indofarma	PURCHASING SPECIFICATION Ranitidin Hydrochloride Powder (for Injection)	No. : RPB114 Rev : 07 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	Bacteria Endotoxine	: NMT. 7	USP Endotoksin Unit/mg
2.2	Microbial Limit Test		
2.2.1.	Total plate count	: NMT. 10^3	kol/g
2.2.2.	Amounts of fungi and yeast	: NMT. 10^2	kol/g
2.2.3.	Microbial Pathogen (E. Coli, Salmonella)	: Negative	
2.2.4.	Staphylococcus aureus	: Negative	
2.2.5.	Pseudomonas (Aeruginosa)	: Negative	
2.3	Limit of NDMA (N-Nitrosodimethylamine)	: 0.32	ppm
2.4	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: crystal powder, white to pale yellow, 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, 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, light resistant 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

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6 Reference Documents

6.1 USP 39, 2016

6.2 BP 2016

6.3 Inhouse Indofarma

7 History

Revision	Eff. Date	Change
06	13 Jul 2018	1. Change in the quality 2. Change format document 3. Deleting the review point
07	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 4. Change into new logo 5. Change in the header format

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		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