

**CETRIMIDA FARMA GRADE (EUR. PH.)**

PRODUCT CODE: 0390	CAS Nº: 8044-71-1	ANALYSIS Nº: 268/23
MANUFACTURER BATCH: CTM/017/07/22	CERTIFICATE ID: 40.130	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 01/07/2022	
METAPH BATCH: 0051123	RETEST DATE: 30/06/2027	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white, voluminous, free-flowing powder	White, voluminous, free-flowing powder
Solubility	Freely soluble in water and in alcohol	Complies (*)
Identification A	Complies	Complies
Identification B	Complies	Complies
Identification C	Complies	Complies
Identification D	Complies	Complies
Identification E	Complies	Complies
Appearance of solution	Clear and colourless	Clear and colourless
Acidity or alkalinity	=< 0.1 mL 0.1 M NaOH or HCl	0.04 mL of 0.1 M NaOH
Amines and amine salts	Complies	Complies
Loss on drying	=< 2.0 %	0.3 %
Sulfated ash	=< 0.5 %	0.02 %
Assay	96.0 - 101.0 %	98.3 %

COMPLIES WITH

European Pharmacopoeia 11.0

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".

(*) Data adapted from the manufacturer's certificate of analysis.

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.

STORAGE

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

Analysis date: 24/11/2023
Signature: Albert Sánchez López (QP)
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40001251
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