

**POLIVINILPIRROLIDONA K 30 (EUR. PH. / E 121)**

PRODUCT CODE: 009740		CAS Nº: 9003-39-8	ANALYSIS Nº: 252/22
MANUFACTURER BATCH:	20220506	CERTIFICATE ID:	36.497
SUPPLIER BATCH:	U0974002	MANUFACTURING DATE:	31/05/2022
METAPH BATCH:	0121122	EXPIRY DATE:	31/05/2025

ATTRIBUTES	SHOULD BE	IS
Appearance	White or yellowish-white, hygroscopic powder or flakes	White hygroscopic powder (*)
Solubility	Freely soluble in water, in ethanol (96 per cent) and in methanol, very slightly soluble in acetone	Complies
Identification A	Complies	Complies (*)
Identification D	Complies	Complies (*)
Appearance of solution	Clear and not more intensely coloured than ref. sol. B6, BY6 o R6	Complies
pH	3.0 - 5.0	3.0
Viscosity, expressed as K-value	27.0 - 32.4	30.0
Aldehydes	=< 500 ppm	39 ppm
Peroxides	=< 400 ppm	74 ppm
Formic Acid	=< 0.5 %	0.20 %
Limit of hydrazine	=< 1 ppm	< 1.0 ppm
Impurity A	=< 10 ppm	Not Detected
Impurity B	=< 3.0 %	1.1 % (*)
Water	=< 5.0 %	4.6 % (*)
Sulfated ash	=< 0.1 %	< 0.01 % (*)
Riqueza (N content)	11.5 - 12.8 %	12.2 %

COMPLIES WITH

European Pharmacopoeia 10.6

REMARKS

Product fully analysed inside the EU.

Povidone 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

Keep the container tightly closed in a dry, cool and well-ventilated place.

Analysis date: 02/12/2022

Manufacturer: 40001216

Signature: Albert Sánchez López (QP)

Conclusion: Complies