



AN ISO 9001 : 2015 Company
CIN-U24231GJ1989PTC012430

CERTIFICATE OF ANALYSIS

PRODUCT: RANITIDINE HYDROCHLORIDE USP - POWDER (SUITABLE FOR INJECTION) (FORM-II)

BATCH NO. : R-012PD0624	A.R. NO.: FG/2406032	MFG. DATE: MAY - 2024	MFG. BY: ORCHEV PHARMA PVT. LTD.
BATCH SIZE (KG): 1500	CAS NO.: 86357-68-3	RETEST DATE: OCTOBER - 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.

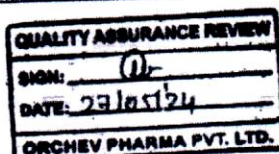
SR. NO.	TEST	SPECIFICATION	RESULT
1	Description	White to pale yellow practically odourless crystalline powder	WHITE, PRACTICALLY ODOURLESS CRYSTALLINE POWDER
2	Solubility	Very soluble in water, sparingly soluble in alcohol.	COMPLIES
3	Identification <197> <197M> <197U> and <191>	Infrared Absorption, 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	5.62
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%	0.18 % NOT DETECTED NOT DETECTED NOT DETECTED NOT DETECTED NOT DETECTED BELOW DISREGARD LIMIT NOT DETECTED NOT DETECTED BELOW DISREGARD LIMIT 0.18 %
6	Loss on drying <731>	NMT 0.75%	0.25 %
7	Residue on ignition <281>	NMT 0.10%	0.039 %
8	Assay (Dry basis) <621>	97.5 % - 102.0 %	99.53 %
9	Residual solvents (in ppm) <467>	1 Chloroform NMT 60 ppm 2. Isopropyl alcohol NMT 5000 ppm	NOT DETECTED 289 ppm
1*	Melting range (in house)	ABOUT 140 °C	139.9 °C
2*	Clarity: 10% Soln:430 nm (in house) Absorbance	NMT 0.075	0.040
3*	Bulk density (in house) Untapped Tapped (1250).	0.40 ± 0.2 g/mL 0.56 ± 0.2 g/mL	0.43 g/mL 0.54 g/mL
4*	Particles % by weight	NLT 90 % PASS THROUGH 80 mesh	99.06 % PASS THROUGH 80 mesh
1**	BACTERIAL ENDOTOXIN	NMT 7 EU / mg	LESS THAN 1.76 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**	Escherichia coli Pseudomonas aeruginosa Staphylococcus aureus Salmonella spp.	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 2021 & In House Limits.

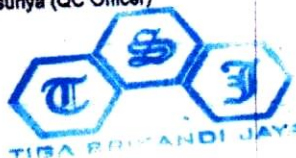
Date: 27/05/2024

(*) Indicates In House tests

(**) Indicates microbial tests



Prepared by
Ms. Urviha Pansuriya (QC Officer)



Check & Approved by
Mr. Brijesh Hapani (QC Manager)
For, Orchev Pharma Pvt. Ltd.

Viren Patel
Director

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[illegible]

PAGE 1 OF 1

CERTIFICATE OF ANALYSIS
Form 39 (Rule 150-F (f) - Report of test or analysis by approved institution)
Raw Material

Product Name	Ranitidine HCL		
Party Name And Address	Orchev Pharma Pvt. Ltd. Rangoli,Gondal Road,,Rajkot- 360002		
Mfg. By	Orchev Pharma Pvt. Ltd. (India)		
Manufacturer License No.	G/25/1017	Testing Date	18/05/2024 to 20/05/2024
Batch No.	R-012PD0524	Document No.	AKI 2580_2024
Mfg. Date	2024-05	Qty. Received	5.00 Gms
Exp. Date	N/A	Test Qty.	3.00 Gms
Date Of Sample Receipt	16/05/2024	TR No.	N/A
Sample Id	ARI/ORC/04114/2024	Release Date	20-05-2024

Sr.No	Tests	Test Guideline	Acceptance Limit	Observation	LOD	LOQ
1	N-nitroso-dimethylamine (NDMA)	QC/FG/MOA/R-HCL/NDMA/001	NMT 320 ng/g	Not Detected	As Such LOD: 0.520 ng/g W.R.T LOD: 17.33 ng/g	As Such LOQ: 1.575 ng/g W.R.T LOQ: 52.5ng/g

Conclusion: In the opinion of the undersigned, the sample referred to above is of standard quality and complies with the prescribed standards.

Remarks on behalf of Orchev Pharma Pvt. Ltd.

- 1) Results of NDMA at the time of release for information purpose only.
2) Stability data in term of NDMA impurity not available.

	Reviewed By	Checked By	Digitized By
Name	Piyush Aeriya (20/05/2024)	Bhavesht Patel (20/05/2024)	Jinal Shah (20/05/2024)
Sign. Date	Signature valid Digitally signed by Piyush Aeriya DN: cn=Piyush Aeriya, o=Vishal, ou Location: Ahmedabad	Signature valid Digitally signed by Bhavesht Patel DN: cn=Bhavesht Patel, o=Vishal, ou Location: Ahmedabad	Signature valid Digitally signed by Jinal Shah DN: cn=Jinal Shah, o=Vishal, ou Location: Ahmedabad

END OF REPORT



Note:

1. The results listed refer only to the samples and applicable parameters; endorsement of product is neither inferred nor implied.
2. Total liability of our laboratory is limited to the supplied test samples by the customer pertaining to above specified batch only, and capped to the invoiced amount only.
3. Sample drawn and submitted by the sponsor for Analysis unless otherwise stated.

FOR 341 N2	Reference SOP No	Effective Date
Exhibit 1.08	ARL/SOP/QA.047	03/17/2013

Accuprec Inc. • 100/101, Changan Road - Daxin Highway No. 1, Matoda Patta, Post. Matoda Ahmedabad - 382215, Gujarat, India
 Tel: +91-79-6616 8911 • +91-90991 15445 • +91-90991 381023 Email: info@accuprec.com Web: www.accuprec.com
 Global Business Office • Sudbury, ON, Canada • Pittsburgh, PA, USA


ORCHEV PHARMA PVT. LTD.

AN ISO 9001 : 2015 Company

CIN-U24231GJ1988PTC012430

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

BATCH NO.: R-086PD0825

A.R. NO.: FG/2506082

MFG. DATE: MAY-2025

MFG. BY: ORCHEV PHARMA PVT. LTD.

BATCH SIZE (KG): 1400

CAS NO.: 86357-89-3

RETEST DATE: OCTOBER-2026

MFG. LIC. NO.: G/25/1017

Storage condition: Store the material in light light resistance container below 25 °C temperature. After usage tie the poly bags tightly to prevent access of air and moisture. Expiration 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 8.0	5.62
5	Chromatographic purity (By HPLC) <821> a) Ranitidine bis-compound (imp-B) b) Ranitidine simple nitroacetamide c) Ranitidine oxime d) Ranitidine amino alcohol hemitartrate e) Ranitidine diamine hemitartrate (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%	0.18 % NOT DETECTED NOT DETECTED NOT DETECTED NOT DETECTED NOT DETECTED BELOW DISREGARD LIMIT NOT DETECTED NOT DETECTED BELOW DISREGARD LIMIT 0.18 %
6	Loss on drying <731>	NMT 0.75%	0.24 %
7	Residue on ignition <281>	NMT 0.10%	0.038 %
8	Assay (Dry basis) <821>	97.5 % - 102.0 %	100.24 %
9	Residual solvents (in ppm) <467>	1 Chloroform NMT 80 ppm 2. Isopropyl alcohol NMT 5000 ppm	01 ppm 241 ppm
1*	Melting range (In house)	ABOUT 140 °C	139.3 °C
2*	Clarity: 10% Soln: 430 nm (In house) Absorbance	NMT 0.075	0.043
3*	Bulk density (In house) Untapped Tapped (1250)	0.40 ± 0.2 g/mL 0.55 ± 0.2 g/mL	0.46 g/mL 0.56 g/mL
4*	Particles % by weight	NLT 90 % PASS THROUGH 80 mesh	93.41 % 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**	Escherichia coli Pseudomonas aeruginosa Staphylococcus aureus Salmonella spp.	SHOULD BE ABSENT / g SHOULD BE ABSENT / g SHOULD BE ABSENT / g SHOULD BE ABSENT / 10 g	ABSENT ABSENT ABSENT ABSENT

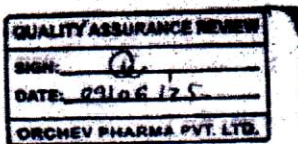
The material complies with the specification as laid down in USP-NF 2024 & In House Limits.

