

Povidone (Polyvinyl Pyrrolidone)			
No. : RPB 187	Rev : 03	Eff. date : 160302	Sign : 

1 Quality

- 1.1 USP 37, 2014
- 1.2 Internal specification

2 Additional Requirements

2.1 Viscosity

- Capillary (solution 1%, 20⁰)

Povidone K- 25	Cps	1,163 - 1,201
Povidone K-30	Cps	1,210 - 1,280
Povidone K-29/32	Cps	1,210 - 1,280

- JP Selecta ST-2020-L (solution 10%,spd 0)

99,9% rpm, accuracy of reading 50-100%

Povidone K-25	Cps	3,5 - 4,5
Povidone K-30	Cps	4,0 - 5,5
Povidone K-29/32	Cps	4,0 - 5,5

- 2.2 Arrival Date : Max. 12 months from manufacturing date

3 Certificate of Analysis from Manufacturer

To be stated on the certificate

- 3.1 Manufacturer name and address
- 3.2 Product name , batch/lot number
- 3.3 Results of test and assays
- 3.4 Compliance with USP 37
- 3.5 Quality designation
- 3.6 Date of manufacturing, expiration (year-month) and date of released (year- month-day)
- 3.7 Approval/signature of QA/QC responsibility

4 Package

Cardboard drum @ 50 kg kg, with original seal (inside and outside) from manufacture.

To be stated on goods, label original from manufacture at primary and secondary package each . Preserve in tight containers.

5 Labeling

To be stated on goods **label original from manufacturer**, packing list and invoice :

- 5.1 Name of manufacturer and address
- 5.2 Product name, batch/lot number, manufacturing and expiration date
- 5.3 Quality designation
- 5.4 Gross/net weight
- 5.5 Number of packages

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6 Reference Documents

6.1 USP 37, 2014

6.2 Internal specification

7 History

Purchasing specification is revision of RPB 187 revision 02 with change in the quality of USP 34 to USP 37 and format document

8 Review

This specification will be reviewed every 2 years or less (if necessary) by the Quality Control Manager, Research & Development Manager and Quality Assurance Manager

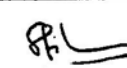
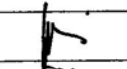
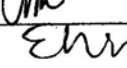
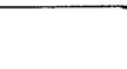
9 Distribution

In general, a copy of this specification is distributed to :

9.1 Procurement Dept.

9.2 Quality Control Dept.

10 Approval

Preparation steps	Position	Code	Signature	Date
Prepared by	Starting and Packaging Material Testing Assistant Manager	C		160302
Checked by	Analytical Method Assistant Manager	L		160302
Approved by	Quality Control Manager	C		160302
	Research & Development Manager	L		160302
	Quality Assurance Manager	Q		160302

11 Review

No.	Position	Date	Signature	Recommendation
1	Quality Control Manager			
	Research & Development Manager			
	Quality Assurance Manager			
2	Quality Control Manager			
	Research & Development Manager			
	Quality Assurance Manager			