

Bagian : QC

ANALISA PERMINTAAN JASA

Due Date : 25 Juli 2026

Tanggal : 08 Juni 2026

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 :

- Jasa pengujian cemaran NDMA untuk pengujian bahan baku Ranitidine HCl, dengan No. Batch :

1. R-001DC0426

2 R-049PD1225

- Estimasi harga pengujian : Rp 800.000 / batch

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

Metode analisa bahan baku, CoA bahan awal dan penawaran harga.

Dibuat Oleh,

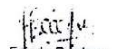

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06

Mengetahui


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SPESIFIKASI BAHAN AWAL
RANITIDIN HIDROKLORIDA
RAW MATERIAL SPECIFICATION
RANITIDINE HYDROCHLORIDE

Page 2 of 3
Document No
RD.02-SBA/092.02
Valid Date

	DEPARTMENT RESEARCH AND DEVELOPMENT	SECTION ANALYTICAL DEVELOPMENT	
Disusun Oleh : Prepared by :	Diperiksa Oleh : Checked by :	Disetujui Oleh : Approved by :	
 Fendy Pradana AD Staff Date : 10/10/23	 Ita Aryan AD Supervisor Date : 10/10/23	 Juwita Ristiani AD Manager Date : 10/10/23	 Head of R&D Date : 28/10/23
		 QA Manager Date : 28/10/23	Changed No : RD.02-SBA/092.01 Date : 27 th October 2023

SUSUT PENGERINGAN⁽¹⁾ <i>LOSS ON DRYING</i>	≤ 0.75%								
SISA PEMIJARAN⁽¹⁾ <i>RESIDU ON IGNITION</i>	≤ 0.1%								
KEMURNIAN KROMATOGRAFI⁽¹⁾ <i>CHROMATOGRAPHIC PURITY</i>	<table border="1"> <tr> <th>Nama Name</th><th>Batas (%) Limit (%)</th></tr> <tr> <td>Ranitidine bis-compound</td><td>0.3</td></tr> <tr> <td>Cemaran lain Other Impurity</td><td>0.1</td></tr> <tr> <td>Total cemaran Total Impurity</td><td>0.5</td></tr> </table>	Nama Name	Batas (%) Limit (%)	Ranitidine bis-compound	0.3	Cemaran lain Other Impurity	0.1	Total cemaran Total Impurity	0.5
Nama Name	Batas (%) Limit (%)								
Ranitidine bis-compound	0.3								
Cemaran lain Other Impurity	0.1								
Total cemaran Total Impurity	0.5								
PENETAPAN KADAR⁽¹⁾ <i>ASSAY</i>	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⁾ <i>BACTERIAL ENDOTOXIN</i>	≤ 7.0 EU/mg (Jika digunakan untuk produk steril) (If use for sterile product)								
NITROSODIMETILAMIN NDMA⁽²⁾	≤ 320 ng/g								
WADAH DAN PENYIMPANAN⁽¹⁾ <i>PACKAGING AND STORAGE</i>	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.



**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-001DC0426	A.R. NO. : FG/2604002	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/26/1017

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	5.58
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%	0.23 %
7	Residue on ignition <281>	NMT 0.10%	0.038 %
8	Assay (Dry basis) <621>	97.5 % - 102.0 %	100.18 %
9	Residual solvents (In ppm) <467>	1. Chloroform NMT 60 ppm 2. Isopropyl alcohol NMT 5000 ppm	NOT DETECTED 867 ppm
1*	Melting range (In house)	ABOUT 140 °C	139.3 °C
2*	Clarity: 10% Soln:430 nm (In house) Absorbance	NMT 0.20	0.058
3*	Bulk density (In house) Untapped Tapped (1250)	0.50 ± 0.2 g / mL 0.75 ± 0.2 g / mL	0.66 g / mL 0.78 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 %	0.73 % 25.21 % 3.06 %

The material complies with the specification as laid down in USP-NF 2025 & In House Limits.

