Hydrocortisone Acetate (Hidrokortison Asetat)			
No. : RPB 213	**Rev : 10**	**Eff. date : 180129**	**Sign :**

1 **Quality**

1.1 Farmakope Indonesia V, 2014

1.2 USP 39, 2016

1.3 BP 2016

2 **Additional Requirements**

2.1 Particle size : ≤ 10 µm Min 90,0 %

2.2 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 **Attached update Good Manufacture Practice Certificate**

5 **Package**

Tin @ 5 kg, 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 well-closed 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 Farmakope Indonesia V, 2014

7.2 USP 39, 2016

7.3 BP 2016

8 **History**

Purchasing specification is revision of RPB 213 revision 09 with change in the quality and format document.

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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.

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		180129
Checked by	Analytical Method Assistant Manager	LB		180129
Approved by	Quality Control Manager	AM		180129
	Research & Development Manager	LB		180129
	Quality Assurance Manager	PM		180129

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			