

 indofarma	PURCHASING SPECIFICATION Cyanocobalamin	No : RPB223
		Revisi : 04
		Berlaku : 06 AUG 2018
		Paraf : 

1 Quality

- 1.1 USP 39, 2016
- 1.2 BP 2016

2 Additional Requirements

- 2.1 Assay by Spectrofotometry : 96,0 – 102,0 %
- 2.2 Arrival Date : NMT. 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 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 Tin @100 gr, 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, light resistant 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 BP 2016

7 History

Revision	Eff. Date	Change
03	24 MAY 2018	1. Change in the document format and field code
04	06 AUG 2018	2. Change into new logo 3. Change in the header format 4. Change of reference document from USP 37 to USP 39, and from BP 2013 to BP 2016

 indofarma	PURCHASING SPECIFICATION Cyanocobalamin	No : RPB223
		Revisi : 04
		Berlaku : 06 AUG 2018
		Paraf : 

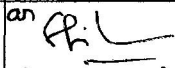
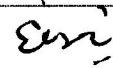
8 Distribution

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