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| Clonidine Hydrochloride | | | |
| No. : RPB 190 | Rev : 08 | Eff. date : 18 07 10 | Sign : J. |

1 Quality

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

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 Package

Cardboard drum @ 25 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

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 Farmakope Indonesia V, 2014
- 6.2 USP 39, 2016


7 History

Purchasing specification is revision of RPB 190 revision 07 with change in the quality of USP 35 to Farmakope Indonesia V and USP 39 and deleting the review point.



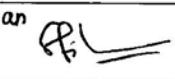
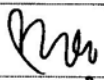
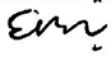
8 Distribution

In general, a copy of this specification is distributed to :

- 8.1 Procurement Dept.
- 8.2 Quality Control Dept.

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9 Approval

| Preparation steps | Position | Code | Signature | Date |
|-------------------|-----------------------------------------------------------|------|---------------------------------------------------------------------------------------------------|--------|
| Prepared by | Starting and Packaging Material Testing Assistant Manager | AM |  | 180710 |
| Checked by | Analytical Method Assistant Manager | LB |  | 180710 |
| Approved by | Quality Control Manager | AM | ^{an}  | 180710 |
| | Research & Development Manager | LB |  | 180710 |
| | Quality Assurance Manager | PM |  | 180710 |