


|                               |                 |                             |   |
|-------------------------------|-----------------|-----------------------------|---|
| <b>Kapsul Kosong No. 0</b>    |                 |                             |   |
| <b>Untuk Omeprazole 40 mg</b> |                 |                             |   |
| <b>No. : RPB 194</b>          | <b>Rev : 01</b> | <b>Eff. date : 18 05 18</b> | <b>Sign : </b> |

**1 Quality**

- 1.1 Farmakope Indonesia V, 2014
- 1.2 USP 39, 2016
- 1.2 Multistate File, Capsugel, 3<sup>th</sup> edition, 1998

**2 Additional Requirements**

- 2.1 Marking Of Capsule : OMP 40 and INF to cap and body, green color of marking
- 2.2 Color Of Capsule :
  - Cap : Orange Op. 21.723
  - Body : Grey Op. 12.723
- 2.3 Uniformity of weight : 89,0 - 107,0 mg
- 2.4 Uniformity of measure :
  - Body length : 17,98 – 18,90 mm
  - Length cap : 10,26 – 11,18 mm
  - Diameter of body : 7,28 – 7,40 mm
  - Diameter of cap : 7,58 – 7,70 mm
  - Total length of body : 21,4 – 22,0 mm
- 2.4 Microbial Limit Test
  - Total microbial aerobic numbers : NMT. 1000 kol/g
  - Yeast & mould numbers : NMT. 100 kol/g
  - Escherichia coli : Negative
  - Salmonella : Negative
  - Pseudomonas aeruginosa : Negative
  - Staphylococcus aureus : Negative
- 2.5 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 Manufacture Practice Certificate**

**5 Package**

Carton @ 2.000 pcs, double plastic PE, with original seal ( inside and outside ) from manufacture. To be stated on goods, label original manufacture at primary and secondary in well-closed containers.

|   |          |                      |                           |
|---|----------|----------------------|---------------------------|
| <b>Kapsul Kosong No. 0</b><br><b>Untuk Omeprazole 40 mg</b> |          |                      |                           |
| No. : RPB 194   | Rev : 01 | Eff. date : 18 05 18 | Sign : <i>[Signature]</i> |

**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 V, 2014
- 7.2 USP 39, 2016
- 7.3 Multistate File, Capsugel, 3<sup>th</sup> edition, 1998

**8 History**

Purchasing specification is revision of RPB 194 revision 00 with change in the quality, additional requirements, format document, and deleting the review point.

**9 Distribution**

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

- 9.1 Procurement Dept.
- 9.2 Quality Control Dept

**10 Approval**

| Preparation steps | Position  | Code | Signature          | Date     |
|-------------------|---|------|--------------------|----------|
| Prepared by       | Starting and Packaging Material Testing Assistant Manager | AM   | <i>[Signature]</i> | 18 05 18 |
| Checked by        | Analytical Method Assistant Manager                       | LB   | <i>[Signature]</i> | 18 05 18 |
| Approved by       | Quality Control Manager                                   | AM   | <i>[Signature]</i> | 18 05 18 |
|                   | Research & Development Manager                            | LB   | <i>[Signature]</i> | 18 05 18 |
|                   | Quality Assurance Manager                                 | PM   | <i>[Signature]</i> | 18 05 18 |