

**ORCHEV PHARMA PVT. LTD.**

AN ISO 9001 : 2015 Company

CIN-U24231GJ1989PTC012430

CERTIFICATE OF ANALYSIS**PRODUCT: RANITIDINE HYDROCHLORIDE USP – DC GRADE (FORM-II)**

BATCH NO. : R-020DC1123	A.R. NO.: FG/2311160	MFG. DATE: NOVEMBER – 2023	MFG. BY: ORCHEV PHARMA PVT. LTD.
BATCH SIZE (KG): 1500	CAS NO.: 66357-59-3	RETEST DATE: APRIL – 2025	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 granules	WHITE, PRACTICALLY ODOURLESS CRYSTALLINE GRANULES
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	5.63
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 BELOW DISREGARD LIMIT NOT DETECTED NOT DETECTED BELOW DISREGARD LIMIT 0.19 %
6	Loss on drying <731>	NMT 0.75%	0.24 %
7	Residue on ignition <281>	NMT 0.10%	0.037 %
8	Assay (Dry basis) <621>	97.5 % - 102.0 %	100.15 %
1*	Melting range (In house)	ABOUT 140 °C	140 °C
2*	Clarity: 10% Soln:430 nm (In house) Absorbance	NMT 0.20	0.047
3*	Bulk density (In house) Untapped Tapped (1250)	0.50 ± 0.2 g / mL 0.75 ± 0.2 g / mL	0.53 g / mL 0.71 g / mL
4*	Particle size by sieving (In house) More than 500 µm (30 mesh) More than 250 µm (60 mesh) Less than 90 µm (170 mesh)	NMT 10 % NMT 55 % NMT 15 %	4.21 % 39.24 % 4.80 %

The material complies with the specification as laid down in **USP-NF 2024 (USP 47) & In House Limits.**

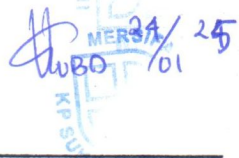
Date: 23/01/2025

(*) indicates In House Tests


23/01/25
Prepared by
Ms. Foram Bhalodia (QC Chemist)


23/01/25
Check & Approved by
Ms. Urvisha Pansuriya (QC Officer)

QUALITY ASSURANCE REVIEW
SIGN: 
DATE: 23/01/25
ORCHEV PHARMA PVT. LTD.


23/01/25