who's responsibly solving for healthier lives?

we are.

pharmaceutical product and solution guide

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advancing drug delivery

Ashland's pharmaceutical business is core to the company's organic growth. As such, we're focusing resources on high value applications to meet customer priorities.

Well known for acetylenics, cellulosics, and film coatings, our polymers have a rich and diverse history supporting active pharmaceutical ingredient delivery. Using careful design and compositional selection, our scholarly, cited scientists possess the formulation and process expertise to match polymer architecture, material and physical characteristics to meet the challenges facing the most demanding pharma applications.

In addition to our commitment to pharmaceuticals and our foundational expertise, we offer the broadest range of excipients to compose effective oral solid dosage (OSD) and injectable pharmaceuticals. Deploying resources to build on our existing high impact and high value technologies, we are widening our portfolio of cellulose-based polymers (HPMC, HPC, CMC, HRC), growing our excipient portfolio for injectables/biologics, including the possibility for customization, and we're focusing on film coatings that live up to customer needs.

Our oral solid dosage and liquid dosage ingredients include controlled release agents, coatings, disintegrants, binders, rheology modifiers, and our expanding list of injectable excipient ingredients includes solubilizers, stabilizers, drug carriers, and other polymers used in long-acting formulations. These comprise Ashland's pharma portfolio, and it is the diamond at the center of Ashland.

Through direct-to-customer sales, along with select distribution partners, we reach more than 1,000 customers around the globe. They are our highest priority, and we back them with technical support when it's needed, anywhere in the world. Because we do business in ninety-five countries, we can source products and make them available whenever and wherever required. That makes us a reliable partner for the current and future needs of our global pharmaceutical partners.

Our products are primarily manufactured in-house, and we have been agile, resilient and steady, faring well during tough supply chain-related environments. For key product lines, the backwards integration strategy we employ enables the reliable supply our customers expect, and we possess the regulatory expertise to support our customers across all world regions.

As the pharmaceutical industry moves towards new methods of manufacturing, the Ashland pharmaceutical business can skillfully match chemistry to evolving needs. Ashland is investing in developing solutions for novel, fast growing therapeutics in the injectables and OSD marketplace. Leveraging exceptional strategic positioning and working collaboratively with our customers all over the world, we are helping to develop and deliver safe, high quality, effective ingredients for formulating and manufacturing medicine now and into the future.

Building on a strong reputation of trust, reliability, and high quality in this regulated space, Ashland is responsibly solving for healthier lives everywhere.

helping to ensure the efficacy, integrity and usability of pharmaceutical formulations

At Ashland, our number one goal is creating a zero incident culture where every employee is focused on continuously driving to zero incidents.

We strive to apply pharmaceutical excipients in ways that ensure the **efficacy**, **integrity** and **usability** of your formulations. Explore how our molecular scientists, chemists, formulation development scientists and process engineers can help advance formulation development, support the commercialization of complex drug molecules, and reduce time to market. Our problem-solving team leverages a diverse polymer portfolio to enable comprehensive solutions, so when you're ready to develop a formulation, we've got you covered.

	application											process			
	tablet binding	modified release	tablet film coating	drug solubilization	disintegration	lyophilization stabilizer	liquid rheology modification	suspending agent	stabilizer	crystallization inhibitor	parenteral/injectable controlled release	hot-melt extrusion	wet granulation	direct-compression tableting	continuous manufacturing
cellulosics – pages 6 - 11															
aqualon™ and blanose™ sodium carboxymethylcellulose	✓	✓	✓			✓	✓	✓		✓	✓		✓		✓
aqualon™ ethylcellulose **Ashland® EC pharm ultra**	✓	✓	✓									✓	✓	✓	✓
benecel™ hypromellose	✓	✓		✓			✓			✓			✓	✓	✓
benecel™ methylcellulose	✓	✓		✓			✓			✓			✓	✓	✓
benecel™ xrf															
klucel™ hydroxypropylcellulose	✓	✓	✓				✓					✓	✓	✓	✓
vinyl pyrrolidones – pages 12 - 13															
pharmasolve™ N-methyl-2-pyrrolidone				✓							✓				
plasdone™ povidone c grades				✓		✓	✓	✓		✓	✓				✓
plasdone™ povidone k grades	✓			✓			✓			✓			✓		✓
plasdone™ S-630 copovidone	✓		✓	✓						✓		✓	✓	✓	✓
polyplasdone™ crospovidone				✓	✓									✓	✓
bioresorbable polymers – pages 14 - 15															
viatel™ bioresorbable polymers											✓	✓			✓
sugars – pages 16 - 17															
CAVAMAX®, cavitron™ and **CAVASOL®** cyclodextrins				✓		✓			✓						
vialose™ trehalose dihydrate						✓									
film coating systems – pages 18 - 21															
aquarius™ film coating systems		✓	✓												✓

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cellulosics

aqualon™ and **blanose**™ sodium carboxymethylcellulose

Aqualon™ and Blanose™ CMC are anionic, water-soluble cellulose ethers, produced by reacting alkali cellulose with monochloroacetic acid under controlled conditions. A variety of grades with different degrees of substitution, viscosities and particle sizes to meet specific formulation requirements are available. Ashland provides CMC under the tradenames aqualon™ cmc and blanose™ cmc depending on site of manufacture.

features and benefits

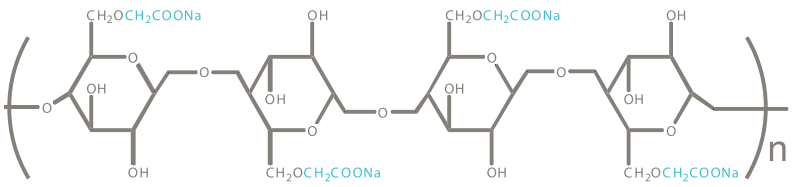
- bioburden and endotoxin tested (BET) grades available for parenteral applications
- suspending agent for two-component, injectable controlled-release systems
- stabilizer, thickener, and film-former for ointments, creams, and lotions
- thickener, gelling agent, protective colloid, and film-former for jellies and salves
- thickener and suspending aid for syrups and suspensions
- physiologically inert water binding agent for bulk laxatives
- absorbency and sustained-release properties for mucoadhesives
- enhanced organoleptic properties for orally disintegrating tablets (ODTs)

aqualon™ sodium carboxymethylcellulose (CMC)

viscosity (mPa•s)	solution concentration	degree of substitution		
		0.7	0.9	1.2
1500 - 2800	1%	7HF PH		
1500 - 2800	1%	7H3F PH		
1500 - 2800	1%	7HOF PH		
1840 - 2760	2%		9M31F PH	
1340 - 2000	2%			12M31P
470 - 700	2%	7MF PH		
470 - 700	2%	7MF PH BET		
400 - 720	2%	7M8SF PH		
400 - 720	2%		9M8F PH	
30 - 45	2%	7LF PH		
30 - 45	2%	7LF PH BET		
133 - 199	4%	7L2P		
133 - 199	4%	7L2P BET		

blanose™ sodium carboxymethylcellulose (CMC)

