

**POLIETILENGLICOL 4000 POLVO (EUR. PH.)**

PRODUCT CODE: 1461		CAS Nº: 25322-68-3	ANALYSIS Nº: 157/24
MANUFACTURER BATCH:	D684NAVBG1	CERTIFICATE ID:	42.478
SUPPLIER BATCH:	----	MANUFACTURING DATE:	31/10/2023
METAPH BATCH:	0030624	RETEST DATE:	31/10/2026

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white solid with a waxy or paraffin-like appearance	White solid with a waxy appearance (*)
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	Complies
Viscosity	110 - 170 mPa·s	131 mPa·s (*)
Freezing point	53 - 59 °C	Complies
Hydroxyl value	25 - 32	28
Reducing substances	Not more intensely coloured than ref. sol. R3	Complies
Formaldehyde	=< 30 ppm	Complies
Ethylene oxide and dioxan		
Ethylene oxide	=< 1 ppm	< 0.01 ppm
Dioxan	=< 10 ppm	< 0.01 ppm
Water	=< 2.0 %	0.1 %
Sulfated ash	=< 0.2 %	Complies

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

Product intended for pharmaceutical purposes.

(*) Data controlled by Metapharmaceutical Industrial SL.

BSE/TSE (CPMP/BWP/1230/98 REV 1)

This product was prepared without using Materials of animal origin for which a BSE-risk exists. A BSE-risk estimation is therefore not necessary.

GMO (Regulation (EC) No. 1829/2003 and 1830/2003)

For above product there is no obligation of GMO-labelling. It can be labelled as "without genetechnology".

Residual solvents (Guideline CPMP/ICH/283/95)

This product contains solvents. It complies with this guideline because the concentrations are below the limits:

1,4-Dioxane (Class 2): < 1 ppm

Ethylene glycol (Class 2): < 500 ppm

Allergens (1223/2009/EG)

This product does not contain any allergens listed in above mentioned directive.

Nitrosamines Risk Evaluation

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.

Analysis date: 15/07/2024
Signature: Albert Sanchez Lopez (QP)
Conclusion: Complies

Manufacturer: 40000370



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Elemental impurities (EMA/CHMP/SWP/4446/2000, ICH-Q3D)

This product does not contain any metal residues listed in above mentioned directives.

STORAGE

Tightly closed. Store at a dry place. At room temperature. Protect from water and moisture.

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Conclusion: Complies

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