

**POLIVINILPIRROLIDONA (KOLLIDON 30) (EUR. PH.)**

PRODUCT CODE: 001166		CAS Nº: 9003-39-8	ANALYSIS Nº: 209/24
MANUFACTURER BATCH:		CERTIFICATE ID:	43.199
SUPPLIER BATCH:	V0116601	MANUFACTURING DATE:	08/04/2023
METAPH BATCH:	0040824	RETEST DATE:	07/04/2027

ATTRIBUTES	SHOULD BE	IS
Appearance	White or yellowish-white, hygroscopic powder or flakes	White powder, hygroscopic (*)
Solubility	Freely soluble in water, in ethanol (96 %) and in methanol, very slightly soluble in acetone	
Identification A	Complies	Complies (*)
Identification D	Complies	Complies (*)
Appearance of solution	Clear and not more intensely coloured than ref. sol. B6, BY6 or R6	Complies
pH	3.0 - 5.0	3.6
Viscosity, expressed as K-value	27.0 - 32.4	29.4
Aldehydes	=< 500 ppm	69 ppm
Peroxides	=< 400 ppm	< 30 ppm
Formic Acid	=< 0.5 %	0.3 %
Limit of hydrazine	=< 1 ppm	< 1 ppm
Impurity A	=< 10 ppm	< 2 ppm
Impurity B	=< 3.0 %	0.08 % (*)
Water	=< 5.0 %	2.9 % (*)
Sulfated ash	=< 0.1 %	0.06 % (*)
Assay	11.5 % - 12.8 %	12.4 %

COMPLIES WITH

European Pharmacopoeia 11.4

REMARKS

Povidone is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline.

Certificates of residual solvents, allergens, irradiation, non-GMO and BSE-TSE, among others, are available upon request.

The product is suitable for pharmaceutical purposes.

(*) Data controlled by Metapharmaceutical Industrial SL.

STORAGE

Store in the original container in a cool and dry place.

Analysis date: 29/10/2024
Signature: Albert Sanchez Lopez (QP)
Conclusion: Complies

Manufacturer: 40000338