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|----------------------------------------------------------------------------------------------------|--------------------------------------------------|---------------------------------------------------------------------------------------------|
|  <b>indofarma</b> | <b>PURCHASING SPECIFICATION</b><br>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<br>2. Deleting the review point |

|                                                                                   |                                                  |                                                                                             |
|-----------------------------------------------------------------------------------|--------------------------------------------------|---------------------------------------------------------------------------------------------|
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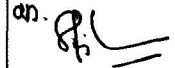
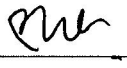
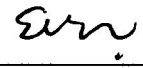
## 8 Distribution

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 |