viscosity (mPa•s)	solution concentration	degree of substitution		
		0.7	0.9	1.2
2500 -4500 6750 - 12600	NF: 1% EP: 2%	7H4XF PH		
2500 -4500 6750 - 12600	NF: 1% EP: 2%		9H4XF PH	
1500 - 2800 6750 - 12600	NF: 1% EP: 2%	7H3SF PH		
1500 - 2800 6750 - 12600	NF: 1% EP: 2%	7H3SXF PH		
1500 - 2800 6750 - 12600	NF: 1% EP: 2%	7HOF PH		
1500 - 2500 6750 - 12600	NF: 1% EP: 2%	7HF PH		
1500 - 2500 6750 - 12600	NF: 1% EP: 2%	7HXF PH		
1500 - 2500 3750 - 12600	NF: 1% EP: 2%	7HCF PH		
N/A 1500 - 3100	NF: N/A EP: 2%	7M31F PH		
2075 - 3100 N/A	NF: 2% EP: N/A			12M31P
2075 - 3100 N/A	NF: 2% EP: N/A			12M31XP
1500 - 3100 1425 - 2660	NF: 2% EP: 2%		9M31F PH	
1500 - 3100 1425 - 2660	NF: 2% EP: 2%		9M31XF PH	
530 - 790 N/A	NF: 1% EP: N/A			12M8P
400 - 600 415 - 770	NF: 2% EP: 2%	7MF PH		
400 - 600 415 - 770	NF: 2% EP: 2%	7MXF PH		
400 - 600 415 - 770	NF: 2% EP: 2%	7MCF PH		
320 - 480 375 - 700	NF: 2% EP: 2%	7M8SF PH		
320 - 480 375 - 700	NF: 2% EP: 2%	7M8SXF PH		
27 – 50 34 - 63	NF: 2% EP: 2%	7LP EP		



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aqualon™ ethylcellulose and Ashland® EC pharm ultra

Aqualon™ ethylcellulose (EC) and Ashland® EC pharm ultra are non-ionic ethyl ethers of cellulose, soluble in a wide range of organic solvents. aqualon™ ec is produced using an aqueous slurry based process while Ashland® EC is produced using an organic solvent based process. Typically, ethylcellulose is used as a non-swellable, insoluble component in matrix or coating systems. When water-soluble binders cannot be used in dosage processing because of water sensitivity of the active ingredient, ethylcellulose is often chosen.

features and benefits

- rough, yet ductile thermoplastic polymer for compression molding or extrusion
- suitable for coating one or more active ingredients of a tablet to prevent APIs from reacting with other materials or one another
- yields flexible films over a wide range of temperatures
- non-ionic, pH insensitive
- prevents discoloration of easily oxidizable substances
- optimized compactability and good powder flow (aqualon™ ec T10)

aqualon™ ethylcellulose (EC)

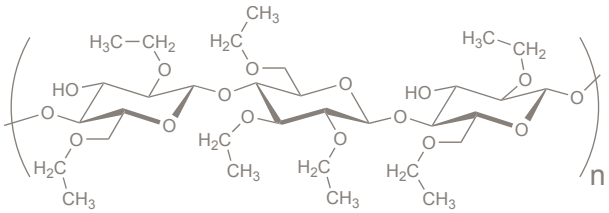
grade	ethoxyl substitution (%)	weight average molecular weight	typical Brookfield viscosity (mPa•s)[1]	solution concentration (%)
T10 Pharm	49.6–51.0	75,000	8–11	5
N7 Pharm	48.0–49.5	65,000	6–8	5
N10 Pharm	48.0–49.5	75,000	8–11	5
N14 Pharm	48.0–49.5	120,000	12–16	5
N22 Pharm	48.0–49.5	140,000	18–24	5
N50 Pharm	48.0–49.5	160,000	40–52	5
N100 Pharm	48.0–49.5	215,000	80–105	5

[1]Viscosity measured in 80:20 mixture of toluene/ethanol

Ashland® EC pharm ultra

grade	ethoxyl substitution (%)	weight average molecular weight	typical Brookfield viscosity (mPa•s)[1]	solution concentration (%)
N4			3.0 – 5.5	
N7			6.0 – 8.0	
N10			9.0 – 11.0	
N14			12.5 – 15.5	
N20			18.0 – 22.0	
N45			41.0 – 49.0	
N50			45.0 – 55.0	
N100			90.0 – 110.0	

[2] 5% solution of 80/20 mixture of toluene/ethanol



benecel™ hydroxypropyl methylcellulose (HPMC) or hypromellose

Benecel™ HPMC is the most widely used polymer in hydrophilic matrix systems with widespread use in controlled-release dosage forms. The benecel™ family of pharmaceutical products provides a full portfolio to support the controlled release of a broad range of APIs and manufacturing processes.

benecel™ **XRF** HPMC

grades: K4M, K15M, K100M, K200M

Benecel™ XRF is a high-viscosity grade of HPMC with optimized polymer structure and particle morphology for use in matrix controlled-release systems.

features and benefits

- enhanced compactibility at high tableting speeds vs standard grades
- optimized polymer structure and particle morphology
- consistent particle size distribution and bulk density

substitution type	grade	weight average molecular weight	solution concentration	nominal viscosity (mPa•s)[a]
hypromellose 2910 "E" types	E4M Pharm, E4M Pharm CR	400,000	2%	2,700–5,040
	E10M Pharm, E10M Pharm CR	746,000	2%	7,500–14,000
hypromellose 2208 "K" types	K4M Pharm XRF	400,000	2%	2,700 – 5,040
	K15M Pharm XRF	575,000	2%	13,500 – 25,200
	K35M Pharm	675,000	2%	26,250 – 49,000
	K100M Pharm XRF	1,000,000	2%	75,000 – 140,000
	K200M Pharm XR	1,200,000	2%	150,000 – 280,000

[a]NF/EP/JP viscosity method

directly compressible
benecel™ **PH DC** HPMC

grades: K4M, K15M, K100M

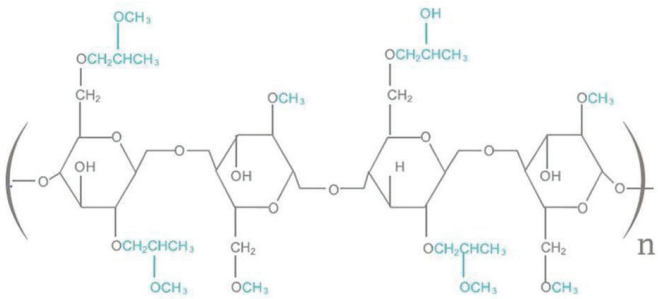
Benecel™ DC HPMC grades offer good powder flow, content uniformity, and compressibility, making them well suited for direct compression.

