



POLIETILENGLICOL 400 (EUR. PH. / USP)

PRODUCT CODE: 006056	CAS Nº: 25322-68-3	ANALYSIS Nº: 293/24
MANUFACTURER BATCH:	CERTIFICATE ID: 44.201	
SUPPLIER BATCH: W0605602	MANUFACTURING DATE: 13/06/2024	
METAPH BATCH: 0181124	EXPIRY DATE: 13/06/2026	

ATTRIBUTES	SHOULD BE	IS
Appearance	Clear, viscous, colourless or almost colourless, hygroscopic liquid	Clear, viscous, colourless, hygroscopic liquid (*)
Identification A	Complies	Complies (*)
Identification B	Complies	Complies (*)
Identification C	Complies	Complies (*)
Appearance of solution	Clear and not more intensely coloured than ref. sol. BY6	Complies
Acidity or alkalinity	=< 0.1 mL of 0.1 M NaOH	< 0.1 mL of 0.1 M NaOH
Viscosity	105 - 130 mPa·s	130 mPa·s (*)
Hydroxyl value	264 - 300	282
Reducing substances	Not more intensely coloured than ref. sol. R3	Complies
Formaldehyde	=< 30 ppm	4 ppm
Ethylene glycol and diethylene glycol	=< 0.4 %	0.03 %
Ethylene oxide and dioxan		
Ethylene oxide	=< 1 ppm	< 1.0 ppm
Dioxan	=< 10 ppm	< 1.0 ppm
Water	=< 2.0 %	0.11 %
Sulfated ash	=< 0.2 %	< 0.1 %

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

Polyethyleneglycol 400 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.

STORAGE

Store it in a fresh, dry and well-ventilated place.

Analysis date: 04/02/2025

Signature: Albert Sanchez Lopez (QP)

Conclusion: Complies

Manufacturer: 40000395