Date: 09/06/2025

() Indicates In House tests

() Indicates Microbial tests

 09/06/25
Prepared by:
Mr. Urviha Pansuriya (QC Officer)

 (R)
09/06/25
Check & Approved by
Mr. Ravi Jani (QC Manager)


For Orchev Pharma Pvt. Ltd

 Viren Patel
Director

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 FACTORY : Shaper Industrial Area, Rajkot-Gondal Highway, Vezavel, Dist: Rajkot INDIA Phone : +91-2827-252114/15, Fax : +91-2827-252113

FDCA LICENCE NO. GTL/37/31

(FDCA, FDCA-GUP, OECD-GUP, AAH AC, CSEA, ISO 9001:2015, AYUSH, DIN, CDSCO, DUNE, POLA-CU, CIRC, BIS, USFDA)

PAGE 1 OF 1

CERTIFICATE OF ANALYSIS Form 39 (Rule 150-E (f) - Report of test or analysis by approved institution) Raw Material			
Product Name	Ranitidine HCL		
Party Name And Address	Orchev Pharma Pvt. Ltd. - Rajkot Shapar Industrial Area, Rajkot-Gondal Highway, Veraval, Dist. Rajkot, - 360 024.		
Mfg. By	Orchev Pharma Pvt. Ltd. (India)		
Manufacturer License No.	G/25/1017	Testing Date	09/06/2025 to 10/06/2025
Batch No.	R-005PD0525	Document No.	ARL/4749/2025
Mfg. Date	2025-05	Qty. Received	5.00 Gms
Exp. Date	N/A	Test Qty.	5.00 Gms
Date Of Sample Receipt	06/06/2025	TR No.	N/A
Sample Id	ARL/ORC/05578/2025	Release Date	10-06-2025

Sr.No	Tests	Test Guideline	Acceptance Limit	Observation	LOD	LOQ
1	N-nitrosodimethylamine (NDMA)	QC/FG/MOA/R-HCL/NDMA/001	NMT 320 ng/g	Not Detected	As Such LOD: 0.520 ng/g W.R.T LOD: 17.33 ng/g	As Such LOQ: 1.575 ng/g W.R.T LOQ: 52.5ng/g
Conclusion: In the opinion of the undersigned, the sample referred to above is of standard quality and complies with the prescribed standards. Remarks on behalf of Orchev Pharma Pvt. Ltd. 1) Results of NDMA at the time of release for information purpose only. 2) Stability data in term of NDMA impurity not available.						

Name	Reviewed By	Checked By	Authorized By
Signature valid	Rohit Keshvi (10/06/2025)	Devenkumar Rasadiya (10/06/2025)	Dr. Kalpesh Patil (10/06/2025)
Signature valid	Signature valid	Signature valid	Signature valid

END OF REPORT

QUALITY ASSURANCE REVIEW

SIGN: T.K.H.
DATE: 11/06/25

ORCHEV PHARMA PVT. LTD.



Note:

- The results listed refer only to the samples and applicable parameters, endorsement of product is neither offered nor implied.
- Total liability of our laboratory is limited to the supplied test samples by the customer pertaining to above specified batch only and up to the invoiced amount only.
- Sample drawn and submitted by the sponsor for Analysis unless otherwise specified.

Exhibit No	Reference SOP	Effective Date
Exhibit I_01	ARL/SOP/QA/001	03/02/2025

Opp. Zydus Pharmez, Changodar - Bavla Highway, Matoda, Rajkot, Post: Matoda, Ahmedabad - 382213, Gujarat, India
 Contact : +91 9099616769 / +91 9909919545 / +91 9099581022 Email : info@accuprec.com Web : www.accuprec.com
 Global Business Office • Hamilton, ON, Canada • Pittsburgh, PA, USA

**ORCHEV PHARMA PVT. LTD.**AN : ISO 9001 : 2015 Company
CIN - U24231GJ1989PTC012430

AAJ 002.00

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

BATCH NO. : R-020PD0925	A.R. NO.: FG/2509087	MFG. DATE: SEPTEMBER-2025	MFG. BY: ORCHEV PHARMA PVT. LTD.
BATCH SIZE (KG): 1500	CAS NO.: 66357-59-3	RETEST DATE: FEBRUARY-2027	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	5.61
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%	0.041 %
8	Assay (Dry basis) <621>	97.5 % - 102.0 %	100.56 %
9	Residual solvents (in ppm) <467>	1 Chloroform NMT 60 ppm 2. Isopropyl alcohol NMT 5000 ppm	NOT DETECTED 213 ppm

