INDOFARMA

PURCHASING SPECIFICATION

Amlodipin Besilat			
No. : RPB 287	**Rev : 01**	**Eff. date :** 18 07 10	**Sign :**

1 **Quality** : USP 39, 2016

2 **Additional Requirements**

2.1 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 USP 39
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 **Package**

Cardboard drum @ 10 kg, 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.

5 **Labeling**

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

5.1 Name of manufacturer and address
5.2 Product name, batch/lot number, manufacturing and expiration date
5.3 Quality designation
5.4 Gross/net weight
5.5 Number of packages

6 **Reference Documents**

USP 39, 2016

7 **History**

This specification is revision of RPB 287 revision 00 with change in the quality of USP 34 to USP 39, format document, and deleting the review point.

8 **Distribution**

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

8.1 Procurement Dept.
8.2 Quality Control Dept.

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9 **Approval**

Preparation steps	Position	Code	Signature	Date
Prepared by	Starting and Packaging Material Testing Assistant Manager	AM		180710
Checked by	Analytical Method Assistant Manager	LB		180710
Approved by	Quality Control Manager	AM		180710
	Research & Development Manager	LB		180710
	Quality Assurance Manager	PM		180710