Prednisone, *Superfine Powder*			
No. : RPB 214	**Rev : 06**	**Eff. date : 17 06 20**	**Sign :**

1 Quality

1.1 Farmakope Indonesia V, 2014
1.2 USP 37, 2014
1.3 BP 2009

2 Additional Requirements

2.1 Particle size : ≤ 10 µm Min 90,0 %
2.2 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 Farmakope Indonesia V, BP 2009 and USP 37
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 Manufacturing Practise Certificate

5 Package

Tin @ 10 kg, 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

6.1 Farmakope Indonesia V, 2014
6.2 USP 37, 2014
6.3 BP, 2009

8 History

Purchasing specification is revision of RPB 214 revision 06 with change in the format document

Prednisone, *Superfine Powder*			
No. : RPB 214	**Rev : 06**	**Eff. date : 170620**	**Sign :**

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		170620
Checked by	Analytical Method Assistant Manager	LB		170620
Approved by	Quality Control Manager	AM		170620
	Research & Development Manager	LB		170620
	Quality Assurance Manager	PM		170620

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			