



## Polyplasdone® Ultra and Ultra-10 Crosprovidones Product Overview

### Premier quality crosprovidone superdisintegrant

Polyplasdone Ultra and Ultra-10 crosprovidones meet the ultimate standard for purity and quality. With a commitment to provide pharmaceutical excipients that meet the highest quality standards, ISP has developed two new grades of Polyplasdone crosprovidone, Polyplasdone Ultra and Ultra-10 that are chemically and morphologically identical to Polyplasdone XL crosprovidone, Type A and Polyplasdone XL-10 crosprovidone, Type B, respectively. The only difference is the peroxide specification (Table 1). Polyplasdone Ultra and Ultra-10 crosprovidones represent the next generation of high-quality pharmaceutical excipients.

Table 1: Grades of Polyplasdone superdisintegrants

Product	Ph. Eur. Crosprovidone Monograph Type	Typical Average Particle Size (Microns)	Peroxide Specification (ppm)
Polyplasdone Ultra	Type A	110-140	30 Max
Polyplasdone XL	Type A	110-140	400 Max
Polyplasdone Ultra-10	Type B	25-40	50 Max
Polyplasdone XL-10	Type B	25-40	400 Max



### Benefits

Meets low specification limits for peroxides

Acts as non-ionic superdisintegrant in tablet formulation at low use levels

Enhances the dissolution of poorly soluble drugs

Provides rapid disintegration and increases rate of drug release

Available in 2 particle sizes

### Innovative manufacturing and packaging technology

Produced in Texas City, TX, Polyplasdone Ultra and Ultra-10 polymers are specially manufactured in a state-of-the-art manufacturing and packaging facility that carefully controls product quality resulting in a purer product with significantly lower peroxide levels throughout the shelf-life of the product. In addition to the lower peroxide specification, the Polyplasdone Ultra and Ultra-10 manufacturing process was designed to produce a product with a more uniform, physical appearance with gentler drying steps while providing the same superior performance as our traditional Polyplasdone grades. Designed to carefully control operating conditions in all steps of the process from the reaction, through purification and drying to packaging and storage, the new plant was built to produce these new grades of crospovidone.

The Polyplasdone Ultra grades are specially packaged under nitrogen in a thermally sealed, polymer-lined, multi-layer foil bag placed inside a polyethylene drum with tamper-evident seals. This packaging system helps maintain the high quality of the material during storage and shipment. The suggested retest interval for Polyplasdone Ultra and Ultra-10 polymers is 24 months from the manufacturing date.

### The same disintegration performance

Polyplasdone Ultra and Ultra-10 superdisintegrants have all the properties and performance attributes of Polyplasdone XL and Polyplasdone XL-10 crospovidones, but with the added benefits of higher purity, higher quality and lower peroxides. The peroxide specifications for Polyplasdone Ultra and Ultra-10 superdisintegrants (Table 1) are considerably lower than the current Ph. Eur. monograph specifications of 400 ppm for Type A crospovidone and 1000 ppm for Type B crospovidone and offer the familiar performance attributes in tablet formulations:

- Unlike anionic superdisintegrants, Polyplasdone superdisintegrants are non-ionic, thus they do not form ionic complexes with ionic drug actives that may retard drug release.
- Polyplasdone crospovidones swell rapidly and wick water into the particle and tablet by capillary action, hence, providing fast disintegration and dissolution at low use levels.
- Polyplasdone crospovidones have high surface area and interfacial activity enhancing the rate of dissolution of poorly soluble (<1 mg/mL) drug actives.
- Polyplasdone polymers are highly compressible materials providing tablets with high breaking force and low friability – an excellent choice for poorly compressible actives.
- Polyplasdone superdisintegrants do not form gels that can impede disintegration, dissolution and drug release.
- In orally disintegrating tablets (ODT) and chewable tablets, Polyplasdone polymers provide rapid disintegration and smoother mouth feel without the formation of gels.

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