Date: 22/04/2026

(*) Indicates In House Tests

Prepared by
Mr. Krishna Ghodasara (QC Officer)

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

QUALITY ASSURANCE REVIEW
SIGN: <i>[Signature]</i>
DATE: 22/04/26
ORCHEV PHARMA PVT. LTD.



ACCUPREC[®]
RESEARCH LABS PVT. LTD.

Ultimate solution...

EUCA, FDA-GMP, OECD-GMP, AAALAC, CESEA, ISO 9001:2015, ISO/IEC 17025: 2017(NABL), APUSH, USRB, CDSCO-MRL-40, DUNS, FDA/CDR, CDRG, NCDM-007, BIS, USFDA, EMA, ASCA (AZLA), CDSCO CDTC, HEALTH CANADA

**RESEARCH
REDEFINE**

PAGE 1 OF 1

CERTIFICATE OF ANALYSIS Form 39 (Rule 150-E (i) - 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.		
Manufacturer License No.	G/25/1017	Testing Date	18/04/2026 to 20/04/2026
Batch No.	R-001DC0426	Document No.	ARL/4185/2026
Mfg. Date	2026-04	Qty. Received	2.00 GM
Exp. Date	N/A	Test Qty.	1.00 GM
Date Of Sample Receipt	15/04/2026	TR No.	N/A
Sample Id	ARL/ORC/04605/2026	Release Date	21-04-2026

Sl.No	Tests	Test Guideline	Acceptance Limit	Observation	LOD	LOQ
1	NDMA Test	AD/ MVeR/2026/014-00	Not more than 320ppb	Not Detected	As Such: LOD: 0.5317ppb W.R.T LOD: 17.7235ppb	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	Rohini Panchal (21/04/2026)	Tushar Ravat (21/04/2026)	Dr. Kalpesh Patel (21/04/2026)
Sign/Date	Signature valid Digitally signed by Rohini Panchal Date: 2026.04.21 10:30 Location: Mumbai, India	Signature valid Digitally signed by Tushar Ravat Date: 2026.04.21 10:30 Location: Mumbai, India	Signature valid Digitally signed by Dr. Kalpesh Patel Date: 2026.04.21 10:30 Location: Mumbai, India

END OF REPORT

QUALITY ASSURANCE REVIEW	
SIGN:	<i>[Signature]</i>
DATE:	21/04/26
ORCHEV PHARMA 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 1-01	ARL/SOP/QA/047	03/02/2025

Opp. Zydus Pharmaz, Changodar - Bavl Highway, Nr. Matoda Patia, Post: Matoda, 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 • Delaware, USA

**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) <731>	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%	0.14 % 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 %	99.64 %
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: <i>[Signature]</i>
DATE: 11/12/25
ORCHEV PHARMA PVT. LTD.

Prepared by
Ms. Kaushika Rupapara (QC Officer)

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



Ultimate solution...

FDCA LICENCE NO. GTL/37/31

(FDCA, FDCA-GP, OECD-GP, AAALAC, CCSEA, ISO 9001:2015, AYUSH, ISOIR, CDSCO, DUNS, FDCA Cos, CLBC, BIS, USFDA)

RESEARCH
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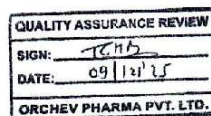
PAGE 1 OF 1

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 Shapur Industrial Area, Rajkot-Gandhi 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 I.O.D: 0.520 ng/g W.R.T I.O.D: 17.33 ng/g	As Such I.O.Q: 1.575 ng/g W.R.T I.O.Q: 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 Acharya (08/12/2025)	Anita Patel (08/12/2025)	Ritesh Shah (08/12/2025)
Signature			

END OF REPORT



Note:		
1. The results listed refer only to the samples and applicable parameters, endorsement of product is neither intended 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 1.01	ARL/SOP/QA/047	03/02/2025

Opp. Zydus Pharmoz, Changodar - Bavla Highway, Nr. Matoda Patia, Post: Matoda, 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

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

 29/10/24

Nama: Oc Mar
Jabatan: