PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

ANALYTICAL SPECIFICATION FOR CROSPOVIDONE (BP) (POLYPLASDONE)

Manufacturer Name :		**Supplier Name :**
Manufacturer's Batch No. :		**Manufacturer's Batch Size :**
Manufacturing Date :		**Expiry Date :**
Quantity Received :		**Test Quantity :**
Document No. :	**Effective Date :**	**Change Control No. :**
Control No./ A.R. No. :		**Retest Date :**

Reference : BP 2002

Description : White or yellowish white powder or flakes, hygroscpic
Complies/Does Not Comply

Solubility : Practically insoluble in Water and in alcohol and in methylene chloride.
(1 in More Than 10000)
Complies/Does Not Comply

S.No.	Test	Reference	Result	Specification	Remark
1.	**Identification** **A. IR spectrum** **B. Colour reaction** **C.**	BP		A. IR absorption spectrum of test is concordant with spectrum obtained with crospovidone WRS. B. No blue colour develops. C.A suspension is formed and no clear solution is obtained within 15 min.	

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S.No.	Test	Reference	Result	Specification	Remark
	Identification (contd.) **D.**	BP		D. The majority of particles are in the range 50µm to 300µm.	
2.	**Peroxides**	BP		Not more than 400 ppm	
3.	**Water soluble substances**	BP		Not more than 1.0 %	
4.	**Impurity A**			Not more than 10 ppm	
6.	**Heavy metals**	BP		Not more than 10 ppm	
7.	**Loss on drying**	BP		Not more than 5.0 %	
8.	**Sulphated ash**	BP		Not more than 0.1 %	
9.	**Assay as nitrogen (On dried substances)**	BP		Not less than 11.0 % and Not more than 12.8 %	

Raw Data Reference :

Analyst Name :

Analyst Name :

Analyst Name :

Analyst Hard Book No. : **Page No. :**

Analyst Hard Book No. : **Page No. :**

Analyst Hard Book No. : **Page No. :**

Results : Sample Conforms / Does Not Conform to Specification

Analyzed By : _____ **Date :** _____

Checked By : _____ **Date :** _____

Approved By : _____ **Date :** _____