features and benefits

- improves product flow characteristics
- improves content uniformity
- identical, stable dissolution profiles compared with "XR" grades
- dissolution profile similar to non-directly compressible grades of hypromellose
- reduces production costs
- retains tensile strength after double compaction (roller compaction) process

substitution type	grade	weight average molecular weight	solution concentration	nominal viscosity (mPa•s)[a]
hypromellose 2208 "K" types	K4M PH DC[1]	400,000	2%	2,700–5,040
	K15M PH DC[1]	575,000	2%	13,500–25,200
	K100M PH DC[1]	1,000,000	2%	75,000–140,000

[a]NF/EP/JP viscosity method
[1]these grades are co-processed with silica at <1 %



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custom grades

benecel™ PH PRM

grades: K100LV, K250, K750, K1500

For certain drugs, achieving a desired drug release profile has traditionally involved blends of different molecular weights of polymers. Blending, however, can increase release profile variability. Custom grades of benecel™ hpmc were developed to obviate the need for blending and offer a potential solution to the problem of dissolution variability.

features and benefits

- increases predictability and reproducibility of drug release profiles
- decreases research and development time needed to optimize blend ratio
- decreases manufacturing time–no need to blend and manage multiple raw materials

substitution type	grade	weight average molecular weight	solution concentration	nominal viscosity (mPa•s)[a]
hypromellose 2208 "K" types	K100 LV PH PRM	164,000	2%	80 – 120
	K250 PH PRM	200,000	2%	200 – 300
	K750 PH PRM	250,000	2%	562 – 1050
	K1500 PH PRM	300,000	2%	1,125 – 2,100

[a] NF/EP/JP viscosity method

benecel™ methylcellulose (MC)

Benecel™ methylcellulose (MC) is a versatile excipient with a variety of applications.

features and benefits

- suspending/thickening agent for suspensions
- viscosity modifier
- acceptable binder for tablets

substitution type	grade	nominal viscosity (mPa•s)[a]
methylcellulose	A15 LV PH PRM	12–18
	A4C Pharm	300–560
	A15C Pharm	1,312–2,450
	A4M Pharm	2,700–5,040

[a] NF/EP/JP viscosity method

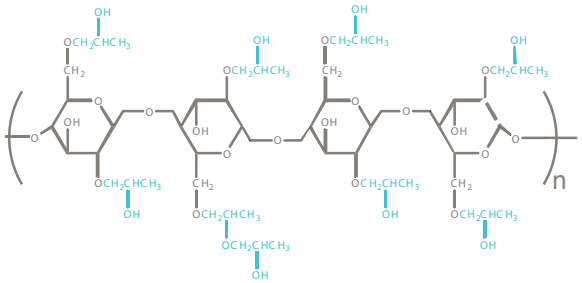
klucel™ hydroxypropylcellulose

Klucel™ hydroxypropylcellulose (HPC) provides a remarkable set of physical properties for tablet binding, modified release, film coating, and hot melt extrusion. The versatility of klucel™ hpc is apparent in a variety of pharmaceutical applications. Low molecular weight grades provide not only unmatched, efficient tablet binding but also adhesive and elastic tablet coating. They can also be used in melt-extrusion applications. High molecular weight grades are typically used for modified release, especially in matrix tablets.

features and benefits

- unsurpassed tablet hardness and friability
- excellent thermoplastic and mechanical properties for tablet binding
- soluble in aqueous and organic solvents
- fine particle size grades available for enhanced performance when dry processing
- save costs through improving yields and reducing the amount of other additives
- flexible films without plasticizers and non-tacky at high humidity

grade (X = Fine)	weight average molecular weight	typical brookfield viscosity (mPa•s)	solution concentration (%)
HF Pharm, HXF Pharm Xtend HXF Pharm	1,150,000	1,500–3,000	1
MF Pharm, MXF Pharm	850,000	4,000–6,500	2
GF Pharm, GXF Pharm	370,000	150–400	2
JF Pharm, JXF Pharm	140,000	150–400	5
LF Pharm, LXF Pharm	95,000	75–150	5
EF Pharm, EXF Pharm, EXF Ultra Pharm	80,000	300–600	10
ELF Pharm	40,000	150–300	10



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klucel™ EXF ultra hydroxypropylcellulose

Klucel™ EXF Ultra HPC takes tablet binding effectiveness to the next level. Need premium performance that assures formulation predictability, reliability and robustness? Klucel™ EXF Ultra HPC is your solution.

features and benefits

- exceptional plasticity
- outstanding compressibility
- enhanced tablet strength
- enables smaller tablets
- low friability even at low usage levels
- low impact on disintegration time

NEW klucel™ xtend hydroxypropylcellulose

Klucel™ xtend hydroxypropylcellulose (HPC) is the new gold standard in oral matrix formers for extended-release tablets. Designed to deliver unsurpassed process versatility and release profile efficiency. Klucel™ xtend HPC, extending your options and allowing you to do more with less.

features and benefits

- high gel strength
- consistent release profiles at significantly lower concentrations than hydroxypropyl methylcellulose (HPMC)
- enables smaller tablets and improved consumer usability
- reduced burst effect and lower risk of dose dumping after reduced burst effect
- low melt processing temperature
- enables robust formulation regardless of process technology
- excellent performance in direct compression, wet granulation, dry granulation, and hot melt extrusion
- the only cellulosic excipient that provides a compendial extended-release polymer option for plasticizer-free HME.

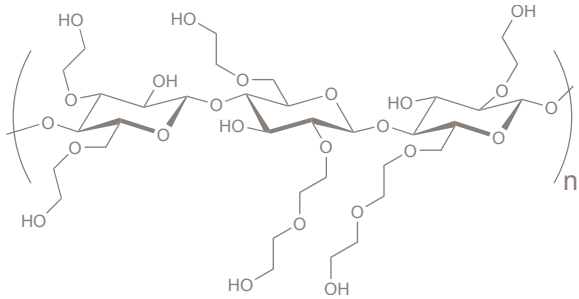
natrosol™ 250 hydroxyethylcellulose

Natrosol™ 250 hydroxyethylcellulose (HEC) is a nonionic water-soluble cellulose ether. Natrosol™ 250 HEC is easily dispersed in cold or hot water to give solutions of varying viscosities and desired properties, though it is insoluble in organic solvents. It is used in solutions and gels to control rheology, in emulsions for high-salt tolerance and surfactant compatibility and in modified-release matrix tablets, where high-viscosity grades provide effective diffusion-limiting release of active pharmaceutical ingredients (API) with low water solubility.

