

| Sulfamethoxazole |          |                      |                                                                                            |
|------------------|----------|----------------------|--------------------------------------------------------------------------------------------|
| No. : RPB 142    | Rev : 04 | Eff. date : 18 03 23 | Sign :  |

**1 Quality**

- 1.1 Farmakope Indonesia Edition V, 2014
- 1.2 USP 37, 2014

**2 Additional Requirements**

- 2.1 Particle Size :
  - ≤ 125 µm : NLT. 40 %
  - ≤ 180 µm : NLT. 100 %
- 2.3 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 Attached update Good Manufacturing Practise Certificate**
**5 Package**

Vat @ 25 kg, double plastic PE, with original seal (inside and outside) from manufacture. To be stated on goods, label original from manufacture at primary and secondary package each. Preserve in well-closed containers.

**6 Labeling**

To be stated on goods **label original from manufacturer**, packing list and invoice:

- 6.1 Name of manufacturer and address
- 6.2 Product name, batch/lot number, manufacturing and expiration date
- 6.3 Quality designation
- 6.4 Gross/net weight
- 6.5 Number of packages

**7 Reference Documents**

- 7.1 Farmakope Indonesia Edition V, 2014
- 7.2 USP 37, 2014

**8 History**

Purchasing Specification is revision of RPB 142 revision 03 with change in the format document.

| Sulfamethoxazole |          |                    |                                                                                            |
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| No. : RPB 142    | Rev : 04 | Eff. date : 180323 | Sign :  |

**9 Review**

This specification will be reviewed every 2 years or less (if necessary) by the Quality Control Manager, Research & Development Manager and Quality Assurance Manager.

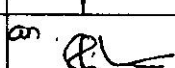
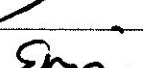
**10 Distribution**

In general, a copy of this specification is distributed to :

10.1 Procurement Dept.

10.2 Quality Control Dept

**11 Approval**

| Preparation steps | Position                                                  | Code | Signature                                                                             | Date   |
|-------------------|-----------------------------------------------------------|------|---------------------------------------------------------------------------------------|--------|
| Prepared by       | Starting and Packaging Material Testing Assistant Manager | AM   |    | 180323 |
| Checked by        | Analytical Method Assistant Manager                       | LB   |   | 180323 |
| Approved by       | Quality Control Manager                                   | AM   |  | 180323 |
|                   | Research & Development Manager                            | LB   |  | 180323 |
|                   | Quality Assurance Manager                                 | PM   |  | 180323 |

**12 Review**

| No. | Position                       | Date | Signature | Recommendation |
|-----|--------------------------------|------|-----------|----------------|
| 1   | Quality Control Manager        |      |           |                |
|     | Research & Development Manager |      |           |                |
|     | Quality Assurance Manager      |      |           |                |
| 2   | Quality Control Manager        |      |           |                |
|     | Research & Development Manager |      |           |                |
|     | Quality Assurance Manager      |      |           |                |