1*	Melting range (In house)	ABOUT 140 °C	139.9 °C
2*	Clarity: 10% Soln:430 nm (In house) Absorbance	NMT 0.075	0.050
3*	Bulk density (In house) Untapped Tapped (1250)	0.40 ± 0.2 g / mL 0.55 ± 0.2 g / mL	0.42 g / mL 0.57 g / mL
4*	Particles % by weight	NLT 90 % PASS THROUGH 80 mesh	92.33 % 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 & MOLD 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: 29/09/2025

(*) indicates In House tests

(**) indicates microbial tests

QUALITY ASSURANCE REVIEW	
SIGN: <u>T. N. S.</u>	
DATE: <u>29/09/25</u>	
ORCHEV PHARMA PVT. LTD.	

Ru
29/09/25
Prepared by
Ms. Kaushika Rupapara (QC Officer)

R
29/09/25
Check & Approved by
Mr. Ravi Jani (QC Manager)



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FACTORY : Shapur Industrial Area, Rajkot-Gondal Highway, Veraval, Dist. Rajkot INDIA. Phone : +91-2827-252114/15. Fax : +91-2827-252113



Ultimate solution...

FDCA LICENCE NO. GTI/37/34

(FDCA, FDCA-GLP, OECD-GLP, AAALAC, CESEA, ISO 9001:2015, AYUSH, DSIR, CDSCO, DUNS, FDCA-Cos, CIBRC, BIS, USFDA)

RESEARCH
REDEFINE

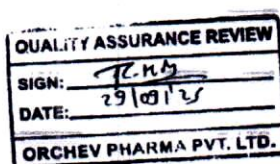
PAGE 1 OF 1

CERTIFICATE OF ANALYSIS			
Form 39 (Rule 150-E (f) - Report of test or analysis by approved institution)			
Raw Material			
Product Name	Ranitidine- HCl		
Party Name And Address	Orchev Pharma Pvt. Ltd. - Rajkot Shapar Industrial Area, Rajkot-Gondal Highway, Veraval, Dist. Rajkot, - 360 024.		
Mfg. By	Orchev Pharma Pvt. Ltd. (India)		
Manufacturer License No.	G/25/1017	Testing Date	26/09/2025 to 29/09/2025
Batch No.	R-020PD0925	Document No.	ARL/7975/2025
Mfg. Date	2025-09	Qty. Received	5.00 Gms
Exp. Date	N/A	Test Qty.	1.00 Gms
Date Of Sample Receipt	24/09/2025	TR No.	N/A
Sample Id	ARL/ORC/09543/2025	Release Date	29-09-2025

Sr.No	Tests	Test Guideline	Acceptance Limit	Observation	LOD	LOQ
1	N-nitrosodimethylamine (NDMA)	QC/FG/MOA/R-HCL/NDMA/001	Not more than 320 ppb	Not Detected	As Such LOD: 0.520 ng/g W.R.T LOD: 17.33 ng/g	As Such LOQ: 1.575 ng/g W.R.T LOQ: 52.5ng/g
Conclusion: In the opinion of the undersigned, the sample referred to above is of standard quality and complies with the prescribed standards. Remarks on behalf of Orchev Pharma Pvt. Ltd. 1) Results of NDMA at the time of release for information purpose only. 2) Stability data in term of NDMA impurity not available.						

	Reviewed By	Checked By	Authorized By
Name	Piyush Aeviya (29/09/2025)	Anita Patel (29/09/2025)	Dr. Kalpesh Patil (29/09/2025)
Sign/Date	Signature valid Digitally signed by Piyush Aeviya Date: 2025.09.29 10:30:24 +05'30' Location: Ahmedabad	Signature valid Digitally signed by Anita Patel Date: 2025.09.29 11:22:41 +05'30' Location: Ahmedabad	Signature valid Digitally signed by Dr. Kalpesh Patil Date: 2025.09.29 11:22:41 +05'30' Location: Ahmedabad

END OF REPORT



Note:		
1. The results listed refer only to the samples and applicable parameters, endorsement of product is neither inferred nor implied.		
2. Total liability of our laboratory is limited to the supplied test samples by the customer pertaining to above specified batch only and up to the invoiced amount only.		
3. Sample drawn and submitted by the sponsor for Analysis unless otherwise stated.		
Exhibit No	Reference No	Effective Date
Exhibit I_01	ARL/SOP/09543	03/02/2025

Opp. Zydus Pharmez, Changodar - Bavla Highway, Near Matoda Station, Post : Matoda, Ahmedabad - 382213, Gujarat, India
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