

HIDROXIPROPILMETILCELULOSA PHARMA (EUR. PH.)

PRODUCT CODE: 002350		CAS Nº: 9004-65-3	ANALYSIS Nº: 092/25
MANUFACTURER BATCH:		CERTIFICATE ID:	45.880
SUPPLIER BATCH:	X0942201	MANUFACTURING DATE:	24/10/2024
METAPH BATCH:	0090425	RETEST DATE:	24/10/2027

ATTRIBUTES	SHOULD BE	IS
Appearance	White, yellowish-white or greyish-white powder or granules, hygroscopic after drying	White powder, hygroscopic after drying (*)
Identification A	Complies	Complies (*)
Identification B	Complies	Complies (*)
Identification C	Complies	Complies (*)
Identification D	Complies	Complies (*)
Identification E	Complies	Complies (*)
Appearance of solution	Not more opalescent than ref. sus. III and not more intensely coloured than ref. sol. Y6	Complies
pH	5.0 - 8.0	7.2
Viscosity	2700 - 5040 mPa·s	4060 mPa·s
Loss on drying	=< 5.0 %	1.1 %
Sulfated ash	=< 1.5 %	0.6 %
Assay		(*)
Hydroxypropoxy groups content	7.0 - 12.0 %	8.6 %
Methoxy groups content	28.0 - 30.0 %	28.9 %

COMPLIES WITH

European Pharmacopoeia 11.4

REMARKS

Hypromellose 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.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.

STORAGE

Keep tightly closed in a cool, dry place away from heat, flames, sparks and other sources of ignition.

Analysis date: 13/05/2025
 Signature: Albert Sánchez López (QP)
 Conclusion: Complies

Manufacturer: 40000814

