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

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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 | | | |