

No	Kode Barang	Nama Barang	Satuan	Stok Saat Ini (A)	Rencana Kebutuhan (B)	Kekurangan (A -B + C)	Pending Penerimaan (C)	Jumlah	Realisasi Pembelian	Realisasi Penggunaan
1	IMO10028	Jasa Analisa NDMA Bahan Baku Ranitidine HCl	Js	0	2	-2	0	2	0	0

Catatan :

- Pemenuhan parameter analisa NDMA pada bahan baku Ranitidine HCl untuk pelulusan bahan awal dengan No. Batch sebagai berikut:
 - 1. R-049PD1225
 - 2. R-012PD0426
- Estimasi harga pengujian: Rp.800.000/batch.
- Pengujian terakhir NDMA pada bulan Juli 2026 (PF001566)

Latar belakang permintaan:

- Terdapat keterbatasan alat dan penunjang menggunakan metode LC-MS, serta adanya update metode dan spesifikasi terbaru sesuai Farmakope Indonesia VI. Melihat kondisi tersebut sehingga diperlukan pengujian lab eksternal.
- Pengujian ini merupakan pemenuhan parameter analisa NDMA pada bahan baku Ranitidine HCl untuk pelulusan bahan awal.
- Pengujian dilakukan di PT. Pharma Metric Labs

Terlampir spesifikasi bahan awal, CoA dan penawaran harga.

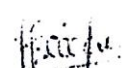
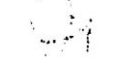
Dibuat Oleh,

 19/26
ADA 08

Mengetahui

 19/26
K 08

SPESIFIKASI BAHAN AWAL
RANITIDIN HIDROKLORIDA
RAW MATERIAL SPECIFICATION
RANITIDINE HYDROCHLORIDE

DEPARTMENT RESEARCH AND DEVELOPMENT		SECTION ANALYTICAL DEVELOPMENT	
Disusun Oleh : <i>Prepared by</i>	Diperiksa Oleh : <i>Checked by</i>	Disetujui Oleh : <i>Approved by</i>	
 Fandy Pradana AD Staff	 Ita Aryani AD Supervisor	 Juwita Ristiani AD Manager	 Head of R&D
Date : 10/10/25	Date : 10/10/25	Date : 10/10/25	Date : 10/10/25

Changed No

RD.02-SBA/092.01

Date

 27th October 2023

SUSUT
PENGERINGAN⁽¹⁾
LOSS ON DRYING

≤ 0.75%

SISA PEMIJARAN⁽¹⁾
RESIDU ON IGNITION

≤ 0.1%

KEMURNIAN
KROMATOGRAFI⁽¹⁾
CHROMATOGRAPHIC
PURITY

Nama Name	Batas (%) Limit (%)
Ranitidine bis-compound	0.3
Cemaran lain Other Impurity	0.1
Total cemaran Total Impurity	0.5

PENETAPAN KADAR⁽¹⁾
ASSAY

97.5 % - 102.0 % $C_{13}H_{22}N_4O_3S.HCl$ dihitung terhadap zat kering.
 97.5% - 102.0% $C_{13}H_{22}N_4O_3S.HCl$ calculated on the dried basis.

ENDOTOKSIN
BAKTERI⁽¹⁾
BACTERIAL
ENDOTOXIN

≤ 7.0 EU/mg
 (Jika digunakan untuk produk steril)
 (If use for sterile product)

NITROSODIMETILAMIN
NDMA⁽²⁾

≤ 320 ng/g

PADAH DAN
PENYIMPANAN⁽¹⁾
PACKAGING AND
STORAGE

Dalam wadah tertutup rapat.
 Preserve in tight containers.

REKAM JEJAK PERUBAHAN
HISTORY OF CHANGE

2RD20/SPBAA/092.00

: 1. Menggantikan no. 3VA00/SPSBB/092.00B.2.
 Replaced no 3VA00/SPSBB/092.00B.2.