features and benefits

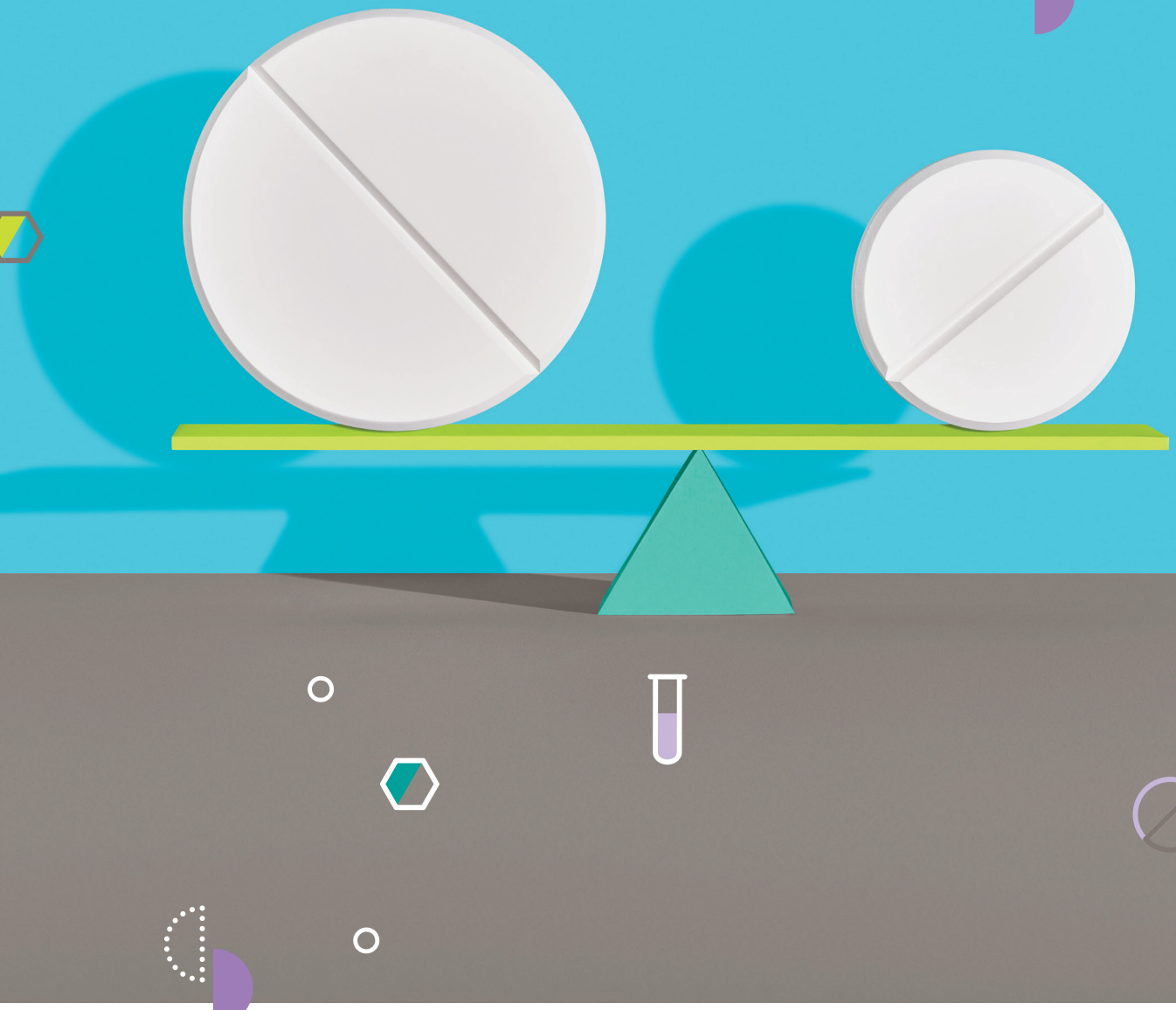
- any desired thickening efficiency can be achieved with the wide variety of grades available
- compatible in solutions with many inorganic salts, as well as with a broad range of other materials such as surfactants, solubilizers, and preservatives
- stable over a broad pH range, with the viscosity of the solutions being largely unaffected
- suitable to match typical viscosity profiles of pharmaceutical syrups
- gels in solution to control rheology
- easily dispersed in cold or hot water

grade (X = Fine, W = Superfine)	weight average molecular weight	typical brookfield viscosity (mPa•s)	solution concentration
HHX Pharm, HHW Pharm	1,300,000	3,500–5,500	1%
HX Pharm, H Pharm	1,000,000	1,500–2,500	1%
M Pharm	720,000	4,500–6,500	2%
G Pharm	300,000	250–400	2%
L Pharm	90,000	75–150	5%



who gives more for less?

new klucel™ xtend hpc



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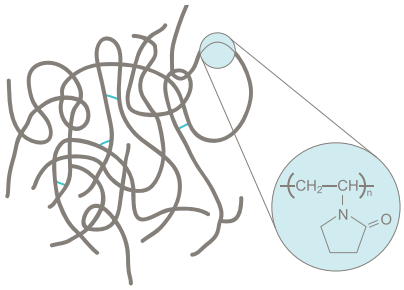
vinyl pyrrolidones

polyplasdone™ crospovidone

Polyplasdone™ crospovidone superdisintegrants are synthetic, insoluble, but rapidly swellable, crosslinked homopolymers of N-vinyl-2-pyrrolidone. Polyplasdone™ crospovidone particles are granular and porous compared with other superdisintegrants. The high surface area combined with unique chemistry results in high interfacial activity that enhances the dissolution of poorly water-soluble active pharmaceutical ingredients (APIs) in a way that is not possible with other disintegrant technologies.

features and benefits

- provides rapid disintegration in wet and dry granulation and direct compression tablet processes
- combines multiple mechanisms to achieve disintegration at low use levels (2-5 wt%)
- swells without forming gels that can slow tablet disintegration or dissolution
- increases tablet breaking force and reduces friability
- enhances the dissolution of poorly soluble drugs
- available in Type A and Type B crospovidone grades
- **polyplasdone**™ **ultra** and **ultra-10** grades provide the same great performance with very low peroxide levels



grade	typical average particle size (microns)	peroxide specification (ppm)
Ultra[1]	110–140	30 max
XL[1]	110–140	400 max
Ultra-10[2]	25–40	50 max
XL-10[2]	25–40	400 max
INF-10[2]	10–15	400 max

[1] Crospovidone monograph type A
[2] Crospovidone monograph type B

plasdone™ S-630 copovidone

Plasdone™ S630 copovidone is a 60:40 random, linear copolymer produced by the free radical polymerization of N-vinyl-2-pyrrolidone and vinyl acetate. It is commonly used to enhance the solubility of APIs and increase bioavailability of poorly water-soluble APIs through the formation of melt-extruded or spray-dried solid dispersions. It can also be used as a binder in direct compression, dry granulation, or wet granulation, resulting in hard, non-friable tablets.

features and benefits

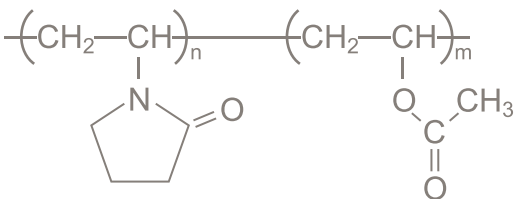
- excellent thermoplastic properties for HME
- amorphous solid dispersion stabilizer
- compatible with most plasticizers

plasdone™ S-630 ultra copovidone

Plasdone™ S630 Ultra copovidone is a new and improved version of copovidone. It was designed to provide improved stability in tablet formulations, and processability in hot melt extrusion, and continuous processing.

features and benefits

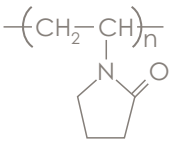
- provides greater long-term stability for oxidative sensitive APIs
- efficient, high throughput, energy saving binder/solubilizer/carrier for hot melt extrusion and continuous processes



grade	weight average molecular weight[a]	K-value viscosity
S-630	43,000	25.0–31.0
S-630 ultra	34,000	23.4–28.6

[a] Absolute molecular weight (SEC/MALLS)

plasdone™ povidone



Plasdone™ povidones are a family of water-soluble polymers based on N-vinylpyrrolidone that combine a unique set of properties for application in a wide variety of dosage forms. Plasdone™ povidones are commonly used as binders for the development of tablet formulations, whether manufactured by wet granulation, dry granulation, or direct compression. Plasdone™ K polymers are used in solid dispersion formulations to enhance the solubility of active pharmaceutical ingredients and increase bioavailability. Plasdone™ K grades are also used to inhibit recrystallization in liquid soft gels. Plasdone™ C grades can inhibit crystallization in injectable dosage forms.

