

**ORCHEV PHARMA PVT. LTD.**

AN ISO 9001 : 2015 Company

CIN-U24231GJ1989PTC012430

CERTIFICATE OF ANALYSIS**PRODUCT: RANITIDINE HYDROCHLORIDE USP – POWDER (SUITABLE FOR INJECTION) (FORM-II)**

BATCH NO. : R-035PD0225	A.R. NO.: FG/2502284	MFG. DATE: FEB – 2025	MFG. BY: ORCHEV PHARMA PVT. LTD.
BATCH SIZE (KG): 1525	CAS NO.: 66357-59-3	RETEST DATE: JULY – 2026	MFG. LIC. NO.: G / 25 / 1017

Storage condition: Store the material in tight light resistance container below 25 °C temperature. After usage tie the poly bags tightly to prevent access of air and moisture. Excursion allowed up to 40°C.

SR. NO.	TEST	SPECIFICATION	RESULT
1	Description	White to pale yellow practically odourless crystalline powder	WHITE, PRACTICALLY ODOURLESS CRYSTALLINE POWDER
2	Solubility	Very soluble in water, sparingly soluble in alcohol.	COMPLIES
3	Identification <197> <197M> , <197U> and <191>	Infrared Absorption, Ultraviolet Absorption and A solution of it meets the requirements of the tests for Chlorides	COMPLIES
4	pH (1 in 100) <791>	4.5 to 6.0	5.59
5	Chromatographic purity (By HPLC) <621> a) Ranitidine bis-compound (Imp-B) b) Ranitidine simple nitroacetamide c) Ranitidine oxime d) Ranitidine amino alcohol hemifumarate e) Ranitidine diamine hemifumarate (Imp-A) f) Ranitidine S-oxide (Imp-C) g) Ranitidine N-oxide h) Ranitidine complex nitroacetamide i) Ranitidine formaldehyde adduct j) Major / Largest single unknown Impurity k) Total impurities	 NMT 0.3% NMT 0.1% NMT 0.1% NMT 0.1% NMT 0.1% NMT 0.1% NMT 0.1% NMT 0.1% NMT 0.1% NMT 0.1% NMT 0.5%	 0.19 % NOT DETECTED NOT DETECTED NOT DETECTED NOT DETECTED NOT DETECTED 0.05 % NOT DETECTED NOT DETECTED BELOW DISREGARD LIMIT 0.24 %
6	Loss on drying <731>	NMT 0.75%	0.23 %
7	Residue on ignition <281>	NMT 0.10%	0.041 %
8	Assay (Dry basis) <621>	97.5 % - 102.0 %	100.08 %

1*	Melting range (In house)	ABOUT 140 °C	140.1 °C
2*	Clarity: 10% Soln:430 nm (In house) Absorbance	NMT 0.075	0.046
3*	Bulk density (In house) Untapped Tapped (1250)	0.40 ± 0.2 g / mL 0.55 ± 0.2 g / mL	0.42 g / mL 0.58 g / mL
4*	Particles % by weight	NLT 90 % PASS THROUGH 80 mesh	98.73 % PASS THROUGH 80 mesh

1**	BACTERIAL ENDOTOXIN	NMT 7 EU / mg	LESS THAN 0.85 EU / mg
2**	TOTAL BACTERIAL COUNT	NMT 1000 CFU / g	LESS THAN 10 CFU / g
3**	TOTAL YEAST & MOULD COUNT	NMT 100 CFU / g	LESS THAN 10 CFU / g
4**	<i>Escherichia coli</i> <i>Pseudomonas aeruginosa</i> <i>Staphylococcus aureus</i> <i>Salmonella spp.</i>	SHOULD BE ABSENT / g SHOULD BE ABSENT / g SHOULD BE ABSENT / g SHOULD BE ABSENT /10 g	ABSENT ABSENT ABSENT ABSENT

The material complies with the specification as laid down in **USP-NF 2024 & In House Limits.**

Date: 17/03/2025

(*) indicates In House tests

(**) indicates microbial tests

17/03/25
Prepared by
Ms. Urvisha Pansuriya (QC Officer)

17/03/25
Check & Approved by
Mr. Ravi Jani (QC Manager)

QUALITY ASSURANCE REVIEW
SIGN:
DATE: 17/03/25
ORCHEV PHARMA

