


|  |                 |                           |   |
|--|-----------------|---------------------------|---|
| <b>Povidone</b><br><b>(Polyvinyl Pyrrolidone )</b> |                 |                           |   |
| <b>No. : RPB 187</b>                               | <b>Rev : 03</b> | <b>Eff. date : 160302</b> | <b>Sign : </b> |

**1 Quality**

- 1.1 USP 37, 2014
- 1.2 Internal specification

**2 Additional Requirements****2.1 Viscosity**

- Capillary ( solution 1%, 20<sup>0</sup> )

|                  |     |               |
|------------------|-----|---------------|
| 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

| Povidone<br>(Polyvinyl Pyrrolidone) |          |                    |  |
|-------------------------------------|----------|--------------------|--|
| No. : RPB 187                       | Rev : 03 | Eff. date : 160302 | Sign :  |

## 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

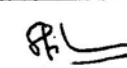
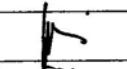

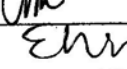
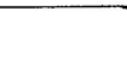
## 9 Distribution

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      |      |           |                |