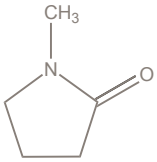
features and benefits

- amorphous solid dispersion stabilizer
- monomer is hydrogen bond acceptor
- compatible with most plasticizers
- low pyrogen grades for injectables (Plasdone™ C grades)

grade[a]	weight average molecular weight[b]	K-value viscosity
K-12	4,000	10.2–13.8
K-17	10,000	16.0–17.5
K-25	34,000	24–26
K-29/32	58,000	29–32
K-90	1,300,000	85–95
C-12	4,000	10.2–13.8
C-15	9,400	15.5–17.5
C-17	10,000	16.0–17.5
C-30	58,000	29.0–32.0

[a] C grades have low pyrogen levels [b] Absolute molecular weight (SEC/MALLS)

pharmasolve™ N-methyl-2-pyrrolidone



Pharmasolve™ N-methyl-2-pyrrolidone (NMP) is a water-miscible polar aprotic solvent with high interfacial activity. It is used as a solubilizer and penetration enhancer in human parenteral and topical-dosage forms, as well as parenteral and topical veterinary products.

features and benefits

- dissolves a variety of poorly soluble APIs

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bioresorbable polymers

viatel™ bioresorbable polymers

Ashland offers five families of bioresorbable polymers for parenteral controlled release drug delivery systems and medical devices. For drug delivery, Ashland offers amorphous homopolymers and copolymers, including:

- Poly(D, L-lactide) (PDLLA) and
- Poly(D, L-lactide-co-glycolide) (PLGA)

For medical devices, Ashland offers semi-crystalline and amorphous homopolymers and copolymers including:

- Poly(L-lactide) (PLLA),
- Poly(ε-caprolactone) (PCL) and
- Poly(L-lactide-co-ε-caprolactone) (PLCL)

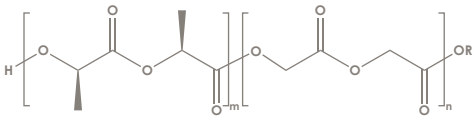
All Ashland viatel™ bioresorbable polymers can be custom produced with defined chemical structures, molar masses (molecular weight or inherent viscosity) and selective terminal end groups.

features and benefits

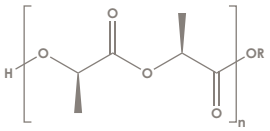
- excellent product quality
- high purity
- stock and custom made to order grades available
- available in granule and powder forms

R = H = Acid R = CH_3 = Ester

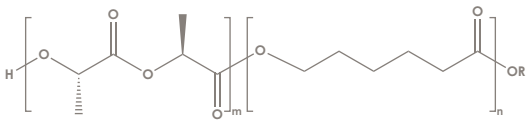
PLGA [Poly(D,L-lactide-co-glycolide)]



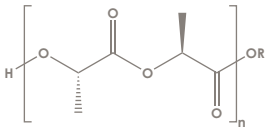
PDLLA [Poly(D,L-lactide)]



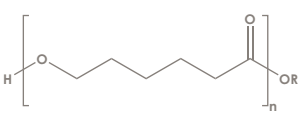
PLCL [Poly(L-lactide-co-caprolactone)]



PLLA [Poly(L-lactide)]



PCL [Polycaprolactone]



viatel™ bioresorbable polymers for drug delivery

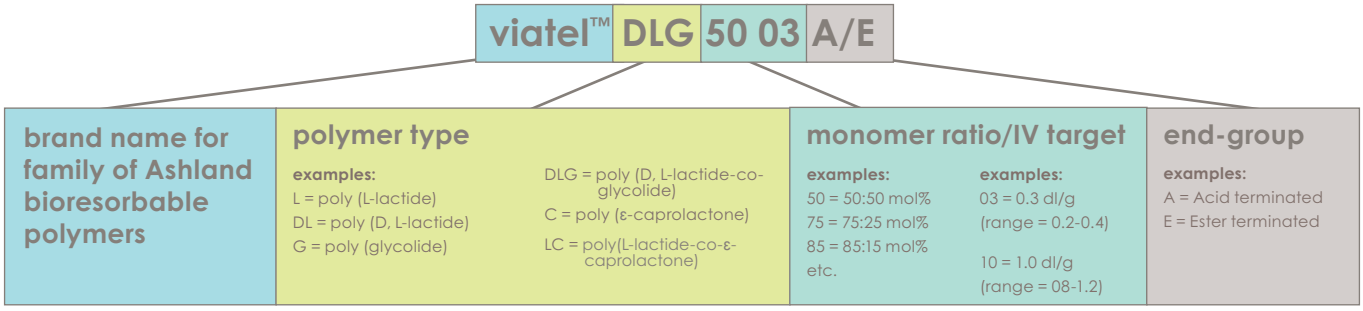
product**	polymer	*molar ratio (D,L LA: GA)	inherent viscosity range (dl/g)**	end group	product grade
PLGA	poly(D, L-lactide-co-glycolide)	50:50	0.1 – 0.3	Acid / Ester	Viatel™ DLG 5002 A/E
PLGA			0.2 – 0.4	Acid / Ester	Viatel™ DLG 5003 A/E
PLGA			0.4 – 0.6	Acid / Ester	Viatel™ DLG 5005 A/E
PLGA			0.6 – 0.8	Acid / Ester	Viatel™ DLG 5007 A/E
PLGA			0.8 – 1.0	Acid / Ester	Viatel™ DLG 5009 A/E
PLGA		55:45	0.2 – 0.4	Acid / Ester	Viatel™ DLG 5503 A/E
PLGA			0.4 – 0.6	Acid / Ester	Viatel™ DLG 5505 A/E
PLGA		65:35	0.2 – 0.4	Acid / Ester	Viatel™ DLG 6503 A/E
PLGA		75:25	0.1 – 0.3	Acid / Ester	Viatel™ DLG 7502 A/E
PLGA			0.2 – 0.4	Acid / Ester	Viatel™ DLG 7503 A/E
PLGA			0.4 – 0.6	Acid / Ester	Viatel™ DLG 7505 A/E
PLGA			0.6 – 0.8	Acid / Ester	Viatel™ DLG 7507 A/E
PLGA			0.8 – 1.0	Acid / Ester	Viatel™ DLG 7509 A/E
PLGA			1.0 – 1.2	Acid / Ester	Viatel™ DLG 7511 A/E
PLGA			1.2 – 1.4	Acid / Ester	Viatel™ DLG 7513 A/E
PLGA		80:20	0.1 – 0.3	Acid / Ester	Viatel™ DLG 8002 A/E
PLGA			0.2 – 0.4	Acid / Ester	Viatel™ DLG 8003 A/E
PLGA		85:15	0.1 – 0.3	Acid / Ester	Viatel™ DLG 8502 A/E
PLGA			0.2 – 0.4	Acid / Ester	Viatel™ DLG 8503 A/E
PLGA			0.4 – 0.6	Acid / Ester	Viatel™ DLG 8505 A/E
PLGA			0.6 – 0.8	Acid / Ester	Viatel™ DLG 8507 A/E
PLGA			0.8 – 1.0	Acid / Ester	Viatel™ DLG 8509 A/E
PDLLA	poly(D, L-lactide)	100:0	0.1 – 0.3	Acid / Ester	Viatel™ DL 02 A/E
PDLLA			0.2 – 0.4	Acid / Ester	Viatel™ DL 03 A/E
PDLLA			0.4 – 0.6	Acid / Ester	Viatel™ DL 05 A/E
PDLLA			0.6 – 0.8	Acid / Ester	Viatel™ DL 07 A/E
PDLLA			0.8 – 1.0	Ester	Viatel™ DL 09 E
	Poly(ethylene glycol) methyl ether-block-poly(D,L lactide)	—	0.33 – 0.38*	mPEG (Mn 5,000 Da)	Viatel™ DL 03 PEG5K

