

polyplasdone™ ultra and ultra-10 crospovidone

premier quality crospovidone superdisintegrant

description

Polyplasdone™ Ultra and Ultra-10 crospovidones meet the ultimate standard for purity and quality. With a commitment to provide pharmaceutical excipients that meet the highest quality standards, Ashland has developed Polyplasdone™ Ultra and Ultra-10 crospovidones, which are chemically and morphologically identical to Polyplasdone™ XL crospovidone, Type A and Polyplasdone™ XL-10 crospovidone, Type B, respectively. The difference is the very low peroxide specification. Polyplasdone™ Ultra and Ultra-10 crospovidones represent the next generation of high-quality pharmaceutical excipients.



key features and benefits

- meets low specification limits for peroxides
- acts as nonionic 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 two particle sizes

grades of polyplasdone™ superdisintegrants

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

Polyplasdone™ crospovidones conform to the current USP/NF, Ph. Eur. and JP monographs for crospovidone

¹ crospovidone monograph type A

² crospovidone monograph type B

innovative manufacturing and packaging technology

Produced in Texas City, TX, Polyplasdone™ Ultra and Ultra-10 crospovidones are specially manufactured in a manufacturing and packaging facility that carefully controls product quality, resulting in a purer product with significantly lower peroxide levels throughout its shelf life. In addition to the lower peroxide specification, the Polyplasdone™ Ultra and Ultra-10 crospovidones 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 Texas City plant has state-of-the-art facilities for producing these grades of crospovidone.

The Polyplasdone™ Ultra crospovidone 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 crospovidones is 36 months from the manufacturing date.

the same disintegration performance

Polyplasdone™ Ultra and Ultra-10 crospovidone superdisintegrants have all the properties and performance attributes of Polyplasdone™ XL and Polyplasdone™ XL-10 crospovidones, but with the added benefit of lower peroxides. The peroxide specifications for Polyplasdone™ Ultra and Ultra-10 crospovidone 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™ crospovidone 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, 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 mouthfeel without the formation of gels.



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