LIST PARAMETER BAHAN BAKU BELUM BISA DIKERJAKAN OLEH QC

No.	Parameter	Nama Bahan	Kendala di QC	Keterangan (Bisa/Tidak oleh R&D)
19	EG DEG	PEG 6000	Belum pengembangan metode dan belum tersedia kolom GC	Belum pengembangan
20	Kadar Menthol Total	Peppermint Oil	Belum ada labu asetilasi, belum pengembangan metode/trial	Bisa, tetapi perlu verifikasi
21	Bilangan hidroksil	Polysorbate 80	Sudah dilakukan trial oleh QC namun belum berhasil, butuh pendampingan R&D untuk trial ulang	Belum pengembangan, Belum tersedia: - erlenmeyer tersumbat kaca
22	Identifikasi B	Polysorbate 80	Belum tersedia reagen brom	Belum tersedia reagen brom
23	Kadar Nitrogen	Povidone K30	Sudah dilakukan trial oleh QC namun belum berhasil, butuh pendampingan R&D untuk trial ulang	Akan dijadwalkan trial R&D
24	Vinylpyrrolidinone	Povidone K30	Belum tersedia kolom di QC	Bisa dikerjakan oleh R&D
25	2-Pyrrolidone	Povidone K30	Belum tersedia kolom di QC	Bisa dikerjakan oleh R&D
26	K-Value	Povidone K30	Sudah dilakukan trial oleh QC namun belum berhasil, butuh pendampingan R&D untuk trial ulang	Viscosimeter kapiler belum tersedia
27	Asam Format	Povidone K30	Belum tersedia kolom di QC	Kolom 4 hingga 8 mm x 25 hingga 30-cm (L17) belum tersedia
28	Kadar	Propylenglycol	Tidak tersedia detektor TCD pada GC, sedang proses pengembangan metode dengan GC-FID	detektor TDC belum tersedia
29	NDMA	Ranitidine HCL	Tidak tersedia instrumen LC-MS	LC MS belum tersedia
30	Alumunium	Sodium Chloride	Tidak tersedia instrumen Fluorometer	Bisa, menggunakan metode ICP
31	Kalium	Sodium Chloride	Tidak tersedia instrumen AAS	Bisa, menggunakan metode ICP

 18/08/24
 OR

**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-049PD1225	A.R. NO.: FG/2512130	MFG. DATE: DECEMBER-2025	MFG. BY: ORCHEV PHARMA PVT. LTD.
BATCH SIZE (KG): 1500	CAS NO.: 66357-59-3	RETEST DATE: MAY-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	5.62
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 0.1% NMT 0.5%	0.14 % NOT DETECTED NOT DETECTED NOT DETECTED NOT DETECTED NOT DETECTED BELOW DISREGARD LIMIT NOT DETECTED NOT DETECTED BELOW DISREGARD LIMIT 0.14%
6	Loss on drying <731>	NMT 0.75%	0.24 %
7	Residue on ignition <281>	NMT 0.10%	0.042 %
8	Assay (Dry basis) <621>	97.5 % - 102.0 %	99.54 %
9	Residual solvents (in ppm) <467>	1 Chloroform NMT 80 ppm 2. Isopropyl alcohol NMT 5000 ppm	1 ppm 14 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	0.43 g / mL 0.54 g / mL
4*	Particles % by weight	NLT 90 % PASS THROUGH 80 mesh	91.43 % 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 2025 & In House Limits.

Date: 11/12/2025

(*) indicates In House tests

(**) Indicates microbial tests

QUALITY ASSURANCE REVIEW	
SIGN: <u>TC.H.B</u>	
DATE: <u>11/12/25</u>	
ORCHEV PHARMA PVT. LTD.	

