

	PURCHASING SPECIFICATION Crospovidone (Polypiasdone XL)	No : RPB180c
		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 : 0,20 – 0,35 g/ml
- 2.2 Tapping Density : 0,25 – 0,45 g/ml
- 2.3 Particle Size Distribution :
 - 2.3.1 Mesh 60 : NMT. 10 %
 - 2.3.2 Mesh 200 : NMT. 95 %
 - 2.3.3 Mesh 200 (Passed) : NLT. 5,0 %
- 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

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 180c

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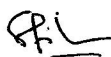
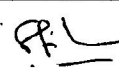
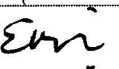
8 Distribution

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	an. 	06 Agu 2018
	Research & Development Manager	LB		06 Agu 2018
	Quality Assurance Manager	PM		06 Agu 2018