

# Polyplasdone® Crospovidone

PERFORMANCE ENHANCING PRODUCTS FOR PHARMACEUTICALS



INTERNATIONAL SPECIALTY PRODUCTS

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## Introduction

Polyplasdone® Crospovidone is a synthetic, insoluble but rapidly swellable, crosslinked homopolymer of N-vinyl-2-pyrrolidone. Unlike other crosslinked polymers, Polyplasdone polymers are synthesized by a unique one-step polymerization process known as “popcorn” polymerization where the crosslinking agent is generated in situ and is, thus, chemically similar to the bulk of the polymer. This unique manufacturing process results in a densely crosslinked polymer with porous particle morphology. This distinctive morphology rapidly wicks liquids into the particle to speed swelling and enhance disintegration and dissolution of tablets. The particle morphology of Polyplasdone polymers also provides for a highly compressible powder with good flow properties that result in hard, non-friable tablets.

In addition to its unique particle morphology, Polyplasdone polymers are non-ionic and, as a result, their disintegration performance will not be impacted by pH changes in the gastrointestinal tract nor will they complex with ionic drug actives. Furthermore, Polyplasdone polymers will not retard the disintegration and dissolution processes since they do not form gels. Consequently, Polyplasdone polymers are well suited for use as super disintegrants in a wide range of oral solid dosage formulations.

In addition to their use as a disintegrant, Polyplasdone polymers can also be used as adsorptive polymers, suspension stabilizers, and for bioavailability enhancement in a variety of pharmaceutical applications.

## Product Range

ISP offers 3 chemically identical Polyplasdone grades differentiated by particle size:

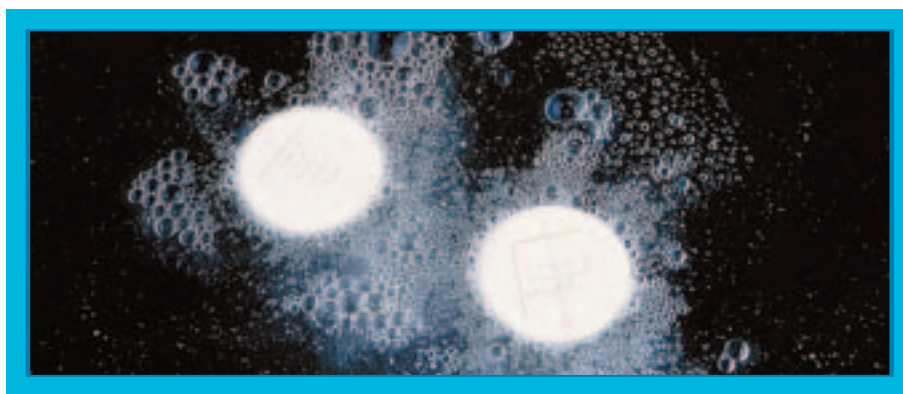
**Polyplasdone XL** polymer has the largest average particle size (100-130  $\mu$ ) and provides the fastest disintegration.

**Polyplasdone XL-10** polymer has a finer average particle size (30-50  $\mu$ ) which enhances content uniformity in the formulation of small tablets (less than 300 mg) and in intragranular applications while still providing rapid disintegration.

**Polyplasdone INF-10** polymer has the finest average particle size (5-10  $\mu$ ) of the Polyplasdone grades and is a highly adsorptive material.

## Pharmacopeia Monographs

All of ISP's Polyplasdone grades conform to the Ph. Eur., USP/NF and JPE monograph specifications for Crospovidone.



