VIVAPHARM® HPMC

Hypromellose
Hydroxypropyl Methylcellulose

Low Viscosity Grades

Cellulose-Based Polymer for Film Coating, Wet Granulation and Hard Capsule Manufacturing

Wide Viscosity Range
Neutral Color and Taste
Rapid Solubility
Clear and Robust Films

JRS PHARMA JRS FAMILY
A Member of the JRS Group

• Excipients • Coatings
• Biopharma Services • Technical Services

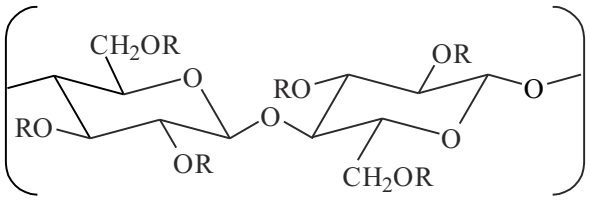
VIVAPHARM® HPMC

Hypromellose
Hydroxypropyl Methylcellulose

What is Hypromellose?

Hypromellose is a multi-functional cellulosic excipient. It is widely used in the pharmaceutical and dietary supplement industries, particularly for film coating, as a wet granulation binder, and for two-piece capsule manufacturing as an alternative to gelatin.
VIVAPHARM® HPMC, JRS PHARMA's hypromellose product line, is an integral ingredient within the broad excipient product range used for solid dosage form development and manufactured by the pharmaceutical and dietary supplement industries.

The Polymer Structure

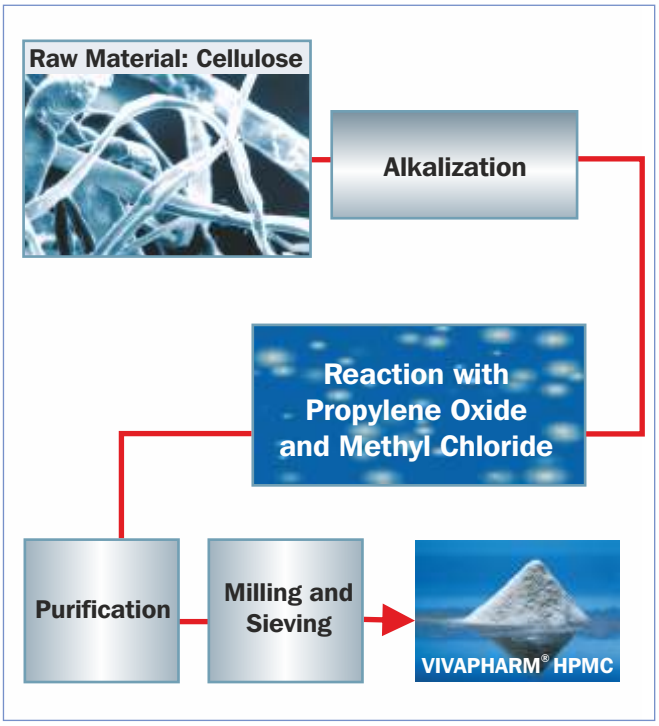


R = - H, - CH_3 or $-CH_2-CH(CH_3)-O-H$

Hydroxypropyl methylcellulose is a propylene glycol ether of methylcellulose.

Variations in molecular weight and the degree of substitution, together with the percentage of hydroxypropyl and methoxyl groups, define the physical properties.

The Manufacturing Process



Picture 1: Production Process HPMC

Product Range and Specification

There are different types of HPMC in use. Most important for pharmaceutical coatings are the types **2910** which means the average content of methoxyl groups is 29 % and the average content of hydroxypropyl groups is 10 %.

Low Viscosity

E Type 2910		Main Application Coating	
Methoxyl [%]	Hydroxy-propyl [%]	Viscosity 2% [mPa•s]	**VIVAPHARM® HPMC E** Grade
28.0 - 30.0	7.0 - 12.0	3	**VIVAPHARM® HPMC E 3**
		5	**VIVAPHARM® HPMC E 5**
		6	**VIVAPHARM® HPMC E 6**
		15	**VIVAPHARM® HPMC E 15**
		50	**VIVAPHARM® HPMC E 50**

Description

- **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.

