

	Specification			
	Product Name	Crospovidone (Type A)	Grade	EP
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Basis: The current version of EP
CAS No: 9003-39-8

Specification	Item	Tolerance
	Appearance	Hygroscopic, white or yellowish-white powder or flakes.
	Solubility	Practically insoluble in water, in ethanol 96 percent and in methylene chloride.
	Identification A	Consistent with the CRS
	Identification B	No blue colour develops within 30 s.
	Identification C	A suspension is formed and no clear solution is obtained within 15 min.
	Identification D	MT 15% (Sieving residue fraction)
	Peroxides (as H ₂ O ₂)	NMT 400 ppm
	Water-Soluble Substances	NMT 1.5%
	Impurity A (NVP)	NMT 10 ppm
	Loss on Drying	NMT 5.0%
	Sulfated Ash	NMT 0.1%
	Content (Nitrogen)	11.0%~12.8%
	TAMC	NMT 10 ³ cfu/g
	TYMC	NMT 10 ² cfu/g
	E. Coli	Negative in 1g

Storage	Packaging: Double PE-lined paper barrels, 10kgs/drum. Double PE-lined cardboard drums, 20kgs/drum. Double PE-lined cardboard drums, 25kgs/drum. Storage condition: Preserve in tight containers. Retest Period: 36 months from the manufacturing date.
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Sampling	Quantity: 450g (in which 300g for retention sample ; 120g for physical & chemical analysis; 30g for microbiological analysis)
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Trade Name	PolyKoVidone [®] XL
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Related Documents	Intermediates & Finished Products Sampling SOP (SOP-QA-OPR-001) Crospovidone (EP) Analysis SOP (SOP-TM-PVPP (EP))
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Approved by		Date	
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