indofarma	PURCHASING SPECIFICATION Ranitidin Hydrochloride, Granul	No. : RPB113 Rev : 06 Eff. Date : 23 JAN 2020 Sign :

1 **Quality**

1.1 USP 39, 2016
1.2 BP 2016
1.3 Inhouse Indofarma

2 **Additional Requirements**

2.1	Tapped density	: 0,65 – 0,85	g/ml
2.2	Bulk density	: 0,40 – 0,60	g/ml
2.3	Particle Size Distribution	:	
2.3.1	> 500 µm (mesh 30)	: NMT. 10,0	%
2.3.2	> 250 µm (mesh 60)	: NMT. 55,0	%
2.3.3	> 125 µm (mesh140)	: NMT. 50,0	%
2.3.4	Passed	: NMT. 20,0	%
2.4	Limit of NDMA (N-Nitrosodimethylamine)	: 0.32	ppm
2.5	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 Description : white granule powder, practically odorless
3.4 Results of test and assays
3.5 Compliance with Quality and Additional Requirements
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**

Corrugated box @ 25 kg, with original seal from manufacture.
To be stated on goods, original label from manufacture at both of primary and secondary package
Preserve in tight, light resistant containers.

5 **Labeling**

To be stated on goods **original label 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 USP 39, 2016
6.2 BP 2016
6.3 Inhouse Indofarma

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7 **History**

Revision	Eff. Date	Change
05	06 Aug 2018	1. Change into new logo 2. Change in the header format 3. Change of reference document from USP 37 to USP 39 and adding BP 2016
06	23 JAN 2020	1. Adding Limit of NDMA based on change control no. 261/UP/XII/2019 2. Adding Description in Certificate of Analysis from Manufacturer

8 **Distribution**

A copy of this purchasing 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		21 JAN 2020
Checked by	Analytical Method Assistant Manager	LB		21 JAN 2020
Approved by	Quality Control Manager	AM		21 JAN 2020
	Research & Development Manager	LB		21 JAN 2020
	Quality Assurance Manager	PM		21 JAN 2020