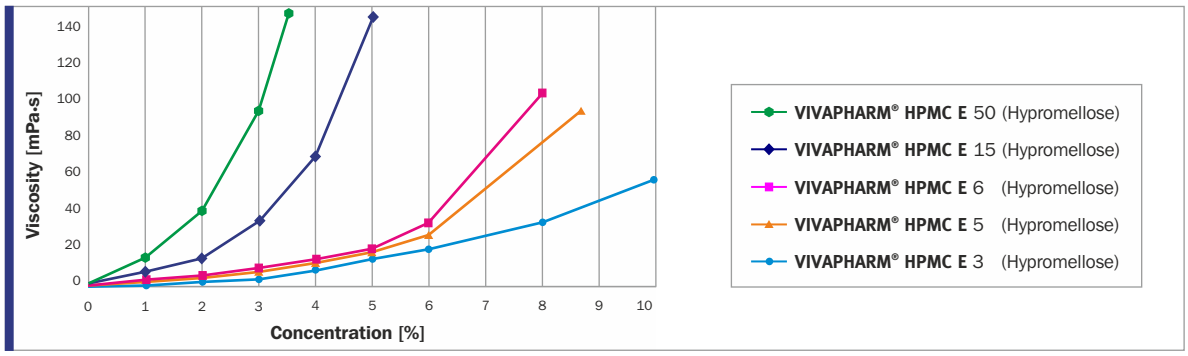
Pharmacopoeian Tests	Type 2910 low viscosity	Test Method
Identification (A, B, C, D, E)	passes	Ph.Eur., USP-NF, JP
Appearence of Solution	passes	Ph.Eur.
Loss on Drying	max. 5.0 %	Ph.Eur., USP-NF, JP
pH-Value	5.0 – 8.0	Ph.Eur., USP-NF, JP
Heavy Metals	max. 20 ppm	Ph.Eur., USP-NF, JP (monitored)
Sulfated Ash	max. 1.5 %	Ph.Eur., JP
Residue on Ignition	max. 1.5 %	USP-NF, JP
Apparent Viscosity	labeled viscosity ± 20 % (mPa•s)	Ph.Eur., USP-NF, JP
Degree of Substitution		
Methyl Content	28.0 % – 30.0 %	Ph.Eur., USP-NF, JP
Hyproxypropyl Content	7.0 % – 12.0 %	Ph.Eur., USP-NF, JP

VIVAPHARM® HPMC

Hypromellose
Hydroxypropyl Methylcellulose

Physical Properties

Viscosity



VIVAPHARM® HPMC forms a viscous aqueous solution depending on grade and concentration.

VIVAPHARM® HPMC E 3 allows a high solid concentration due to the low viscosity.

VIVAPHARM® HPMC E 15 generates a higher viscosity at an equivalent level.

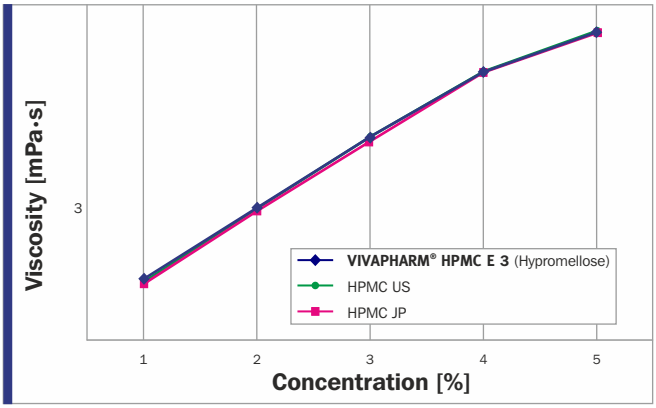
Viscosity in Comparison to Competitors

The viscosity of HPMC is one of its most important properties for the practical application, so a comparison study is useful. **VIVAPHARM® HPMC** is shown on the next page compared with other products of the same grade.