## Features & Benefits

Feature	Benefits
Two particle sizes for disintegration (Polyplasdone XL & XL-10)	<ul style="list-style-type: none"> <li>• Offers formulation flexibility for both small and large tablets.</li> <li>• With its smaller particle size, Polyplasdone XL-10 disintegrant gives excellent content uniformity in intragranular application and in small tablets (less than 300 mg).</li> <li>• Polyplasdone XL-10 disintegrant also gives smoother mouth feel in quick dissolve and chewable formulations compared to other disintegrants with larger particle size.</li> </ul>
Granular particles	<ul style="list-style-type: none"> <li>• Provides good flow properties during tablet manufacturing.</li> </ul>
Porous particle morphology	<ul style="list-style-type: none"> <li>• Swells rapidly and wicks water into the particle and tablet by capillary action, hence providing fast disintegration at low use level.</li> <li>• Highly compressible material providing hard, non-friable tablets. Excellent for use with poorly compressible drug actives.</li> </ul>
Non-gelling	<ul style="list-style-type: none"> <li>• Completely insoluble with relatively high crosslink density. Does not form gels that can impede disintegration, dissolution and drug release.</li> <li>• Excellent disintegration performance even after cycles of wetting and drying.</li> </ul>
Non-ionic	<ul style="list-style-type: none"> <li>• Compatible with most pharmaceutical-acceptable ingredients.</li> <li>• Disintegration is not impacted by changes in pH.</li> <li>• Does not form ionic complexes with ionic drug actives that may retard drug release.</li> </ul>
Low sodium content	<ul style="list-style-type: none"> <li>• When low sodium claims are desired, Polyplasdone polymers do not significantly change total sodium levels, even at high use levels.</li> </ul>
High specific surface area (Polyplasdone INF-10)	<ul style="list-style-type: none"> <li>• Readily absorbs fluids including water, gasses and toxins.</li> <li>• Stabilizes liquid suspensions; prevents sedimentation.</li> </ul>

# Chemical & Physical Properties

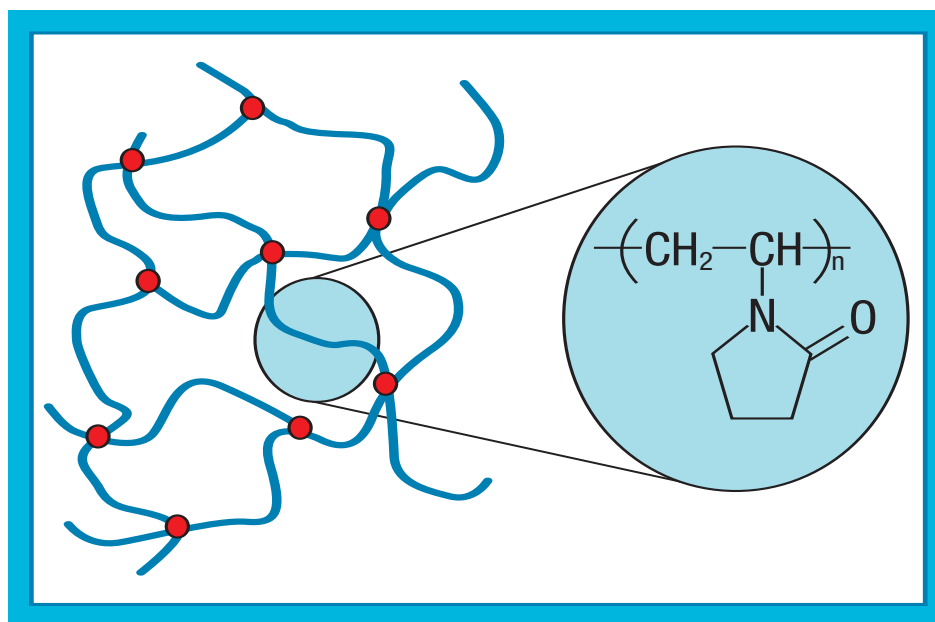
## Chemical Description

Chemical Description:	Polyvinylpyrrolidone, pharmaceutical grade
CAS Registry Number	9003-39-8
CAS Registry Name:	2-Pyrrolidinone, 1-ethenyl-, homopolymer
Chemical Formula:	$(C_6H_9NO)_n$
Synonyms:	Crosslinked polyvinylpyrrolidone (PVP), Insoluble PVP, Polyvinylpyrrolidone (PVPP), Crospovidone, Crospovidonum

## Chemical Structure

The chemical structure for Polyplasdone Crospovidone, a crosslinked homopolymer of N-vinyl-2-pyrrolidone, is shown in *Figure 1*.

