



Certificate of Analysis

Product name : Crospovidone
 Batch number : PKV10100621075
 Batch quantity : 300kgs
 Manufacturing date : JUNE 21, 2010
 Expiry date : JUNE 21, 2013

TESTS	STANDARDS	RESULTS
Appearance	Hygroscopic, white or yellowish-white powder or flakes	White powder
Solubility	Practically insoluble in water, in ethanol (96 percent) and in methylene chloride	Complies
Identification	A. IR spectrum obtained is consistent with that obtained with Crospovidone CRS	Complies
	B. No blue color develops within 30s.	Complies
	C. A suspension is formed and no clear solution is obtained within 15min	Complies
	D. More than 85% of the product particles are below 50um	Complies
Peroxide	Not more than 1000ppm	Complies
Water-soluble substances	Not more than 1.0%	0.23%
Impurity A (N-vinylpyrrolidone)	Not more than 10ppm	3.61ppm
Loss on drying	Not more than 5.0%	3.92%
Heavy metals	Not more than 10ppm	Complies
Sulphated ash	Not more than 0.1%	0.086%
Assay(Nitrogen)	11.5-12.8%	11.89%
Particle size	Not more than 50um	35um
Total aerobic plate count	Not more than 100CFU/g	< 10CFU/g
Mold/Yeast	Not more than 100CFU/g	< 10CFU/g
Staphylococcus aureus	Negative	Negative
Salmonella	Negative	Negative
Pseudomonias aeruginosa	Negative	Negative
E.coli	Negative	Negative

Conclusion : Conform to EP6.5/BP2009