




<b>Epinephrine Bitartrate</b>			
<b>No. : RPB 211</b>	<b>Rev : 05</b>	<b>Eff. date : 180308</b>	<b>Sign : </b>

**1 Quality**

- 1.1 USP 39, 2016
- 1.2 Farmakope Indonesia V, 2014

**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 Quality
- 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 Practise Certificate****5 Package**

Alumunium tin @ 100 gr, 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 USP 35, 2012
- 7.2 Farmakope Indonesia V, 2014

**8 History**

Purchasing specification is revision of RPB 211 revision 04 with change in the quality and format document.

**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.

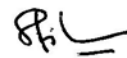

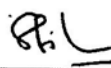


<b>Epinephrine Bitartrate</b>			
No. : RPB 211	Rev : 05	Eff. date : 180308	Sign : 

**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		180308
Checked by	Analytical Method Assistant Manager	LB		180308
Approved by	Quality Control Manager	AM	<sup>an</sup> 	180308
	Research & Development Manager	LB		180308
	Quality Assurance Manager	PM		180308

**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			