INDOFARMA

PURCHASING SPECIFICATION

Lansoprazole Pellet			
No. : RPB 282	**Rev : 07**	**Eff. date :** 17 10 06	**Sign :**

1 **Quality**

1.1 Farmakope Indonesia Edisi V, 2014

1.2 USP 37, 2014

2 **Additional Requirements**

2.1 Particle size distribution

- Mesh 12 : Max. 10,0 %
- Mesh 16 : Min. 90 %
- Mesh 16 (passed) : Max. 10,0 %

2.2 Bulk Density : 0,80 – 0,90 g/ml

2.3 Tapping Density : 0,80 – 0,95 g/ml

2.4 Arrival Date : Max. 12 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 Farmakope Indonesia and USP 37

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**

Cardboard drum @ 50 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 tight, light-resistant 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 Edisi V, 2014

7.2 USP 37, 2014

8 **History**

Purchasing specification revision of RPB 282 revision 06 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		171006
Checked by	Analytical Method Assistant Manager	LB		171006
Approved by	Quality Control Manager	AM		171006
	Research & Development Manager	LB		171006
	Quality Assurance Manager	PM		171006

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			