indofarma	**PURCHASING SPECIFICATION** **Crospovidone** **(Kollidon® CL-F)**	No : RPB180b Revisi : 00 Berlaku : 06 AUG 2018 Paraf :

1 **Quality**

1.1 USP 39, 2016

1.2 Inhouse Indofarma

2 **Additional Requirements**

2.1	Bulk Density	: 0,18 – 0,28	g/ml
2.2	Tapping Density	: 0,25 – 0,35	g/ml
2.3	Particle Size Distribution	:	
2.3.1	Mesh 60	: NMT. 5	%
2.3.2	Mesh 200	: 10, 0 – 20,0	%
2.3.3	Mesh 200 (Passed)	: 80,0 – 90,0	%
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 2. Substitute of RPB 180 with change in the separation of supplier and transformed into RPB 180b

8 **Distribution**

A copy of this 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**		06 Agu 2018
	Research & Development Manager	**LB**		06 Agu 2018
	Quality Assurance Manager	**PM**		06 Agu 2018