

TECHNICAL DATA SHEET

M010226-TDS-ENG-2026

| CISTEAMINA HCL FARMA | | |
|-----------------------------|------------------------|-----------------------------|
| DESCRIPTION DCI: CYSTEAMINE | | DESCRIPTION DOE: CISTEAMINA |
| CAS N°: 156-57-0 | EC N°: 205-858-1 | AEMPS CODE: 7304B |
| MOL. WEIGHT: 113,61 | MOL. FORMULA: C2H8CINS | ARTICLE CODE: M010226 |

| <u>ATTRIBUTES</u> | <u>SHOULD BE</u> |
|-------------------|--|
| Appearance | White or almost white crystalline powder |
| Identification | Complies |
| Melting point | 65 - 70 °C |
| Water | =< 0.5 % |
| Sulfated ash | =< 0.1 % |
| pH | 3.5 - 5.0 |
| Sulfates | =< 0.01 % |
| Heavy metals | =< 0.0001 % |
| Assay | => 99.0 % |

COMPLIES WITH

Manufacturer Specifications

STORAGE

Store in a cool place. Keep the container tightly closed, in a dry and well-ventilated place.

REMARKS

Cysteamine HCl is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006 - ICH Q3C (R6) "Residual solvents".

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.