indofarma	**PURCHASING SPECIFICATION** **Rifampin (Rifampisin)**	No : **RPB 157**
		Revisi : **03**
		Berlaku : **08 AUG 2019**
		Paraf : *ƒ*

1 **Quality** : USP 37

2 **Additional Requirements**
   2.1 Bulk density : 0,35 – 0,60 g/ml
   2.2 Tapping density : 0,50 – 0,80 g/ml
   2.3 Arrival date : Max. 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 37 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 **Package**
   Cardboard drums 25 kg, with original seal (inside and outside) from manufacture

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**
   6.1 USP 37

7 **History**

Revision	Eff. Date	Change
03	08 AUG 2019	Purchasing specification changed format document

	PURCHASING SPECIFICATION Rifampin (Rifampisin)	No : RPB 157
indofarma		Revisi : 03
		Berlaku : 08 AUG 2019
		Paraf :

8 Review

This specification will be reviewed every 2 years or less (if necessary) by the Quality Control Manager
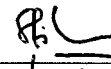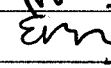
9 Distribution

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	Raw Material and Product Testing Assistant Manager	AM		08 Agu 2019
Checked by	Analytical Method Assistant Manager	LB		08 Agu 2019
Approved by	Quality Control Manager	AM		08 Agu 2019
	Research & Development Manager	LB		08 Agu 2019
	Quality Assurance Manager	PM		08 Agu 2019

11 Review

No.	Position	Date	Signature	Recommendation
1.	Quality Control Manager			
2.	Quality Control Manager			
3.	Quality Control Manager			