Prepared by
Ms. Kaushika Rupapara (QC Officer)

Check & Approved by
Mr. Ravi Jani (QC Manager)

18/12/26
08

FDCA LICENCE NO. GTL/37/31

(FDCA, FDCA-GLP, OECD-GLP, AAALAC, CCSEA, ISO 9001:2015, AVUSH, DSH, CDSCO, DUNS, FDCA-Cos, CIBRC, BIS, USFDA)

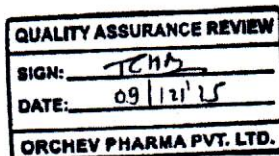
PAGE 1 OF 1

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	05/12/2025 to 08/12/2025
Batch No.	R-049PD1225	Document No.	ARL/10133/2025
Mfg. Date	2025-12	Qty. Received	5.00 Gms
Exp. Date	N/A	Test Qty.	1.00 Gms
Date Of Sample Receipt	04/12/2025	TR No.	N/A
Sample Id	ARL/ORC/12103/2025	Release Date	08-12-2025

Sr.No	Tests	Test Guideline	Acceptance Limit	Observation	LOD	LOQ
1	N-nitrosodimethylamine (NDMA)	Sponsor method	Not more than 320ppb	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 Aevlya (08/12/2025)	Anita Patel (08/12/2025)	Ritesh Shah (08/12/2025)
Sign/Date	Signature valid Digitally signed by Piyush Aevlya Date: 2025.12.08 12:10:46 +05:30 Location: Ahmedabad	Signature valid Digitally signed by Anita Patel Date: 2025.12.08 12:11:46 +05:30 Location: Ahmedabad	Signature valid Digitally signed by Ritesh Shah Date: 2025.12.08 12:11:46 +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 SOP No	Effective Date
Exhibit I_01	ARL/SOP/QA/047	03/02/2025

Opp. Zydus Pharmez, Changodar - Bavla Highway, Nr. Maloda Patia, Post: Maloda, Ahmedabad - 382213, Gujarat, India
 Contact : +91 9099616769 / +91 9909919545 / +91 9099981023 Email : info@accuprec.com Web : www.accuprec.com
 Global Business Office • Hamilton, ON, Canada • Pittsburgh, PA, USA

Handwritten signature and date 18/08/25

**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-012PD0426	A.R. NO.: FG/2604023	MFG. DATE: APRIL-2026	MFG. BY: ORCHEV PHARMA PVT. LTD.
BATCH SIZE (KG): 1500	CAS NO.: 66357-59-3	RETEST DATE: SEPTEMBER-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%	0.17 % NOT DETECTED NOT DETECTED NOT DETECTED NOT DETECTED NOT DETECTED BELOW DISREGARD LIMIT NOT DETECTED NOT DETECTED BELOW DISREGARD LIMIT 0.17 %
6	Loss on drying <731>	NMT 0.75%	0.24 %
7	Residue on ignition <281>	NMT 0.10%	0.039 %
8	Assay (Dry basis) <621>	97.5 % - 102.0 %	100.27 %
9	Residual solvents (in ppm) <467>	1 Chloroform NMT 60 ppm 2. Isopropyl alcohol NMT 5000 ppm	NOT DETECTED 27 ppm
1*	Melting range (In house)	ABOUT 140 °C	139.7 °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	0.26 g / mL 0.36 g / mL
4*	Particles % by weight	NLT 90 % PASS THROUGH 80 mesh	93.73 % 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 & 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 2026 & In House Limits.

Date: 06/05/2026

(*) Indicates In House tests

(**) Indicates microbial tests

QUALITY ASSURANCE REVIEW	
SIGN: _____	_____
DATE: 06/05/26	_____
ORCHEV PHARMA PVT. LTD.	

Prepared by
Mr. Shubham Kasundra (QC Officer)Check & Approved by
Mr. Ravi Jani (QC Manager)

OFFICE : Rangoli, Gondal Road, Rajkot - 360 002, INDIA. Phone : +91-90990 28899, Fax : +91-281 2365733 E-mail : info@orchev.com Web : www.orchev.com
FACTORY : Shapar Industrial Area, Rajkot-Gondal Highway, Veraval, Dist. Rajkot INDIA. Phone : +91-2827-252114/15. Fax : +91-2827-252113

18/05/26
OR



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PDCA, FOCA-GLP, OECD-GLP, AAALAC, CCSEA, ISO 9001:2015, ISO/IEC 17025: 2017 (NABL), AYUSH, DSIR, CDSCO-MD40, DUNS, FOCA-Cos, CIBRC, NCIIM-UBI, BIS, USFDA, EMA, ASCA (AZLA), CDSCO-CTD7C, HEALTH CANADA

