



TECHNICAL DATA SHEET

0390-TDS-ENG-2023

CETRIMIDE PHARMA GRADE (EUR. PH.)		
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: C17H38BrN	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 11.0

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.