

**NIPASOL M (PROPILO P-HIDROXIBENZOATO) (EUR. PH.)**

PRODUCT CODE: 1335		CAS Nº: 94-13-3	ANALYSIS Nº: 290/25
MANUFACTURER BATCH:		CERTIFICATE ID:	48.243
SUPPLIER BATCH:	X1192701	MANUFACTURING DATE:	12/11/2024
METAPH BATCH:	0210925	EXPIRY DATE:	11/11/2029

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white, crystalline powder	White crystalline powder (*)
Melting point	96 - 99 °C	96.7 °C (*)
Identification A	Complies	Complies (*)
Identification B	Complies	Complies (*)
Appearance of solution	Clear and not more intensely coloured than ref. sol. BY6	Complies
Acidity	=< 0.10 mL 0.1 M NaOH	0.01 mL of 0.1M NaOH
Related substances		
Impurity A	=< 0.5 %	< 0.5 %
Unspecified impurities	=< 0.5 %	< 0.5 %
Total impurities	=< 1.0 %	< 1.0 %
Sulfated ash	=< 0.1 %	0.04 % (*)
Assay	98.0 - 102.0 %	99.1 % (*)

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

Propyl parahydroxybenzoate 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. Store in a cool and dry place.

Analysis date: 29/10/2025

Signature: Albert Sánchez López (QP)

Conclusion: Complies

Manufacturer: 40001164