**RESEARCH
REDEFINE**

PAGE 1 OF 1

CERTIFICATE OF ANALYSIS			
Form 39A (Rule 150-E (f) - Report of test or analysis by approved institution for an Individual or Organisation or Procurement agency)			
Raw Material			
Product Name	Ranitidine HCL		
Name Of Individual Or Organisation Or Procurement Agency 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	04/05/2026 to 05/05/2026
Batch No.	R-012PD0426	Document No.	ARL/4594/2026
Mfg. Date	2026-04	Qty. Received	2.00 Gms
Exp. Date	N/A	Test Qty.	1.00 Gms
Date Of Sample Receipt	25/04/2026	TR No.	N/A
Sample Id	ARL/ORC/05093/2026	Release Date	06-05-2026

Sr.No	Tests	Test Guideline	Acceptance Limit	Observation	LOD	LOQ
1	N-nitrosodimethylamine (NDMA)	AD/ MVer/2026/014-00	Not more than 320ppb	Below Detection Limit (6.464ppb)	As Such LOD: 0.5317ppb W.R.T.LOD: 17.7233ppb	As Such LOQ: 1.5510ppb W.R.T.LOQ: 51.7000ppb
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	Rohan Panchal (06/05/2026)	Tushar Raval (06/05/2026)	Chetan Parekh (06/05/2026)
Sign/Date	Signature valid Digitally signed by Rohan Panchal Date: 2026.05.06 15:18:05+0530 Location: Ahmedabad	Signature valid Digitally signed by Tushar Raval Date: 2026.05.06 15:18:05+0530 Location: Ahmedabad	Signature valid Digitally signed by Chetan Parekh Date: 2026.05.06 15:18:05+0530 Location: Ahmedabad

END OF REPORT

QUALITY ASSURANCE REVIEW	
SIGN:	TCHB
DATE:	26/05/26
ORCHEV PHARMAS PVT. LTD.	

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 SOP No	Effective Date
Exhibit III_01	ARL/SOP/QA/047	03/02/2025

Opp. Zydus Pharmez, Changodar - Bavla Highway, Nr. Matoda Patia, Post: Matoda, Ahmedabad - 382213, Gujarat, India
Contact: 079 0000618750 / 079 0000618751 / 079 0000618752 Email: info@accuprec.com Web: www.accuprec.com

Chetan Parekh
06/05/26

Jakarta, 14 Oktober 2024

No : 2039//QUOMKT/X/2024

Perihal : Penawaran Harga Nitrosamine Impurity

Kepada Yth.

Ibu Julfriaeni

PT Mersifarma

No.	Sampel	Parameter Uji	Metode	Qty	Biaya Uji (Belum termasuk PPN 11%)	Lama Pengujian
1	Ranitidine Bahan Baku	NDMA	LCMS-MS	1	800.000	7 HK
2	Ranitidine Bahan Baku	NDEA	LCMS-MS	1	800.000	7 HK
3	Ranitidine Injeksi	NDMA	LCMS-MS	1	800.000	7 HK
4	Ranitidine Injeksi	NDEA	LCMS-MS	1	800.000	7 HK
5	Ranitidine Tablet	NDMA	LCMS-MS	1	800.000	7 HK
6	Ranitidine Tablet	NDEA	LCMS-MS	1	800.000	7 HK

* Timeline terhitung setelah mendapatkan ketersediaan Sample / logistik dari pihak sponsor

Termin Pembayaran :

- Pembayaran : 100% dari biaya penelitian dibayarkan setelah COA/ final report dikirimkan ke Sponsor.
- Mohon konfirmasi pada saat pengiriman sample, serta dapat dilampirkan form R.F.A sebagai pengantar sample

Note :

- Penawaran ini berlaku 3 bulan sejak tanggal penawaran ini

Approval Customer

 24/10/25

Nama: Oc Mar
Jabatan: