INDOFARMA

PURCHASING SPECIFICATION

Kapsul Kosong No. 0 Untuk Omeprazole 40 mg			
No. : RPB 194	Rev : 01	Eff. date : 180518	Sign :

1 **Quality**

1.1 Farmakope Indonesia V, 2014

1.2 USP 39, 2016

1.2 Multistate File, Capsugel,3th 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 manufature at primary and secondary in well-closed containers.

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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,3th 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		180518
Checked by	Analytical Method Assistant Manager	LB		180518
Approved by	Quality Control Manager	AM	an	180518
	Research & Development Manager	LB		180518
	Quality Assurance Manager	PM		180518