

KERRY

Leading to Better

SheffCel

Pharmaceutical Cellulose Ethers

Expanding Your Possibilities

kerry
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SheffCel: Expanding your Possibilities

Building on 75 years of innovation, commitment and reliability as a world class excipient supplier, Kerry introduces pharmaceutical cellulose ethers.

SheffCel cellulose ethers are multi-purpose excipients used in a variety of applications for pharmaceutical and nutritional supplements. We provide formulation, technical, regulatory and quality support through every step of your development, scale-up and production process. Expand your possibilities with SheffCel cellulose ethers.

Manufacturing Expertise

Kerry is committed to exceeding the cGMP expectations of our pharmaceutical customer base with our extensive quality assurance programs. Each batch is produced in accordance within approved specifications and are GMP compliant with IPEC guidelines as well as regional requirements globally.

Global Technical Support

Our core technical expertise and extensive knowledge in industrial pharmaceutical tablet manufacturing enables us to support our customers in optimizing SheffCel

performance and efficiency. We collaborate directly with formulators in the development process and will assist customers with trials and problem solve with production issues.

Regulatory and Quality Assurance

Kerry has a dedicated regulatory group to ensure product compliance to global regulatory requirements. Our regulatory team provides full customer support to customers in every step of the process including regional regulatory agency compliance, vendor forms, and audits. We understand the quality requirements and regulations needed to succeed.



What's In A Name

HPMC Key Criteria

HPMC has three key criteria that are controlled during manufacturing:

- The amount of substitution
- The viscosity
- The particle size



SheffCel Application Matrix

HPMC (Hydroxypropyl Methyl Cellulose)	Substitution Type	Viscosity (cP)	Film Coatings	Controlled Release	Wet Granulation Binder	Capsules	Thickening & Suspending Agent
SheffCel 60 HD3	2910	3	X		X		
SheffCel 60HD5		5	X		X	X	
SheffCel 60HD6		6	X		X	X	
SheffCel 60HD15		15	X		X		
SheffCel 60HD50		50			X	X	
SheffCel 60HD4000		4000					X
SheffCel 65HD50	2906	50			X		
SheffCel 65HD4000		4000					X
SheffCel 75HD100	2208	100					X
SheffCel 75HD4000		4000					X
SheffCel 75HD15000		15000					X
SheffCel 75HD100000		100000					X
SheffCel 75HD200000		200000			X		
SheffCel 75HD100CR		100			X		
SheffCel 75HD4000CR		4000			X		
SheffCel 75HD15000CR		15000			X		
SheffCel 75HD100000CR	100000			X			
HPMC-P (Hydroxypropyl Methyl Cellulose Phthalate)	Substitution Type	Viscosity (cP)	Film Coatings	Controlled Release	Wet Granulation Binder	Capsules	Thickening & Suspending Agent
SheffCel HP55	NA	32-48	X				
SheffCel HP55S		136-204	X				

SheffCel

Hydroxypropyl Methyl Cellulose

(CAS No.): 9004-65-3

HPMC is a multi-purpose excipient used in pharmaceutical and nutritional supplement applications. It is widely used as a film former in aqueous film coatings as well as controlled release formulations. HPMC functions as a thickener, dispersant, emulsifier, and binder in the tablet core.

The combination of HPMC with other polymers and colloidal APIs can prevent water and ethanol separation in colloidal API systems and improve water retention properties. Furthermore, it is used as an important raw material in the production of non-gelatin capsules.

Technical Specification

Complies with USP, EP and JP

Analysis	Specification		
	SheffCel 60HD	SheffCel 65HD	SheffCel 75HD
Substitution Type	2910	2906	2208
Assay – Hydroxypropoxy groups (%)	7.0 - 12.0%	4.0 - 7.5%	4.0% - 12.0%
Assay – Methoxy groups (%)	28.0 - 30.0%	27.0 - 30.0%	19.0% - 24.0%
Gelation temperature (°C)	58.0 - 64.0	62.0 - 68.0	70.0 - 90.0
Identification (A - E)	Conforms	Conforms	Conforms
Viscosity (2% in water)	Conforms to USP and EP	Conforms to USP and EP	Conforms to USP
pH (2% in water)	5.0 – 8.0	5.0 – 8.0	5.0 – 8.0
Heavy Metals	NMT 10 ppm	NMT 10 ppm	NMT 10 ppm
Arsenic	NMT 3 ppm	NMT 3 ppm	NMT 3 ppm
Loss on Drying	NMT 5.0%	NMT 5.0%	NMT 5.0%
Residue on Ignition	NMT 1.5%	NMT 1.5%	NMT 1.5%
Ash, Sulfated	NMT 1%	NMT 1%	NMT 1%
Appearance, opalescence	Conforms to EP	Conforms to EP	Conforms to EP
Appearance, solution	Conforms to EP	Conforms to EP	Conforms to EP
Chlorides	NMT 0.5%	NMT 0.5%	NMT 0.5%