*D, L-LA: D, L-lactide. GA: glycolide **inherent viscosity ranges per grade can be narrowed to meet customer requirements*

viatel™ bioresorbable polymers for medical devices

product**	polymer	*molar ratio (L: CL)	inherent viscosity range (dl/g)	end group	product grade
PLLA	Poly(L-lactide)	—	0.8 – 1.2	Ester	Viatel™ L 10 E
PLLA		—	1.2 – 1.6	Ester	Viatel™ L 14 E
PLLA		—	1.6 – 2.0	Ester	Viatel™ L 18 E
PCL	Poly(ε-caprolactone)	—	1.0 – 1.4	Ester	Viatel™ C 12 E
PCL		—	1.6 – 2.0	Ester	Viatel™ C 18 E
PLCL	Poly(L-lactide-co-ε-caprolactone)	60:40	1.0 – 1.4	Ester	Viatel™ LC 6012 E
PLCL		70:30	1.0 – 1.4	Ester	Viatel™ LC 7012 E
PLCL		80:20	1.0 – 1.4	Ester	Viatel™ LC 8012 E
PLCL		90:10	1.0 – 1.4	Ester	Viatel™ LC 9012 E

* *Molar ratio here only applies to PLCL copolymers: L: L-lactide, CL: ε-caprolactone*



Ashland™ always solving

sugars

CAVAMAX*, CAVASOL* and **cavitron**™ cyclodextrins

The molecular structure of cyclodextrins creates a bucket-like cavity that can complex with molecules or functional groups on molecules to improve solubility of poorly soluble compounds. The same mechanism makes these excipients capable of masking unpleasant taste/odor and stabilizing APIs that are prone to degradation.

CAVAMAX* native cyclodextrins

The number of glucose units in the ring determines the internal diameter of the cavity and its volume, as the height of the cyclodextrin cavity is the same for all the native cyclodextrin grades. CAVAMAX cyclodextrins are compatible with a wide range of ingredients commonly used in pharmaceutical applications.

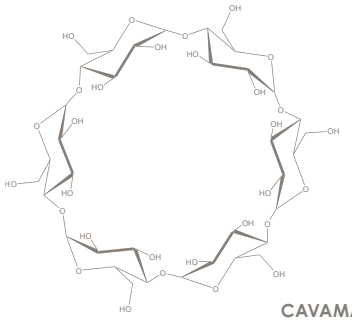
CAVASOL* and **cavitron**™ hydroxypropyl-ß- or hydroxypropyl-γ-cyclodextrins (HPBCD or HBGCD)

The substitution of hydroxyl groups on native cyclodextrins to make hydroxypropyl-ß- or hydroxypropyl-γ-cyclodextrins (HPBCD or HBGCD) significantly enhances their solubility. Both CAVASOL HPBCD and HPGCD are primarily used to increase solubility of poorly soluble compounds in oral drug-delivery systems. Cavitron cyclodextrins are manufactured and tested to meet low bioburden and endotoxin specifications.

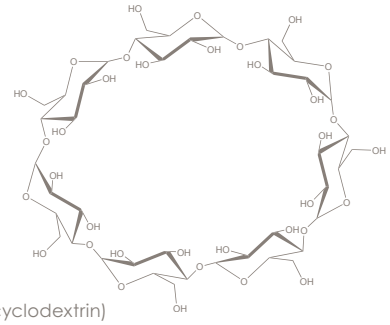
features and benefits

- starch derived, ring shaped molecule
- water soluble
- hydrophilic exterior and hydrophobic interior for improved solubility

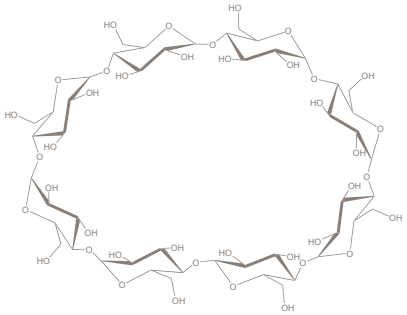
CAVAMAX* w6 (a-cyclodextrin)



CAVAMAX* w7 (ß-cyclodextrin)



CAVAMAX* w8 (γ-cyclodextrin)



native cyclodextrins

product and grade	weight average molecular weight	cyclodextrin type
CAVAMAX® W6 Pharma	973	α-cyclodextrin
CAVAMAX® W7 Pharma	1,135	β-cyclodextrin
CAVAMAX® W8 Pharma	1,297	γ-cyclodextrin

® Registered trademark owned by Wacker Chemie AG. Ashland acts as a worldwide distributor for Wacker.

cyclodextrin derivatives

product and grade	weight average molecular weight	typical degree of substitution
CAVASOL® W7 HP Pharma	1,410	4.1–5.1
cavitron™ W7 HP5 Pharma	1,410	4.1–5.1
cavitron™ W7 HP7 Pharma	1,520	6.0–8.0
CAVASOL® W8 HP Pharma	1,574	3.5-4.9

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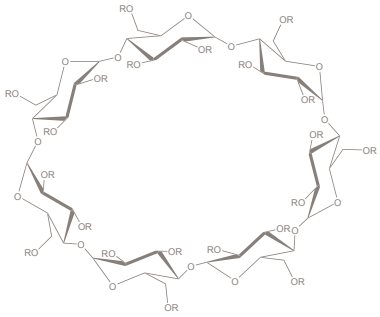
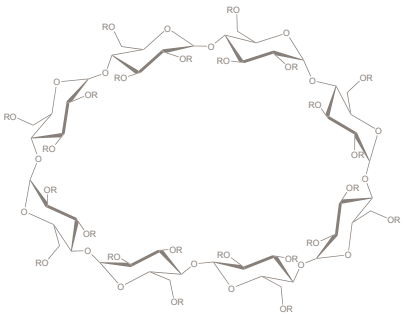
CAVASOL® and **cavitron™** w7(HPBCD)



CAVASOL® and **cavitron™** w8(HPBCD)

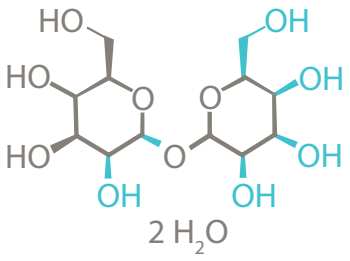


NEW vialose™ trehalose dihydrate

vialose™ trehalose diyhrate is a premier performance sugar used to protect and shield biologic APIs like recombinant proteins and monoclonal antibodies (mAbs) from degradation and aggregation. It can also be used to stabilize and protect valuable components during the lyophilization process including liposomes and cells.

features and benefits

- non-reducing sugar resistant to acid hydrolysis and enzymatic cleavage
- protects therapeutic proteins, mAbs and whole cells during freeze-thaw cycles
- produces non-collapsible lyo-cakes



film coating systems

aquarius™ film coating systems for immediate release

grade	application	detail
genesis*	aesthetic	ultra high-solids based on copovidone and cellulosic polymers that provides a strong film with high adhesion and smooth appearance
preferred*	HSC aesthetic	high-solids coatings based on cellulosic polymers
preferred*	HSP aesthetic	high-solids coatings based on copovidone with cellulosic polymers for significant improvements in adhesion and sprayable solids
prime*	aesthetic	coatings based on traditional cellulosic polymers
prime	LS aesthetic	coatings based on lactose and cellulosic polymers with significant improvements in film adhesion
protect	moisture barrier and odor & flavor masking	label-friendly moisture, odor and taste guard
protect	MB moisture barrier and odor & flavor masking	high-solids moisture barrier coatings based on polyvinyl alcohol (PVA) without the use of polyethylene glycol (PEG)
pva*	aesthetic and mositure barrier	versatile coating systems with improved performance characteristics

* titanium dioxide free options available

aquarius™ genesis film coating systems

Aquarius™ genesis film coating systems are designed for application at up to 35% solids, which can significantly increase productivity of continuous or traditional batch-based coating equipment. They have been formulated to provide a strong film with high adhesion and smooth appearance.

features and benefits

- faster coatings and processing with ultra-high solids (35%)
- lower processing temperatures–suitable for temperature sensitive APIs
- minimizes moisture ingress to tablets
- supports energy and costs savings
- wide processing window helps overcome equipment limitations
- disperses easily in water

aquarius™ preferred HSC film coating systems

Aquarius™ preferred HSC film coating systems are ready-to-use, immediate-release coatings based on cellulosics. These products can be applied at up to 20% solids. They are available as clear, white, or pigmented formulations.

features and benefits

- reduces processing times
- reduces manufacturing costs
- high-solids coatings
- disperses easily in water
- can be tailored to meet customized requirements
- applicable to both pharmaceutical and nutraceutical solid dosage forms

aquarius™ prime film coating systems

Aquarius™ prime film coating systems are immediate-release tablet coatings consisting of a polymer, a plasticizer, and an optional pigment/opacifier. These film coating systems are available off the shelf in clear and white formulations.

features and benefits

- meets general purpose film coating requirements
- good film strength and adequate film adhesion characteristics
- disperses easily in water
- capability to address common film coating problems
- immediate release

aquarius™ preferred HSP film coating systems

Aquarius™ preferred HSP film coating systems are ready-to-use, immediate-release coatings based on cellulosic and copovidone polymers. These products can be applied at up to 25% solids, allowing for shorter processing times. They are available as white, clear, or pigmented formulations.

features and benefits

- excellent adhesion
- minimizes moisture ingress to tablets
- high tablet gloss and smooth finish
- high-solids coatings enabling cost and energy savings
- disperses easily in water
- applicable to both pharmaceutical and nutraceutical solid dosage forms

aquarius™ prime LS film coating systems

Aquarius™ prime LS film coating systems are made from hypromellose (HPMC) and lactose and are intended to be qualitatively, quantitatively, and functionally equivalent to competitive lactose-based film coating systems.

features and benefits

- significant improvement in film adhesion capabilities compared with standard HPMC-based film coating systems
- sprayable at up to 20% w/w solids but, more realistically, at 17–18% w/w solids

aquarius™ protect
film coating systems

Aquarius™ protect is the premium multi-functional barrier coating system that effectively reduces moisture uptake and masks against offensive taste and odor. These coating systems, composed of cellulose derivatives and a natural wax blend, provide superior barrier properties and efficient processing and flexibility without compromising drug release.

features and benefits

- provides protection from moisture and objectionable odors and tastes
- remains non-tacky at low processing temperatures allowing far energy savings
- very effective under environmental conditions defined as zones 4 and 5 by stability guidelines
- available as clear, white, and pigmented formulations

aquarius™ PVA
film coating systems

Aquarius™ PVA film coating systems are versatile coating systems with improved performance characteristics that maximize product quality and enhance processing efficiency. They have been formulated for a wide variety of pharmaceutical and nutritional applications. Aquarius™ PVA film coating systems are intended for use with immediate-release dosage forms.

features and benefits

- high film adhesion
- attractive appearance and finish
- enhanced processing efficiencies
- clean, crisp logos
- clear and pigmented options that can be color matched

aquarius™ protect MB
film coating systems

Aquarius™ protect MB film coating systems are fully formulated, ready to mix, high solids moisture barrier coatings based on polyvinyl alcohol (PVA) without the use of polyethylene glycol (PEG). These coating systems have easy and efficient application using standard spray equipment and process conditions.

features and benefits

- moisture and oxygen barrier functionalities
- PEG free, reduces risk of impurity formation
- effective under environmental conditions defined as zones 4 and 5 by stabiliy guidelines
- available as clear, white, and pigmented formulations

aquarius™ TF
film coating systems

Aquarius™ TF film coating systems are formulated without the use of titanium dioxide as the opacifier filler for application to immediate-release dosage forms.

features and benefits

- white coatings comparable to TiO_2-based coatings
- attractive appearance and finish
- clean, crisp logo definition
- aqueous systems available in clear, white, or pigmented (synthetic or naturally derived color) versions
- available in a wide range of solids applications (15% to 30%) and polymer-based options
- application at high solids overcomes manufacturing inefficiencies associated with the required higher tablet weight gain related to TF coatings





aquarius™ film coating systems for enteric release

grade	descriptor	detail
control	ENA	delayed-release (enteric) coatings based on methacrylic acid-ethyl acrylate copolymer

aquarius™ control ENA film coating systems

Aquarius™ control ENA film coating systems are fully formulated delayed release (enteric) coatings based on methacrylic acid copolymer. They are designed to protect APIs that degrade in gastric fluid or prevent the release of APIs that may irritate the gastric mucosa.

