

## ANNEX I

## E 1202 POLYVINYL POLYPYRROLIDONE

<b>Synonyms</b>	Crospovidone
	Cross linked polyvidone
	Insoluble polyvinylpyrrolidone
<b>Definition</b>	Polyvinylpyrrolidone is a poly-[1-(2-oxo-1-pyrrolidinyl)-ethylene], cross linked in a random fashion. It is produced by the polymerisation of N-vinyl-2-pyrrolidone in the presence of either caustic catalyst or N, N'-divinyl-imidazolidone. Due to its insolubility in all common solvents the molecular weight range is not amenable to analytical determination
Chemical name	Polyvinylpyrrolidone, poly-[1-(2-oxo-1-pyrrolidinyl)-ethylene]
Chemical formula	(C <sub>6</sub> H <sub>9</sub> NO) <sub>n</sub>
Assay	Content not less than 11 % and not more than 12,8 % nitrogen (N) on the anhydrous basis
<b>Description</b>	A white hygroscopic powder with a faint, non-objectionable odour
<b>Identification</b>	
A. Solubility	Insoluble in water, ethanol and ether
B. pH of a 1 % suspension in water	Between 5,0 and 8,0
<b>Purity</b>	
Water	Not more than 6 % (Karl Fischer)
Sulphated ash	Not more than 0,4 %
Water-soluble matter	Not more than 1 %
Free-N-vinylpyrrolidone	Not more than 10 mg/kg
Free-N, N'-divinyl-imidazolidone	Not more than 2 mg/kg
Lead	Not more than 5 mg/kg