*Figure 1. Chemical Structure of Polyplasdone Crospovidone.*



## Compatibility

The Polyplasdone polymers are chemically inert and as such they are compatible with a wide range of drug actives and inactive ingredients commonly used in pharmaceutical formulations. As Polyplasdone polymers are non-ionic, they will not form complexes with ionic actives that may retard drug release and dissolution.

## Solubility & Viscosity

As a result of their crosslinked polymer structure, Polyplasdane polymers are completely insoluble in water and all solvents. However, they are highly hydrophilic polymers which will rapidly disperse in water and quickly swell. In spite of their propensity to swell, Polyplasdane polymers will not form gels or significantly affect the viscosity of water or organic solvents.

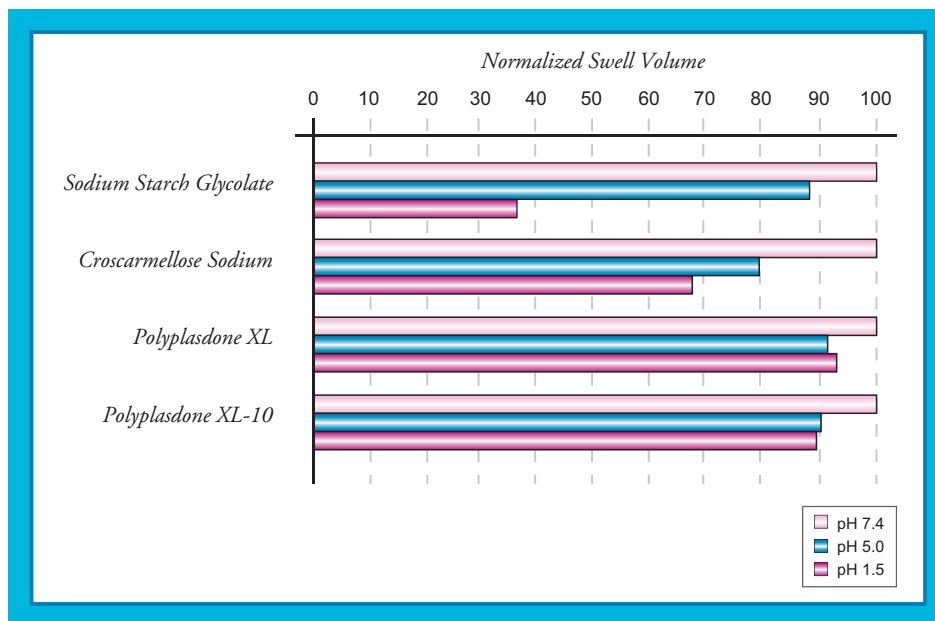
## Swelling & Hydration

Although Polyplasdane XL and XL-10 polymers swell by 95% to 120%, upon contact with water, swelling is not thought to be their primary mechanism for disintegration. Swelling or swell volume is mainly a measure of the change in volume of the disintegrant after it is introduced to an aqueous solution and the system has reached equilibrium. However, swell volume does not measure the rate at which a disintegrant absorbs water or the pressure generated by swelling. Polyplasdane polymers with their porous particle morphology rapidly absorb water (wicking) to generate the rapid volume expansion and hydrostatic pressures that cause tablet disintegration. Unlike other super disintegrants which rely principally on swelling for disintegration, Polyplasdane disintegrants use the combination of swelling and wicking to provide rapid disintegration.

Also, unlike other common super disintegrants, the swell volume of Polyplasdane disintegrants is relatively unaffected by changes in pH. *Figure 2* shows the difference in swell volume under acidic conditions (pH 1.5 and 5.0) compared to neutral pH for Polyplasdane disintegrants and other common super disintegrants. For comparison, the swell volume for each disintegrant was normalized to that of pH 7.4 for that disintegrant. This demonstrates that the performance of Polyplasdane disintegrants will not be affected by the various pH changes within the gastrointestinal tract.