Packaging

25kg net, polyethylene bag in a fiber drum.



Application

Tablets and Capsules

Low viscosity hypromellose grades of SheffCel are used for a number of purposes in pharmaceutical and nutritional supplement dose forms. SheffCel's solubility in water is pH independent. Individual

variations of pH in the GI tract of patients will not affect drug dissolution, making SheffCel an ideal excipient for immediate release film coatings, controlled release tablet matrixes, and tablet binders.

Product	USP substitution	Viscosity (cP)	Function
SheffCel 60HD3	2910	3	<ul style="list-style-type: none"> • Film former in tablet coatings • Binder for wet granulation tablets
SheffCel 60HD5	2910	5	<ul style="list-style-type: none"> • Film former in tablet coatings • Binder for wet granulation tablets • Capsule manufacturing
SheffCel 60HD6	2910	6	<ul style="list-style-type: none"> • Film former in tablet coatings • Binder for wet granulation tablets • Capsule manufacturing
SheffCel 60HD15	2910	15	<ul style="list-style-type: none"> • Film former in tablet coatings (high strength) • Pore former for sustained release coating formulations (in conjunction with ethylcellulose) • Binder for wet granulation tablets
SheffCel 60HD50	2910	50	<ul style="list-style-type: none"> • Binder for wet granulation tablets
SheffCel 65HD50	2906	50	<ul style="list-style-type: none"> • Binder for wet granulation tablets

Preparation of SheffCel Solution

SheffCel is soluble in water, alcohol, or organic solvent mixtures (such as dichloromethane / alcohol). The appropriate liquid should be stirred in the mixing kettle and then SheffCel should be added ensuring the particles are well dispersed and do not clump. Proper dispersion of SheffCel is necessary to provide the fastest dissolution. The well dispersed particles will dissolve in cold water in 30 - 60 minutes.



Film Coatings

SheffCel is widely utilized in immediate release tablet coatings. A clear coating formulation consists of SheffCel combined with appropriate plasticizer, such as polyethylene glycol, triethyl citrate, triacetin, or glycerin to yield an aqueous or solvent dispersion of 5% to 15% solids. The plasticizer should comprise 5% - 25% of the polymer. Pigments such as titanium dioxide, iron oxides, or aluminum lakes may be added at 25% to 50% of the weight of the polymer.



Binder

SheffCel can be used as a wet granulation binder in solution. Low use rates (1-5% of the tablet weight) minimize tablet size. The use of HPMC as a binder to produce granules to make a better flowing and more compressible blend, will lead to improved content uniformity.

Basic wet granulation procedure:

1. Prepare an aqueous solution of SheffCel (10-15%)
2. Blend the API, tablet excipients, and SheffCel solution in a high shear granulator.
3. Dry the granules and mill to the appropriate size.
4. Blend the granules with lubricant and any remaining excipients.
5. Compress tablets to desired weight and hardness.

