

Certificate of Analysis

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NATROSOL 250 HX PHARM BAG 25KG

Material Number:

431292

Natrosol™ 250HX PHARM Hydroxyethylcellulose

Batch:

A 0797

Characteristics	Specification	Results
Loss on Drying, % (QC-103-P)	0.0 - 5.0	2.6
Sulfated Ash, % (QC-104-P)	0.0 - 1.0	0.6
Nitrates, % (QC-203-P)	0.00 - 0.20	0.10
Ashland Brookfield viscosity (1%), sp/rpm:3/30, mPa.s (QC-109-P)	1500.00 - 2500.00	2400.00
Assay - Hydroxyethoxy groups, % (QC-200-P)	30.0 - 70.0	54.9
PSD by laser diffraction (60 Mesh), % (QC-131-P)	0.0 - 15.0	7.0
pH of 1% Solution (QC-225-P)	6.0 - 8.5	6.4
Aldehydes, expressed as Glyoxal, mg/kg (QC-222-P)	0.0 - 10.0	0.5
Viscosity according to EP method (2%), mPa.s (QC-209-P)	6400.000 - 11900.000	10600.000
Date of Manufacture		April 24 , 2025
Next Retest Date		April 24 , 2027

Notes:

Product is best if used within 3 years of production date when stored as recommended in product literature.

Recommended testing protocol: Retest viscosity and moisture content.

The typical values below are based on intermittent testing:

- Identification tests according to EP/NF: Pass
- Heavy metals (as Lead), ppm < 10

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- Lead, ppm < 0.5
- Chlorides, % < 0.2
- Residual solvents: Pass
- Ethylene Oxide, ppm < 1
- 2-Chloroethanol, ppm < 10

This product conforms to the monograph for Hydroxyethylcellulose in the current editions of the European Pharmacopoeia (EP), the United States National Formulary (USP-NF), and the Chinese Pharmacopoeia (ChP). This product also conforms to the Japanese Pharmacopoeia (JP) when the viscosity, as measured by the JP method, is reported on the CoA.

As per the ChP monographs, any of the viscosities reported in this CoA can be used to achieve ChP compliance.

This product has been manufactured in accordance with the current Joint IPEC-PQG Good Manufacturing Practices Guide for Pharmaceutical Excipients.

This product is intended for excipient use only.

This COA is printed from a secure computer system ensuring the batch was properly released by the Quality Department and is valid without signature.

Manufactured by:

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NETHERLANDS

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