

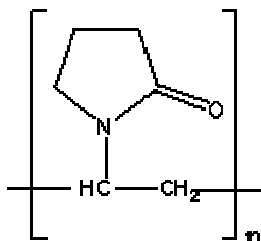
CROSPHARM[®]

Polyvinylpyrrolidone, PVP-P

Product data sheet

Definition

- ✧ Chemical Name: cross-linked homopolymer of 1-ethenylpyrrolidin-2-one.
- ✧ CAS Registry Number: 9003-39-8.
- ✧ INCI Name: Cross-linked PVP.
- ✧ Other Names: PVPP, crospovidone, crospovidonum, crosslinked povidone, insoluble polyvinylpyrrolidone,
- ✧ Molecular and Structural Formula: $(C_6H_9NO)_n$



- ✧ CROSPHARM[®] is a cross-linked homopolymer produced in accordance with the cGMP.
- ✧ CROSPHARM[®] complies with Ph.Eur. and USP/NF.

General properties

- ✧ White to creamy-white, free-flowing, hygroscopic powder.
- ✧ Practically insoluble in water, in alcohol and in methylene chloride.
- ✧ Fast dispersible in water, swells rapidly without gelling even after prolonged exposure.
- ✧ Non-toxic and non-irritant material, accepted for use as a food additive in Europe and in the FDA Inactive Ingredients Guide.

Main applications as pharmaceutical excipient

- ✧ Disintegrant for tablets, granules and hard gelatine capsules;
- ✧ Stabilizer for oral and topical suspensions;
- ✧ Provide rapid disintegration in a wide range of oral solid dosage formulations and processes.

Especially in the following areas:

- In wet granulation tablet processes,
 - Ideally for poorly compressible drug actives and in direct compression tablet processes,
 - Outstanding performance in manufacturing ionic, acidic and alkaline drug actives,
 - Quick dissolve and chewable tablets.
- ✧ Improve solubility, and hence, enhance bioavailability in not only human but also veterinary applications.

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Applications as cosmetic ingredient

- ✧ Humectants and water-keeping,
- ✧ Suspending stabilizing agent.

Chemical and physical specifications

specification	value
<i>Peroxides, as H₂O₂ (ppm)</i>	≤400
<i>Water-soluble substances (%)</i>	≤1.0
<i>Impurity A, 1-vinylpyrrolidone-2-one (ppm)</i>	≤10
<i>Heavy metals (ppm)</i>	≤10
<i>Loss on drying (%)</i>	≤5.0
<i>Sulphated ash (%)</i>	≤0.1
<i>Assay, as Nitrogen content (%)</i>	11.0-12.8
<i>pH (1% suspension)</i>	5.0-8.0
<i>Average particle size (µm)</i>	100 or 50

Pharmaceuticals grades

CROSPHARM[®] exists in two grades: type A and type B according to the Eur.Ph.

Average particle size for type A: 100 µm.

Average particle size for type B : 30 µm.

Compatibility

- ✧ CROSPHARM[®] is compatible with most organic and inorganic pharmaceutical ingredients.

General information

- ✧ Packaging: 20 and 50 kg fibre or plastic drum, inner lined with PE bags.
- ✧ Storage conditions: in a dry place at room temperature.
- ✧ Shelf life 3 years guaranteed.
- ✧ Certificate of analysis and Material Safety Data Sheet attached to each delivery.

For further information, please contact

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