features and benefits

- fully formulated, one step coating
- produces stable release profiles
- delivers stable dissolution profiles over a wide pH range
- prevents release of APIs that may irritate the gastric mucosa
- protects active pharmaceutical ingredients (APIs) that degrade in gastric fluid

aquarius™ film coating systems for controlled release

grade	descriptor	detail
control	ECD	aqueous dispersion for controlled release based on ethylcellulose
control	SRX	controlled release coatings based on ethylcellulose

aquarius™ control SRX film coating systems

Aquarius™ control SRX film coating systems are controlled release coatings for APIs that are most effective when released over time. These film coating systems produce predictable and controllable release profiles, are custom formulated based on solubility and desired release profile, and do not require a curing step.

features and benefits

- modified with hydroxypropyl cellulose or hydroxypropyl methyl cellulose as a pore former
- variable porosities can be matched to active pharmaceutical ingredient solubility and/or desired release profile
- suitable for moisture and heat sensitive actives
- do not require curing after application

aquarius™ control ECD film coating systems

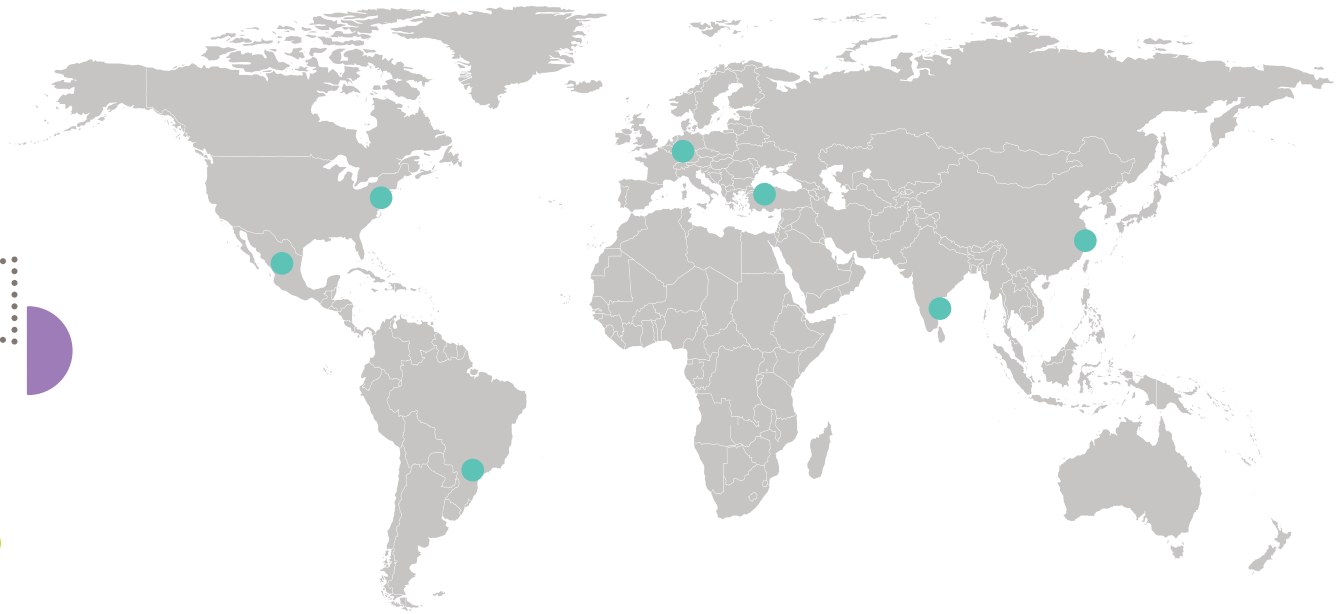
Aquarius™ control ECD is an aqueous dispersion of ethyl cellulose polymer for achieving controlled release, taste-masking, and moisture protection by forming a water insoluble film.

features and benefits

- multifunctional coatings for controlled release, taste masking, and moisture protection
- reproducible release profiles
- reduces environmental impact and improves product safety by eliminating use of hazardous solvents in film coating process
- compatible with a broad range of plasticizers
- supports a solvent and ammonia free coating process
- easy to clean after coating

technical capabilities

Ashland has a focused footprint of technical capabilities to meet the needs of the pharmaceutical and nutraceutical industries. Through a global network of technical service laboratories we provide assistance with formulation development, problem-solving and analytical support.



global technical centers

North America	Latin America	EMEA	Asia Pacific
Wilmington, Delaware*	Mexico City, Mexico	Düsseldorf, Germany	Hyderbad, India*
	Sao Paulo, Brazil	Istanbul, Turkey	Shanghai, China

**center of excellence*

Our scientists support the pharmaceutical industry with formulation and process development in various application areas:

- standard granulation: fluid bed, high shear, and hot-melt extrusion
- tableting: direct compression, bi-layer, multi-layer, tablet in tablet, compaction simulation, 3D printing
- solid dispersion: hot-melt extrusion and spray drying
- controlled-release: release-profile prediction and simulation, melt extrusion, particle and pellet coating, drug layering, and matrix tablets
- film coating: fluid bed coating, pan coating, color matching

Ashland also has considerable expertise in characterization of powder properties including: flow, particle size, surface area, morphology, and more.

analytical and testing capabilities include:

- advanced powder flow and segregation testing
- dissolution USP I, II and III
- differential scanning calorimetry and thermogravimetric analysis
- melt rheology
- microscopy—scanning electron, polarized light, atomic force and high resolution digital
- kinetic dissolution
- advanced mechanical testing
- size exclusion chromatography
- Karl Fischer titration
- coulometry
- nuclear magnetic resonance
- high-performance liquid chromatography and gas chromatography
- infrared and ultraviolet spectroscopy
- x-ray powder diffraction
- laser diffraction
- ASTREE electronic tongue taste masking analyzer
- advanced reverse engineering of dosage forms (including OSD, parenterals and coatings)

pilot manufacturing capabilities include:

- fluid beds with capacity up to 5 kg
- several sizes of tablet coaters
- numerous rotary tablet presses
- MEDELPHARM StylOne Evolution and Stylcam compaction simulators
- extrusion/spheronization
- hot-melt extruders (gram to 10's of kg scale)
- spray dryers (gram to 10's of kg scale)
- formulation design, manufacturing and stability testing
- potent compound handling

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regional centers

North America
Wilmington, DE USA
Tel: +1 877 546 2782

Europe
Switzerland
Tel: +48 22 3955322

India
Maharashtra
Tel: +91 22 62828700

Asia Pacific
Singapore
Tel: +65 6775 5366

Middle East, Africa
Istanbul, Turkey
Tel: +00 90 216 538 08 00

Latin America
Mexico
Tel: +52 55 52 76 6169

Brazil
Tel: +55 11 36 49 0435

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