As a result of its high crosslink density, Polyplasdane disintegrants swell without gelling. Other super disintegrants have a lower crosslink density and, as a result, form gels when fully hydrated. Gels can delay dissolution as the drug must first diffuse through the gel layer before being released into the body. Also, because Polyplasdane disintegrants do not gel upon wetting, they will maintain their full disintegration efficacy even after undergoing several wetting and drying cycles. Therefore, Polyplasdane disintegrants are ideally suited for use in wet granulation processes.

*Figure 2. Unlike other super disintegrants, swelling of Polyplasdane disintegrants is independent of pH.*



## Particle Size & Particle Size Distribution

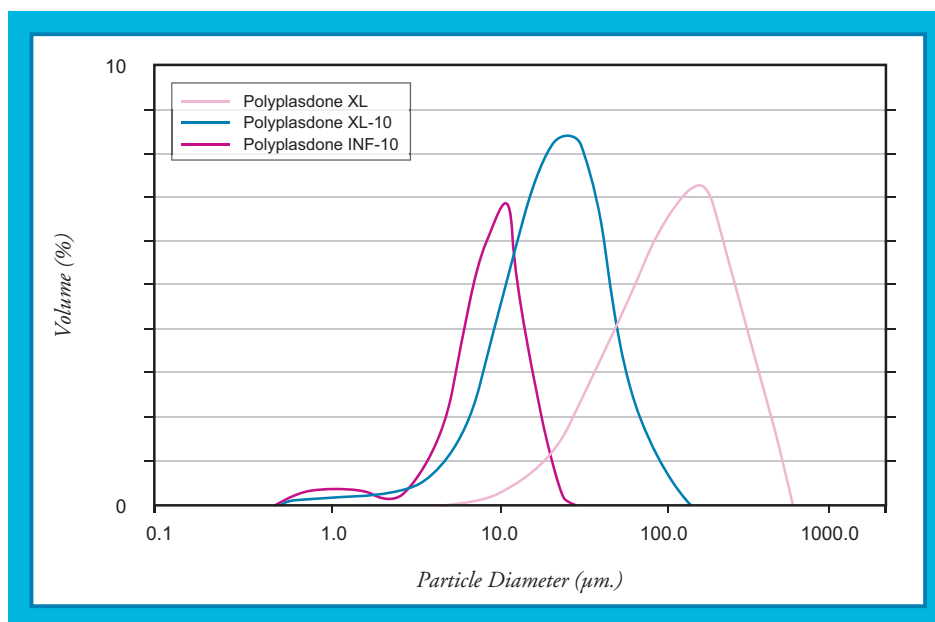
Polyplasdone polymers are available as free-flowing, white powders in 3 particle sizes (*Table 1*). The choice of particle size allows the formulator the flexibility to choose the optimal super disintegrant for best overall performance. For example, Polyplasdone XL polymer has the best disintegration performance of the three, but Polyplasdone XL-10 polymer, with its smaller average particle size, is often preferred for its excellent content uniformity in small tablets (less than 300 mg) and in intragranular applications. Polyplasdone INF-10 polymer with its fine particle size and high specific surface area is an exceptional adsorptive polymer and stabilizer.

*Table 1. Polyplasdone Crospovidone is available in 3 particle sizes for optimum performance.*

Product	Typical Average Particle Size ( $\mu$ )
Polyplasdone XL	100 - 130
Polyplasdone XL-10	30 - 50
Polyplasdone INF-10	5 - 10

As Polyplasdone polymers are spray-dried, they have a relatively narrow particle size distribution (*Figure 3*) which delivers reproducible flow behavior between batches and content uniformity in powder blends.

