

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 Obat Jadi Ranitidine Injeksi	Js	0	2	-2	0	2	0	0
2	IMO10028	Jasa Analisa NDMA Bahan Baku Ranitidine HCl	Js	0	3	-3	0	3	0	0
3	IMO10028	Jasa Analisa NDMA Batch Kompetitor Berno Ranitidine Injeksi	Js	0	1	-1	0	1	0	0

Catatan :

- Jasa pengujian cemaran NDMA untuk pengujian produk jadi Ranitidine Injeksi, bahan baku Ranitidine HCl dan Kompetitor Berno Ranitidine Injeksi, dengan No. Batch :

- **Obat Jadi Ranitidine Injeksi :**

1. D41646
2. D50048

- **Bahan Baku Ranitidine HCl**

1. R-020PD0925
2. R-005PD0526
3. R-012PD0524

- **Batch Kompetitor Berno Ranitidine Injeksi**

- 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, Sehingga diperlu dilakukan pengujian secara eksternal.
- Pengujian tersebut merupakan parameter spesifikasi produk jadi Ranitidine injeksi dan bahan baku Ranitidine HCl.
- Pengujian dilakukan di PT. Omega Medika Farma Laboratori

Terlampir spesifikasi produk dan penawaran harga.

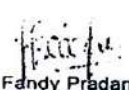
Dibuat

 20/26
ADA 105

Mengetahui


Oka

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 Date: 10/10/23	 Ita Aryani AD Supervisor Date: 10/10/23	 Juwita Ristiani AD Manager Date: 10/10/23	 Head of R&D Date: 20/10/23
		 QA Manager Date: 20/10/23	Changed No : RD.02-SBA/092.01 Date : 27 th October 2023

SUSUT PENGERINGAN⁽¹⁾ <i>LOSS ON DRYING</i>	$\leq 0.75\%$								
SISA PEMIJARAN⁽¹⁾ <i>RESIDU ON IGNITION</i>	$\leq 0.1\%$								
KUMURNIAN KROMATOGRAFI⁽¹⁾ <i>CHROMATOGRAPHIC PURITY</i>	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 70%;">Nama <i>Name</i></th><th style="width: 30%;">Batas (%) <i>Limit (%)</i></th></tr> </thead> <tbody> <tr> <td>Ranitidine bis-compound</td><td style="text-align: center;">0.3</td></tr> <tr> <td>Cemaran lain <i>Other Impurity</i></td><td style="text-align: center;">0.1</td></tr> <tr> <td>Total cemaran <i>Total Impurity</i></td><td style="text-align: center;">0.5</td></tr> </tbody> </table>	Nama <i>Name</i>	Batas (%) <i>Limit (%)</i>	Ranitidine bis-compound	0.3	Cemaran lain <i>Other Impurity</i>	0.1	Total cemaran <i>Total Impurity</i>	0.5
Nama <i>Name</i>	Batas (%) <i>Limit (%)</i>								
Ranitidine bis-compound	0.3								
Cemaran lain <i>Other Impurity</i>	0.1								
Total cemaran <i>Total Impurity</i>	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</i> <i>ENDOTOXIN</i>	≤ 7.0 EU/mg (Jika digunakan untuk produk steril) (If use for sterile product)								
NITROSODIMETILAMIN NDMA⁽²⁾	≤ 320 ng/g								
PAKETAN DAN PENYIMPANAN⁽¹⁾ <i>PACKAGING AND STORAGE</i>	Dalam wadah tertutup rapat. Preserve in tight containers.								

REKAM JEJARAH PERUBAHAN :
 HISTORY OF CHANGE

2RD20/SPBAA/092.00

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





PT. MERSIFARMA TM.
SUKABUMI - INDONESIA

SPESIFIKASI PRODUK OBAT JADI
PRODUCT SPECIFICATION OF
RANITIDINE INJEKSI 50 MG/ 2 ML
(IPJ00246)
RANITIDINE INJECTION 50 MG/ 2 ML
(IPJ00246)

Halaman	: 3 dari 6
Page	: 3 of 6
No. Dokumen	: SPOJ/00246.01
Document No.	
Tanggal Dokumen Disetujui	: 28 JAN 2026
Document Approval Date	
Menggantikan No.	: SPOJ/00246.00
Supersedes no.	

