

ALCOHOL CETILICO (EUR. PH.)

PRODUCT CODE: 119	CAS Nº: 36653-82-4	ANALYSIS Nº: 287/24
MANUFACTURER BATCH: 0000056297	CERTIFICATE ID: 44.109	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 25/07/2024	
METAPH BATCH: 0121124	RETEST DATE: 25/07/2026	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white, unctuous mass, powder, flakes or granules	White granules (*)
Identification	Complies	Complies (*)
Appearance of solution	Clear and not more intensely coloured than ref. sol. B6	Complies (*)
Melting point	46 - 52 °C	49 °C
Acidity index	= < 1.0	0.01
Hydroxyl value	218 - 238 mg KOH/g	231
Iodine index	= < 2.0 g/100g	0.01 g/100g
Saponification index	= < 2.0 mg KOH/g	0.1 mg KOH/g
Assay	= > 95.0 %	98.7 % (*)

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

Cetyl Alcohol is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

(*) Data controlled by Metapharmaceutical Industrial SL.

The product is not of animal origin and no animal product is used in its production, so it is risk-free BSE/TSE.

The product is not derived from GMO. No genetically modified organism is used in its production and no GMO product comes in contact with the product during any stage of production.

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

Store containers between 15 and 25 °C in a dry and well-ventilated place.

Analysis date: 09/01/2025
 Signature: Albert Sanchez Lopez (QP)
 Conclusion: Complies

Manufacturer: 40001074

