METAPHARMACEUTICAL IND SL
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TECHNICAL DATA SHEET

002350-TDS-ENG-2023

HIDROXIPROPILMETILCELULOSA 3600 (HIPROMELOSA 3500)		
DESCRIPTION DCI: HYPROMELLOSE	DESCRIPTION DOE: HIPROMELOSA	
CAS Nº: 9004-65-3	EC Nº: 618-389-6	AEMPS CODE: ---
MOL. WEIGHT: 10000 - 1500000	MOL. FORMULA: ---	ARTICLE CODE: 002350

ATTRIBUTES	SHOULD BE
Appearance	White, yellowish-white or greyish-white powder or granules, hygroscopic after drying
Solubility	Practically insoluble in hot water, in acetone, in anhydrous ethanol and in toluene. It dissolves in cold water giving a colloidal solution
Identification A	Complies
Identification B	Complies
Identification C	Complies
Identification D	Complies
Identification E	Complies
Appearance of solution	Not more oplascent than ref. sus. III and not more intensely coloured than ref. sol. Y6
pH	5.0 - 8.0
Viscosity	2700 - 5040 mPa·s
Loss on drying	=< 5.0 %
Sulfated ash	=< 1.5 %
Assay	
Hydroxypropoxy groups content	7.0 - 12.0 %
Methoxy groups content	28.0 - 30.0 %

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

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

REMARKS

Hypromellose is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

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.

Properties and uses
HYPROMELLOSE is used in the preparation of oral and topical pharmaceutical forms, presenting properties and uses similar to methylcellulose, although its mucilages have greater clarity and less non-dispersible fibers, being preferred in the preparation of ophthalmic solutions. It also prolongs the action of drugs transported in ophthalmic drops.

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Being non-ionic, HYPROMELLOSE is compatible with metal salts and organic ionic compounds.
It is stable in solutions with pH = 3 - 11.
It is the only one, together with HYPERLINKLING, that resists up to 100% alcohol.
In oral preparations it is used as a binder in wet or dry granulation, enteric coating, depending on the degree of viscosity, and as a matrix of controlled release tablets, using high viscosity HYPROMELLOSE.
In topical ophthalmic preparations it is used as a suspending and thickening agent, in artificial eye drops and tears, and as a humectant in hard contact lenses, and eye prosthetic lubricant. It is used in alkaline eye drops used as artificial tears to prevent damage to the cornea in patients with dry keratoconjunctivitis or keratitis, or during manipulations with a gonioscope.
It has also been used as a thickener in the preparation of artificial saliva.
It is also used as a suspending agent, stabilizer, thickener and emulsifier of gels and ointments, and as a protective colloid, since it prevents the coalescence or agglomeration of droplets and particles, thus inhibiting the formation of sediments.
It is also widely used in the cosmetic industry.

Dosage
As a gelling agent: 2 %.
As granulation binder: 2 - 5 %.
For enteric coating: at 2 - 10 %.
For controlled release tablet matrix: at 2 - 5 %.
In eye drops and artificial tears: at 0.45 - 1 %.

Incompatibilities
Oxidizing agents, extreme pH conditions.

Other observations
It is hygroscopic.

Compounding examples

HYPROMELLOSE base gel
HYPROMELLOSE - **2 %**
Propylene glycol - **20 %**
Purified water c.s.p. - **100 g**

Modus operandi: Moisten the HYPROMELLOSE with propylene glycol. Add the water. Leave to gel in slow agitation without heating.

Artificial tears
HYPROMELLOSE - **300 mg**
Sodium chloride - **900 mg**
EDTA disodium salt - **50 mg**
Sol. Benzalkonium chloride 0.1 % - **20 µL**
Purified water c.s.p. - **100 mL**

Modus operandi: Dissolve the sodium chloride and EDTA disodium salt in the purified water. Add the Benzalkonium chloride solution. Disperse the HYPROMELLOSE in slow agitation until it gels. Sterilize the autoclave.