
 <b>indofarma</b>	<b>PURCHASING SPECIFICATION</b> Carbamazepine	No : RPB217
		Revisi : 02
		Berlaku : <b>12 DEC 2018</b>
		Paraf : 

**1 Quality**

- 1.1 USP 37, 2014
- 1.2 BP 2009, A430
- 1.3 Inhouse Indofarma

**2 Additional Requirements**

- 2.1 Particle size :  $\leq 45 \mu\text{m}$  Min 90 %
- 2.2 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 @ 25 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 37, 2014
- 6.2 BP 2009, A430
- 6.3 Inhouse Indofarma

**7 History**

Revision	Eff. Date	Change
02	<b>12 DEC 2018</b>	1. Change in the document format 2. Deleting the review point

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

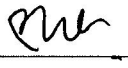

## 8 Distribution

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		12 Des 2018
Checked by	Analytical Method Assistant Manager	LB		12 Des 2018
Approved by	Quality Control Manager	AM	<sup>an.</sup> 	12 Des 2018
	Research & Development Manager	LB		12 Des 2018
	Quality Assurance Manager	PM		12 Des 2018