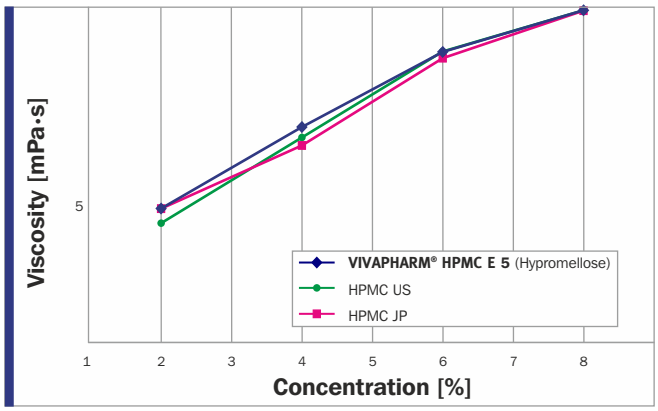
➡ **VIVAPHARM® HPMC in comparison to competitors' established standard materials shows very similar properties.**

VIVAPHARM® demonstrates equivalent functional performance characteristics.

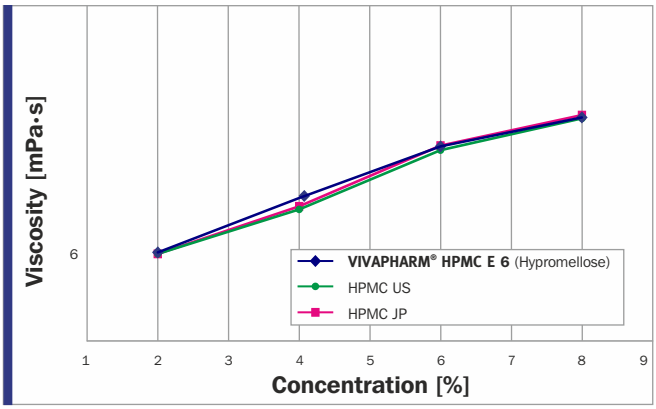
Viscosity 3 mPa•s



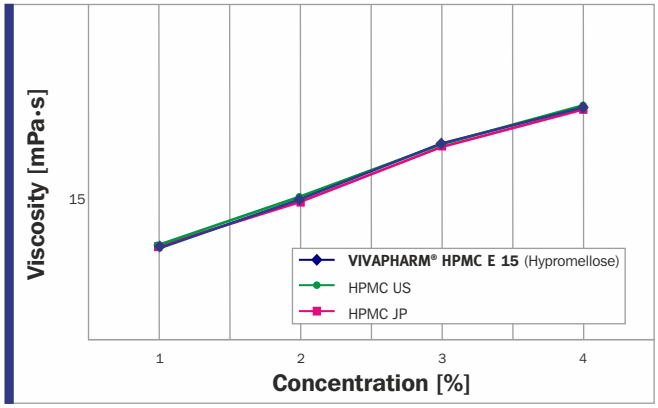
Viscosity 5 mPa•s



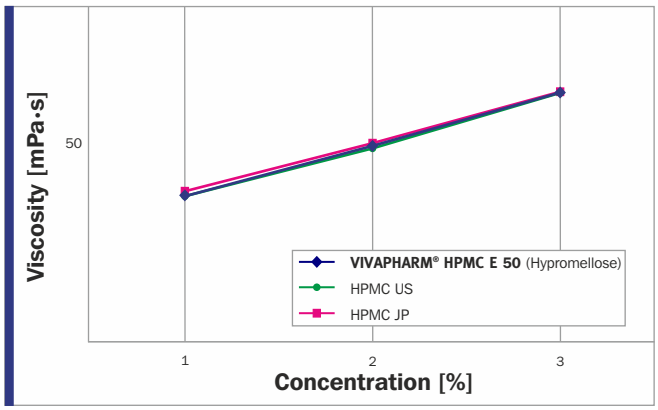
Viscosity 6 mPa•s



Viscosity 15 mPa•s



Viscosity 50 mPa•s



Remark: To simplify comparisons, a logarithmic presentation has been selected.

