


	PURCHASING SPECIFICATION Salbutamol Sulfate (Albuterol Sulfate)	No. : RPB226
		Rev : 09
		Eff. date : 12 MAR 2020
		Sign : 

- 1 **Quality** : Suplemen III FI V, 2018
- 2 **Additional Requirements**
 - 2.1 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 Description : white powder until almost white
 - 3.4 Results of test and assays
 - 3.5 Compliance with Quality
 - 3.6 Quality designation
 - 3.7 Date of manufacturing, expiration (year-month) and date of released (year- month-day)
 - 3.8 Approval/signature of QA/QC responsibility
- 4 **Package**
Cardboard drum @ 25kg, 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 **Labelling**
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**
Suplemen III FI V, 2018

7 **History**

Revision	Eff. Date	Change
08	10 JUL 2018	1. Changes in deleting the review point.
09	12 MAR 2020	1. Changes in the quality of USP 37, 2014 and FI V, 2014 to Suplemen III FI V, 2018 2. Changes into new logo 3. Changes in the header format

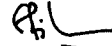




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8 Distribution

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

- 8.1. Procurement Dept.
- 8.2. Quality Control Dept.

9 Approval

Preparation steps	Position	Code	Signature	Date
Prepared by	Product and Raw Material Testing Assistant Manager	AM		12 Mar 2020
Checked by	Analytical Method Assistant Manager	LB		12 Mar 2020
Approved by	Quality Control Manager	AM		12 Mar 2020
	Research & Development Manager	LB		12 Mar 2020
	Quality Assurance Manager	PM		12 Mar 2020