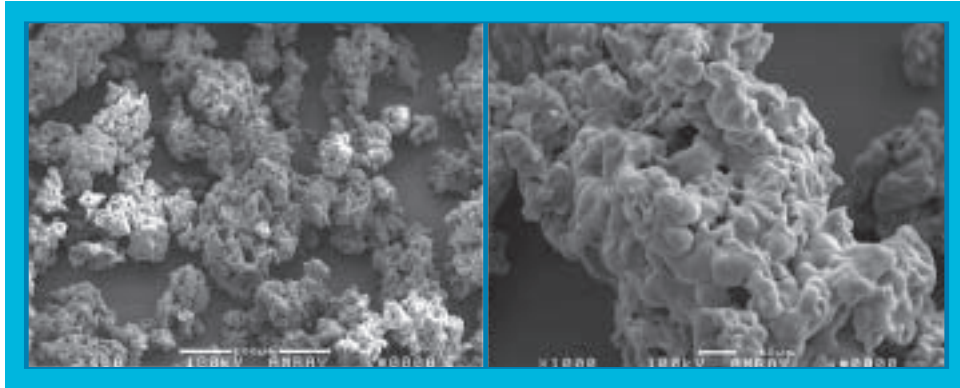
*Figure 3. The narrow particle size distribution of the Polyplasdone polymers offers consistency in tablet manufacturing.*



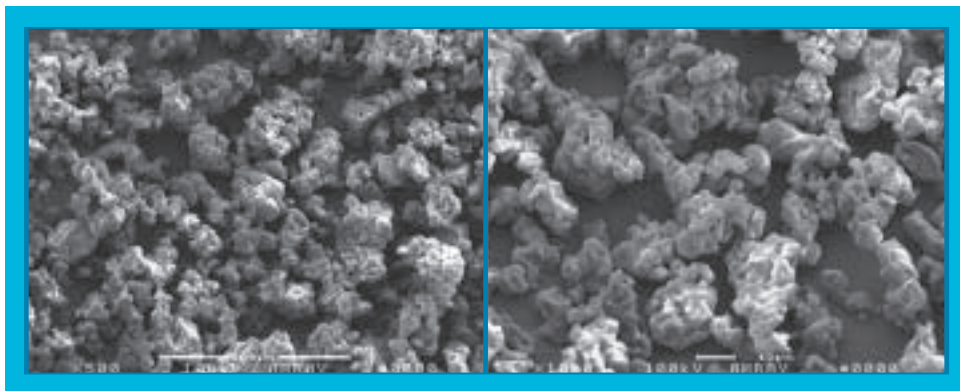
## Particle Morphology

Polyplasdone particles are granular and porous (*Figures 4, 5 and 6*). This unique particle structure allows for improved flow and quick wicking of liquid into the particle and tablet by capillary action. In addition, this particle morphology contributes to the high compressibility of Polyplasdone XL and XL-10 polymers. Although Polyplasdone XL-10 polymer has smaller particles than Polyplasdone XL polymer, the small particles retain their porosity and resulting physical properties (*Figure 5*).

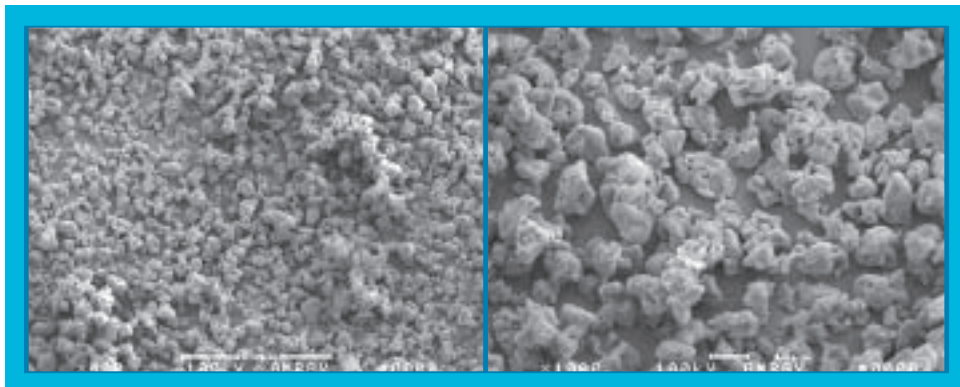
*Figure 4. Polyplasdone XL particles are porous and granular to enhance wicking of liquids into the particles and to provide good flow properties.*



*Figure 5. The smaller particles of Polyplasdone XL-10 polymer are also porous and granular.*



*Figure 6. Polyplasdone INF-10 polymer has very fine particles which are highly adsorptive.*





## Flow

As Polyplasdone polymers are supplied as free-flowing, white powders, they are easy to handle during direct compression and wet and dry granulation manufacturing processes. Polyplasdone XL and XL-10 polymers have good flow properties (*Table 2*) which are attributed to their granular particle morphology. Because of its fine particle size, Polyplasdone INF-10 polymer does not exhibit the same flow properties.

