

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:

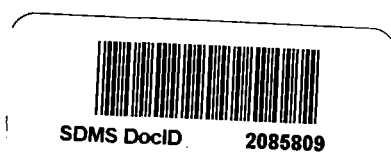
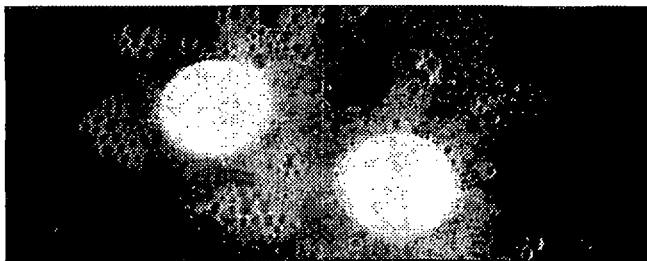
Polyplasdone XL polymer has the largest average particle size (100-130 µ) and provides the fastest disintegration.

Polyplasdone XL-10 polymer has a finer average particle size (30-50 µ) 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 µ) 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"> • Offers formulation flexibility for both small and large tablets. • With its smaller particle size, Polyplasdone XL-10 disintegrant gives excellent content uniformity in intragranular application and in small tablets (less than 300 mg). • Polyplasdone XL-10 disintegrant also gives smoother mouth feel in quick dissolve and chewable formulations compared to other disintegrants with larger particle size.
Granular particles	<ul style="list-style-type: none"> •

	Provides good flow properties during tablet manufacturing.
Porous particle morphology	<ul style="list-style-type: none"> * Swells rapidly and wicks water into the particle and tablet by capillary action, hence providing fast disintegration at low use level. * Highly compressible material providing hard, non-friable tablets. Excellent for use with poorly compressible drug actives.
Non-gelling	<ul style="list-style-type: none"> * Completely insoluble with relatively high crosslink density. Does not form gels that can impede disintegration, dissolution and drug release. * Excellent disintegration performance even after cycles of wetting and drying.
Non-ionic	<ul style="list-style-type: none"> * Compatible with most pharmaceutical-acceptable ingredients. * Disintegration is not impacted by changes in pH. * Does not form ionic complexes with ionic drug actives that may retard drug release.
Low sodium content	<ul style="list-style-type: none"> * When low sodium claims are desired, Polyplasdone polymers do not significantly change total sodium levels, even at high use levels.
High specific surface area (Polyplasdone INF-10)	<ul style="list-style-type: none"> * Readily absorbs fluids including water, gasses and toxins. * Stabilizes liquid suspensions; prevents sedimentation.

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