| indofarma | **PURCHASING SPECIFICATION**<br>**Crospovidone**<br>**(Kollidon® CL)** | No : RPB180a<br>Revisi : 00<br>Berlaku : 06 AUG 2018<br>Paraf : |
|---|---|---|

1 **Quality**

1.1 USP 39, 2016

1.2 Inhouse Indofarma

2 **Additional Requirements**

| | | | |
|---|---|---|---|
| 2.1 | Bulk Density | : 0,30 – 0,40 | g/ml |
| 2.2 | Tapping Density | : 0,40 – 0,50 | g/ml |
| 2.3 | Particle Size Distribution | : | |
| 2.3.1 | Mesh 60 | : NMT. 5 | % |
| 2.3.2 | Mesh 200 | : NLT. 60 | % |
| 2.3.3 | Mesh 200 (Passed) | : NMT. 40 | % |
| 2.4 | Arrival Date | : NMT. 6 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 Quality and Additional Requirements

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, with original seal (inside and outside) from manufacture.

To be stated on goods, original label from manufacture at both of primary and secondary package

Preserve in tight containers.

5 **Labeling**

To be stated on goods **original label 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

6 **Reference Documents**

6.1 USP 39, 2016

6.2 Inhouse Indofarma

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

7 **History**

| Revision | Eff. Date | Change |
|---|---|---|
| 00 | 06 AUG 2018 | 1. The first publication<br>2. Substitute of RPB 180 with change in the separation of supplier and transformed into RPB 180a |

8 **Distribution**

A copy of this purchasing specification is distributed to :

8.1 Procurement Dept.

8.2 Quality Control Dept.

9 **Approval**

| Preparation steps | Position | Code | Signature | Date |
|---|---|---|---|---|
| Prepared by | Starting and Packaging Material Testing Assistant Manager | **AM** | | 06 Agu 2018 |
| Checked by | Analytical Method Assistant Manager | **LB** | | 06 Agu 2018 |
| Approved by | Quality Control Manager | **AM** | an | 06 Agu 2018 |
| | Research & Development Manager | **LB** | | 06 Agu 2018 |
| | Quality Assurance Manager | **PM** | | 06 Agu 2018 |