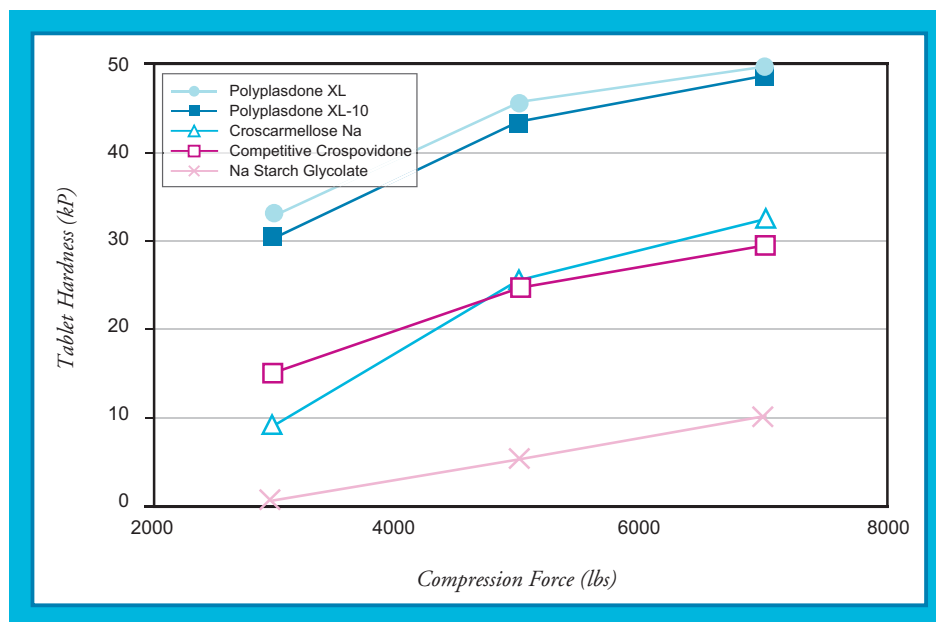
*Table 2. Polyplasdone XL and XL-10 polymers have good flow properties.*

Property	Polyplasdone		
	INF-10	XL-10	XL
Angle of Repose (degrees)	41	30	35
Flowability Index	45	50	47

## Compressibility

Due to their unique particle morphology, Polyplasdone XL and XL-10 disintegrants are significantly more compressible than other super disintegrants, resulting in harder, less friable tablets. The tablet hardness of pure compacts of several super disintegrants, including Polyplasdone XL polymer and Polyplasdone XL-10 polymer, at various compression forces, is shown in *Figure 7*. Polyplasdone XL and XL-10 polymers provide significantly higher hardness of the pure compacts. Consequently, Polyplasdone disintegrant is ideally suited for use with poorly compressible actives and in direct compression tablet processes.

*Figure 7. Polyplasdone XL and XL-10 disintegrant is highly compressible as demonstrated by the hardness of pure compacts.*



## Sodium Content

Polyplasdone polymer has a very low sodium level which is important where low sodium claims may be desired. Typical sodium levels for the Polyplasdone polymers are less than 500 ppm.

## Key Product Specifications & Typical Properties

Table 3 lists some of the key product specifications and typical properties for the commercially available grades of Polyplasdone polymers. Full product specifications are available on request.

Table 3. Key specifications and typical properties.