Application: Ointments, Gels and Creams

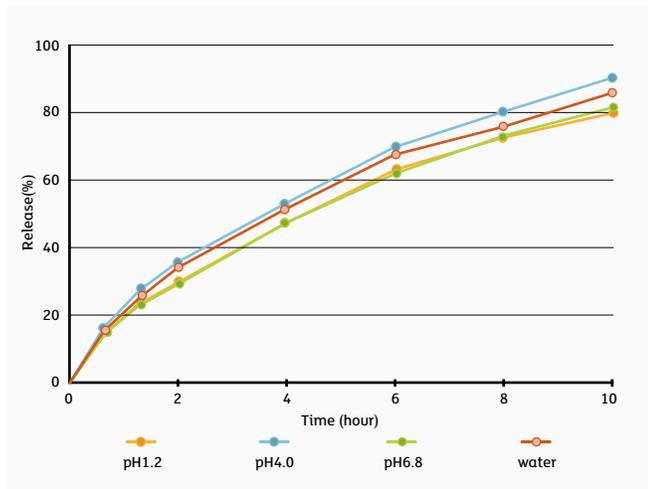
Higher viscosity grades of SheffCel are used as a thickening agent in ointments, gels, and creams. SheffCel can be used in gel drug formulations to prevent water separation.

Product	USP substitution	Viscosity (cP)	Function
SheffCel 60HD4000	2910	4000	Thickening and suspending agent
SheffCel 65HD4000	2906	4000	
SheffCel 75HD100	2208	100	
SheffCel 75HD4000	2208	4000	
SheffCel 75HD15000	2208	15000	
SheffCel 75HD100000	2208	100000	Controlled Release
SheffCel 75HD200000	2208	200000	

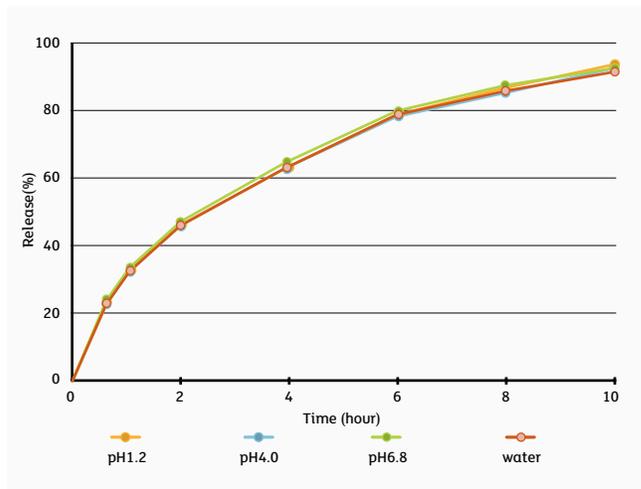
SheffCel CR: Control Released Grade

(CAS No.): 9004-65-3

Itopride HCl Sustained release dissolution test



Metformin HCl Sustained release dissolution test



Note: Extended release metformin tablets consist of 500 mg metformin HCl, 250 mg SheffCel 75HD100000CR, 125 mg SheffCel 75HD150000CR, 125 mg MCC, and 2.5 mg magnesium stearate.

Applications

Product	USP substitution	Viscosity (cP)	Function
SheffCel 75HD100CR	2208	100	Sustained Release tablet matrix with a use level varying between 20-80% of tablet weight
SheffCel 75HD4000CR		4000	
SheffCel 75HD15000CR		15000	
SheffCel 75HD100000CR		100000	

Packaging

25 kg net polyethylene bag in a fiber drum.



SheffCel HP: Hydroxypropyl Methyl Cellulose Phthalate

(CAS No.): 9050-31-1

HPMC-HP is an excellent enteric film coating mainly used for tablets and granules. The enteric coating material is pH dependant. SheffCel HPMC-HP is typically used for acid sensitive APIs when a methacrylic acid polymer cannot be used.

Technical Specification

Complies with USP, EP and JP.

Analysis	Specification	
	SheffCel HP55	SheffCel HP55S
Assay – Hydroxypropoxy groups (%)	5.0-9.0	5.0-9.0
Assay – Methoxy groups (%)	18.0-22.0	18.0-22.0
Assay - Phthaloyl groups (%)	27.0-35.0	27.0-35.0
Viscosity (2% in water)	32-48	136-204
Heavy Metals	NMT 10 ppm	NMT 10 ppm
Loss on Drying	NMT 5.0%	NMT 5.0%
Residue on Ignition	NMT 2.0%	NMT 2.0%
Chlorides	NMT 0.07%	NMT 0.07%

Preparation for Coating Solution

Product	Tablet	Application
SheffCel HP55	6-10%	Enteric film coatings - typical
SheffCel HP55S	5-8%	Enteric film coatings - higher strength

Packaging

12.5 kg net polyethylene bag in a fiber drum.