N-Nitrosodimetilamin : 0.48 ppm ~ 24 ng/ampul
(NDMA)⁽⁶⁾
N-Nitrosodimetilamin : 0.48 ppm ~ 24 ng/ampoule
(NDMA)⁽⁶⁾

UJI MIKROBA Microbial tests	Sterilitas⁽⁴⁾ : Steril Sterility⁽⁴⁾ : Sterile Endotoksin bakteri⁽⁵⁾ : Maks. 7.0 EU/ mg Bacterial endotoxin⁽⁵⁾ : NMT 7.0 EU/ mg
---------------------------------------	---



PENGEMASAN PRIMER (Primary Packaging)

JENIS KEMASAN Packaging Type	Dalam ampul amber 2 mL Package into amber ampoule 2 mL
--	---

UKURAN KEMASAN Packaging Size	2 mL 2 mL
---	--------------

PENGEMASAN SEKUNDER (Secondary Packaging)	FB @ 10 Ampul @ 2 mL FB @ 10 Ampoule @ 2 mL
---	--

KONDISI PENYIMPANAN Storage	Simpan di bawah suhu 30°C, terlindung dari cahaya Stored below 30°C and protected from light
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UMUR OBAT Shelf Life	2 tahun 2 years
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DOKUMEN TERKAIT Related Documents	-
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RIWAYAT PERUBAHAN

Changes History

No.	No. Dokumen Document No.	Tanggal Berlaku Effective Date	Deskripsi Perubahan Changes Description
00	2RD10/SPSPG/296.01	24/03/2022	SPOJ yang berlaku saat ini Current SPOJ
01	SPOJ/00246.00	4/9/2025	1. Perubahan format baru mengacu pada FUP No. 512/MFG/RD/PP/V/25 New format changes referring to FUP No. 512/MFG/RD/PP/V/25

lu kl f h

A A J . 002
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-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) <821> 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 80 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**	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: 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)



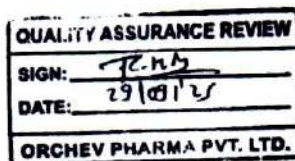
OFFICE : Rangoli, Gondal Road, Rajkot - 360 002. INDIA. Phone : +91-90990 28899, Fax : +91-281 2365733 E-mail : info@orchev.com Web : www.orchev.com
FACTORY : Shapur Industrial Area, Rajkot-Gondal Highway, Veraval, Dist. Rajkot INDIA. Phone : +91-2827-252114/15. Fax : +91-2827-252113

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 10:26 Location: Ahmedabad	Signature valid Digitally signed by Anita Patel Date: 2025.09.29 10:23 Location: Ahmedabad	Signature valid Digitally signed by Dr. Kalpesh Patil Date: 2025.09.29 10:23 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/QA/001	03/02/2025





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-006PD0626

A.R. NO.: FG/2806062

MFG. DATE: MAY-2025

MFG. BY: ORCHEV PHARMA PVT. LTD.

BATCH SIZE (KG): 1400

CAS NO.: 66357-55-3

RETEST DATE: OCTOBER-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	5.62
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%	0.24 %
7	Residue on ignition <281>	NMT 0.10%	0.036 %
8	Assay (Dry basis) <621>	97.5 % - 102.0 %	100.24 %
9	Residual solvents (in ppm) <467>	1 Chloroform NMT 80 ppm 2. Isopropyl alcohol NMT 8000 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 0.66 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

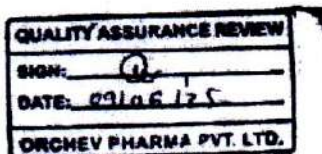
The material complies with the specification as laid down in USP-NF 2024 & In House Limits.

Date: 09/06/2025

☒ Indicates In House tests
☒ Indicates Microbial tests

Prepared by
Mr. Urviha Pansuriya (QC Officer)

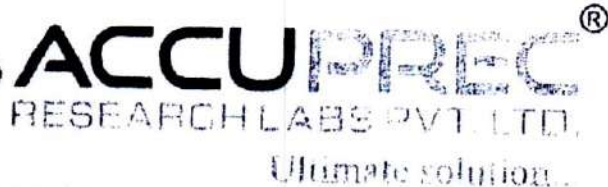
Check & Approved by
Mr. Ravi Jani (QC Manager)



For Orchev Pharma Pvt. Ltd.

