

## Amoxicilin Tryhidrate, Compacted

No. : RPB 150 a	Rev : 01	Eff. date : 18 07 10	Sign : 
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**1 Quality**

- 1.1 USP 39, 2016
- 1.2 British Pharmacopeia 2016
- 1.3 Inhouse Indofarma

**2 Additional Requirements**

- 2.1 Bulk density : 0,55 – 0,65 g/ml
- 2.2 Tapping density : 0,65 – 0,80 g/ml
- 2.3 Particle size distribution
  - Mesh 35 : NLT. 15 %
  - Mesh 60 : 10,0 – 55,0 %
  - Mesh 100 : 0,0 – 40,0 %
  - Mesh 100 (passed) : 0,0 – 40,0 %
- 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 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 Package**

Cardboard drums @ 25 kg, with original seal (inside and outside) from manufacture.  
Tobe 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**

- 6.1 USP 39, 2016
- 6.2 British Pharmacopeia 2016
- 6.3 Inhouse Indofarma



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**7 History**

This specification is revision RPB 150a revision 00 with change in the 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.

**9 Approval**

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