	Polyplasdone		
	INF-10	XL-10	XL
Appearance	White to off white, free-flowing powder	White to off white, free-flowing powder	White to off white, free-flowing powder
Bulk Density (g/cm <sup>3</sup> )*	0.4	0.3	0.3
Tap Density (g/cm <sup>3</sup> )* (1000 taps)	0.5	0.5	0.4
Specific Surface Area (m <sup>2</sup> /g)*	2.0 - 2.5	1.2 - 1.4	0.6 - 0.8
% Adsorptive Activity	30 - 50	-----	-----
pH (1g/100 ml DI water)	5.0 - 8.0	5.0 - 8.0	5.0 - 8.0
% Moisture	5.0 Maximum	5.0 Maximum	5.0 Maximum
% Ash	0.1 Maximum	0.1 Maximum	0.1 Maximum
Heavy Metals (ppm, as Lead)	10 Maximum	10 Maximum	10 Maximum
Vinyl Pyrrolidone (ppm as is, HPLC)	10.0 Maximum	5.0 Maximum	5.0 Maximum
% Nitrogen (Solids Basis)	11.0 - 12.8	11.0 - 12.8	11.0 - 12.8
Peroxide Content (ppm)	400 Maximum	400 Maximum	400 Maximum
Total Aerobic Plate Count (CFU/g)	100 Maximum	100 Maximum	100 Maximum
Mold/Yeast (CFU/g)	100 Maximum	100 Maximum	100 Maximum
Staphylococcus Aureus (CFU/g)	Negative	Negative	Negative
Salmonella (CFU/g)	Negative	Negative	Negative
Pseudomonas aeruginosa (CFU/g)	Negative	Negative	Negative
E. coli (CFU/g)	Negative	Negative	Negative

\* Typical values. Not a specification.

# Applications

Polyplasdone Crospovidone is used in a range of pharmaceutical applications:

- Polyplasdone XL and XL-10 polymers provide rapid disintegration in a wide range of oral solid dosage formulations and processes. In addition, with its unique particle morphology, Polyplasdone Crospovidone is the disintegrant of choice in the following areas:
  - In wet granulation tablet processes, Polyplasdone XL-10 polymer with its smaller average particle size is highly effective at providing rapid disintegration when used intragranularly.
  - Polyplasdone XL and XL-10 disintegrants are highly compressible, thus, they are ideally suited for use with poorly compressible drug actives and in direct compression tablet processes.
  - As Polyplasdone polymers are non-ionic, they will not form complexes with ionic drug actives that would slow drug release and their performance will not vary with changes in pH.
- Polyplasdone XL-10 disintegrant is well suited for quick dissolve and chewable tablets as it provides rapid disintegration, smooth mouth feel and hard tablets with low friability.
- Depending on the structure of the active, Polyplasdone polymers can be used to improve solubility, and hence, enhance bioavailability.
- Polyplasdone INF-10 polymer absorbs water, gases and toxins and is therefore used in some countries to treat gastrointestinal disorders and as an anti-diarrheal agent in human and veterinary applications.\*
- Polyplasdone INF-10 polymer acts as a suspension stabilizer reducing the amount of sedimentation in pharmaceutical liquids, syrups, instant granules and topical formulations.

\* Subject to local regulatory approvals.

## Regulatory & Safety

Polyplasdone Crospovidone has been widely used in pharmaceutical products for many years. It has been found safe and effective as an excipient in a variety of approved finished dosage forms. A toxicity and safety profile for Polyplasdone polymer is available upon request.

The joint FAO/WHO Expert Committee for Food Additives has assigned polyvinylpyrrolidone an Acceptable Daily Intake (ADI) Status of “Not Specified,” since it is not considered a health hazard.

## Storage & Handling

The Polyplasdone products have excellent stability when stored in their original container with a routine retest period of 36 months. Polyplasdone Crospovidone does not present a human or environmental health risk in the form in which it is supplied. However, as with any particulate material, sensible precautions should be taken to avoid dust inhalation. As Polyplasdone polymer is hygroscopic, suitable precautions should be taken to avoid excessive exposure to moisture. For additional storage and handling information, please refer to the Material Safety Data Sheet (MSDS) or contact ISP.

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## Additional Information

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For further information on this or other ISP products and their applications, please contact your local ISP sales office listed on the back of this brochure or visit us at [www.ispcorp.com](http://www.ispcorp.com).

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