specification Version | - v1.0       |
| Date Created          | - 2018-05-17 |

Glentham Life Sciences confirm that the above referenced product conformed to the information displayed in this document on the quality release date. Please check [www.glentham.com](http://www.glentham.com) or contact us using the details above for the current version of this document.

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