VIVAPHARM® HPMC

Hypromellose
Hydroxypropyl Methylcellulose

Application and Manufacturing

VIVAPHARM® for Use in Various Applications:

Application	Function of **VIVAPHARM® HPMC E**	**VIVAPHARM® HPMC E** Grade
Film Coating	Film	**VIVAPHARM® HPMC E 3, 5, 6, 15**
Wet Granulation	Binder	**VIVAPHARM® HPMC E 15**
Suspensions	Thickener	**VIVAPHARM® HPMC E 50**
Capsules	Major Constituent	**VIVAPHARM® HPMC E 3, 5**

A Basic Formulation for Film Coating

The following formulation can be regarded as a guideline for the preparation of a film coating suspension:

Basic Formulation

Function	Recommended Percentage	Substance
Polymer	62 %	**VIVAPHARM® HPMC E 5** or **E 6**
Plasticizer	7 %	Polyethylene Glycol (PEG), Glycerin
Pigments	31 %	Titanium Dioxide, Iron Oxides

JRS plant
Demacsa, Mexico

Packaging, Samples and Storage

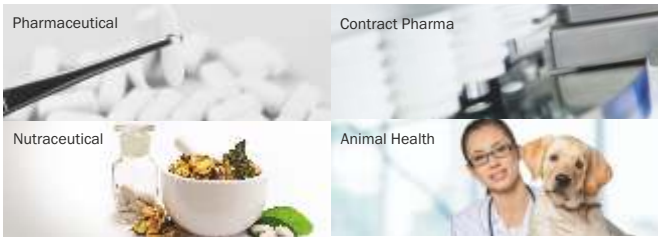
Storage
Protect from excessive heat and moisture.
Keep containers closed.

Packaging
Available in polyethylene-lined cartons

Sample Sizes
300 g or 1 kg aluminum bags available

JRS PHARMA JRS FAMILY
A Member of the JRS Group

• Excipients • Coatings
• Biopharma Services • Technical Services



Bringing Health Science to Life

Products and Services

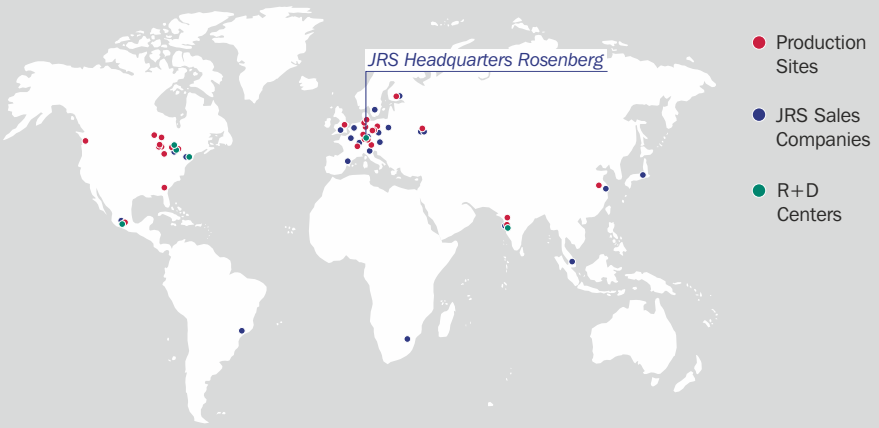
Excipients

Family of High Functionality Excipients
Binders
Functional Fillers
Lubricants
Thickeners+Stabilizers
Carriers
Superdisintegrants

Coatings

Biopharmaceuticals

Contract R+D
Manufacturing



ProJect Pharmaceutics
www.project-pharmaceutics.com

CELONIC
BEYOND BIOMANUFACTURING
www.celonic.com

Customers' Needs

Oral Dosage Forms
Biopharmaceuticals
Outsourcing
Animal Health
Nutraceuticals

Customers' Values

Convenience
Total Cost Savings
Global Services
Innovation

System Solution Supplier

12_02_GB_V7_0.51609KE

www.jrspharma.com