Viren Patel
Director

OFFICE : Rangoli, Gondal Road, Rajkot - 360 002, INDIA Phone : +91-281 2385731/32, Fax : +91-281 2385733 E-mail: info@orchev.com Web: www.orchev.com
FACTORY : Shepar Industrial Area, Rajkot-Gondal Highway, Veraval, Dist. Rajkot INDIA Phone : +91-2827-252114/15, Fax : +91-2827-252113



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FDC A LICENSE NO. 631137151

FDCA, FDCA GLE, GLE D GLE, ADE AL, GLEA, ISO 2001, 2003, AT-USE, 1000, 1000, 1000,
FDCA (e, 1000, 1000, 1000)

PAGE 1 OF 1

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

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

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

BATCH NO. : R-012PD0524	A.R. NO.: FG/2405032	MFG. DATE: MAY – 2024	MFG. BY: ORCHEV PHARMA PVT. LTD.
BATCH SIZE (KG): 1500	CAS NO.: 66357-59-3	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.

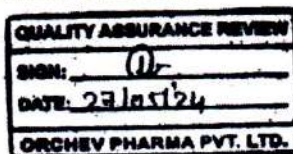
SR. NO.	TEST	SPECIFICATION	RESULT
1	Description	White to pale yellow practically odourless crystalline powder	WHITE, PRACTICALLY ODOURLESS CRYSTALLINE POWDER
2	Solubility	Very soluble in water, sparingly soluble in alcohol.	COMPLIES
3	Identification <197> <197M> ,<197U> and <191>	Infrared Absorption, 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 80 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 0.55 ± 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 1.78 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 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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RESEARCH REDEFINE

RESEARCH REDEFINE

PAGE 1 OF 1

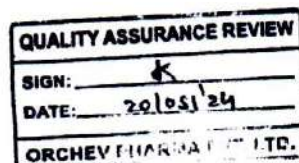
CERTIFICATE OF ANALYSIS
Form 39 (Rule 150-E (f) - Report of test or analysis by approved institution)
Raw Material

Product Name	Ranitidine HCL		
Party Name And Address	Orchev Pharma Pvt. Ltd. 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.	ARL/3586/2024
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	ARL/ORC/04114/2024	Release Date	20-05-2024

Sr.No	Tests	Test Guideline	Acceptance Limit	Observation	LOD	LOQ
1	N-nitroso-di-methylamine (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		Authorized By	
Name	Piyush Achiya (20/05/2024)	Name	Bhavesh Patel (20/05/2024)	Name	Jinkal Joshi (20/05/2024)
Signature		Signature		Signature	

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. 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 client/sponsor for Analysis unless otherwise stated.		
FORMAT No	Reference SOP No	Effective Date
Exhibit 1.00	ARL/SOP/QA/047	23/11/2023

Orchev Pharma Pvt. Ltd. - Gandhinagar, Industrial Estate, Matunga Road, Post Matunga, Ahmedabad - 382213, Gujarat, India
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Global Business Office • Gurgaon, ON, Canada • Pittsburgh, PA, USA

No. : 241/V/B/MEA/26

Jakarta, 20 Mei 2026

Hal : Penawaran harga uji NDMA

Kepada Yth
Ibu Anna
PT Mersifarma

Bersama ini kami sampaikan penawaran harga untuk pengujian yang diminta sebagai berikut :

No.	Nama Sampel	Pengujian	Metode Analisis	Referensi	Jumlah sampel	Biaya Reguler Exclude PPN	Biaya Urgent Exclude PPN
1	Sediaan padat/cair	NDMA	LC-MS/MS	FDA/BPOM	50 mL/10 g	Rp 800.000 (5 HK)	Rp 1.200.000 (3 HK)

Term dan kondisi :

1. Lama waktu analisa sampel dihitung sejak sampel dan PO diterima Pihak Omega
2. Mohon informasikan kandungan analit (jika sampel produk jadi) jika tidak ada di label
3. Mohon informasikan spek/syarat dan atau CoA sampel
4. Pengujian akan dikerjakan setelah sampel dan PO kami terima
5. Penagihan akan dilakukan berdasarkan jumlah sampel/PO yang diterima
6. Sertakan juga placebo untuk pertama kali pengujian/perubahan formula sejumlah 20 g/ 50 mL
7. Cara pembayaran 100% setelah invoice diterima
8. Penawaran berlaku untuk masa 1 (satu) bulan sejak tanggal penawaran
9. **Mohon mencantumkan No Penawaran pada PO.**

Demikian penawaran ini kami sampaikan, mohon PO dapat dikirimkan melalui email ke admin@omegaresearch.id dan finance@omegaresearch.id

Atas perhatiannya kami ucapkan terima kasih.

Hormat kami,
PT Omega Medika Farma Laboratori



apt. Siswati Ika Daliana, S.Farm
Manager Teknis