

**TECHNICAL DATA SHEET**

0390-TDS-ENG-2026

| <b>CETRIMIDA FARMA GRADE (EUR. PH.)</b> |                                                   |                            |
|-----------------------------------------|---------------------------------------------------|----------------------------|
| DESCRIPTION DCI: cetrimide              |                                                   | DESCRIPTION DOE: CETRIMIDA |
| CAS Nº: 8044-71-1                       | EC Nº: 617-073-5                                  | AEMPS CODE: 8146A          |
| MOL. WEIGHT: 336,45                     | MOL. FORMULA: C <sub>17</sub> H <sub>38</sub> BrN | ARTICLE CODE: 0390         |

| ATTRIBUTES             | SHOULD BE                                              |
|------------------------|--------------------------------------------------------|
| Appearance             | White or almost white, voluminous, free-flowing powder |
| Solubility             | Freely soluble in water and in alcohol                 |
| Identification A       | Complies                                               |
| Identification B       | Complies                                               |
| Identification C       | Complies                                               |
| Identification D       | Complies                                               |
| Identification E       | Complies                                               |
| Appearance of solution | Clear and colourless                                   |
| Acidity or alkalinity  | =< 0.1 mL 0.1 M NaOH or HCl                            |
| Amines and amine salts | Complies                                               |
| Loss on drying         | =< 2.0 %                                               |
| Sulfated ash           | =< 0.5 %                                               |
| Assay                  | 96.0 - 101.0 %                                         |

**COMPLIES WITH**

European Pharmacopoeia 12.3

**STORAGE**

Keep it in tightly closed containers. Store it at room temperature and protected from light.

**REMARKS**

Cetrimide 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.