


**Lincomycin Hydrochloride  
( Linkomisin Hidroklorida )**

No. : RPB 237	Rev : 06	Eff. date : 18 05 18	Sign : 
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- 1 **Quality**
  - 1.1 USP 37, 2014
  - 1.2 Inhouse Indofarma
  
- 2 **Additional Requirements**
  - 2.1 Bulk Density : 0,59 - 0,66 g/ml
  - 2.2 Tapping Density : 0,80 - 0,85 g/ml
  - 2.3 Flow rate : Max. 10 second/100 gr
  - 2.4 Particle Size Distribution
    - Mesh 35 : 0,0 - 15,0 %
    - Mesh 60 : 20,0 - 40,0 %
    - Mesh 100 : 20,0 - 45,0 %
    - Mesh 200 : 15,0 - 35,0 %
    - Mesh 200 ( Passed ) : 0,0 - 20,0 %
  - 2.4 Arrival Date : NMT. 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 USP 37 and Internal specification
  - 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 @25 kg, with original seal (inside and outside) from manufacture.  
To be stated on goods, label original from manufacture at primary and secondary packag each  
Preserve in tight 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



**PURCHASING SPECIFICATION**

<b>Lincomycin Hydrochloride ( Linkomisin Hidroklorida )</b>			
<b>No. : RPB 237</b>	<b>Rev : 06</b>	<b>Eff. date : 180518</b>	<b>Sign : </b>

**7 Reference Documents**

- 7.1 USP 37, 2014
- 7.2 Inhouse Indofarma

**8 History**

Purchasing specification is revision of RPB 237 revision 05 with change in 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	<sup>an.</sup>	180518
	Research & Development Manager	LB		180518
	Quality Assurance Manager	PM		180518