




Ambroxol Hydrochloride (Ambroksol Hidroklorida)			
No. : RPB 222	Rev : 02	Eff. date : 180524	Sign : 

1 Quality

1.1. British Pharmacopoeia, 2013

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 Results of test and assays

3.4 Compliance with British Pharmacopoeia 2013

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**

Vat @ 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 tight and 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 British Pharmacopoeia, 2013

8 History


Purchasing specification is revision of RPB 222 revision 01 with change in the format document and deleting the review point.

9 Distribution



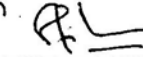
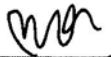

In general, a copy of this specification is distributed to :

9.1 Procurement Dept.

9.2 Quality Control Dept.

Ambroxol Hydrochloride (Ambroksol Hidroklorida)			
No. : RPB 222	Rev : 02	Eff. date : 180524	Sign : 

10 Approval

Preparation steps	Position	Code	Signature	Date
Prepared by	Starting and Packaging Material Testing Assistant Manager	AM		180524
Checked by	Analytical Method Assistant Manager	LB		180524
Approved by	Quality Control Manager	AM	an. 	180524
	Research & Development Manager	LB		180524
	Quality Assurance Manager	PM		180524