

Bagian : QC

ANALISA PERMINTAAN JASA

Due Date : 30 Juni 2026

Tanggal : 28 Mei 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	1	-1	0	1	0	0

Catatan :

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

1. R-018DC0825

- Estimasi harga pengujian : Rp 800.000 / batch

- Pengujian terakhir NDMA bahan baku Ranitidine HCl **PF001029**.

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,



28/26
105

Mengetahui



28/26
105

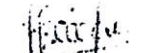
SPESIFIKASI BAHAN AWAL
RANITIDIN HIDROKLORIDA
RAW MATERIAL SPECIFICATION
RANITIDINE HYDROCHLORIDE

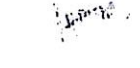
DEPARTMENT
RESEARCH AND DEVELOPMENT

SECTION
ANALYTICAL DEVELOPMENT

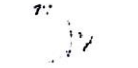
Disusun Oleh :
Prepared by

Diperiksa Oleh :
Checked by

Disetujui Oleh :
Approved by

Fandy Pradana
AD Staff


Ita Aryani
AD Supervisor


Juwita Ristiani
AD Manager


Head of R&D


QA Manager

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%

KUMURNIAN
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.

REJEKARAH 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-018DC0825	A.R. NO.: FG/2508083	MFG. DATE: AUGUST – 2025	MFG. BY: ORCHEV PHARMA PVT. LTD.
BATCH SIZE (KG): 750	CAS NO.: 66357-59-3	RETEST DATE: JANUARY – 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 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 BDL NOT DETECTED NOT DETECTED BDL 0.18 %
6	Loss on drying <731>	NMT 0.75%	0.22 %
7	Residue on ignition <281>	NMT 0.10%	0.041 %
8	Assay (Dry basis) <621>	97.5 % - 102.0 %	99.83 %
9	Residual solvents (in ppm) <467>	1. Chloroform NMT 60 ppm 2. Isopropyl alcohol NMT 5000 ppm	NOT DETECTED 870 ppm
1*	Melting range (In house)	ABOUT 140 °C	140.1 °C
2*	Clarity: 10% Soln:430 nm (In house) Absorbance	NMT 0.20	0.053
3*	Bulk density (In house) Untapped Tapped (1250)	0.50 ± 0.2 g / mL 0.75 ± 0.2 g / mL	0.52 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 %	6.62 % 41.46 % 6.02 %

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

Date: 27/08/2025

(*) indicates In House Tests

QUALITY ASSURANCE REVIEW
SIGN: <u>TZHD</u>
DATE: <u>27/08/25</u>
ORCHEV PHARMA PVT. LTD.

27/08/25
Prepared by
Ms. Kaushika Rupapara (QC Officer)

27/08/25
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 : Shapar Industrial Area, Rajkot-Gondal Highway, Veraval, Dist. Rajkot INDIA. Phone : +91-2827-252114/15. Fax : +91-2827-252113



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FDCA, FDCA-GLP, OECD-GLP, AAALAC, CCSEA, ISO 9001:2015, AYUSH, DSIR, 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	25/08/2025 to 26/08/2025
Batch No.	R-018DC0825	Document No.	ARL/6909/2025
Mfg. Date	2025-08	Qty. Received	5.00 Gms
Exp. Date	N/A	Test Qty.	1.00 Gms
Date Of Sample Receipt	25/08/2025	TR No.	N/A
Sample Id	ARL/ORC/08316/2025	Release Date	26-08-2025

Sr.No	Tests	Test Guideline	Acceptance Limit	Observation	LOD	LOQ
1	N-nitrosodimethylamine (NDMA)	QC/FG/MOA/R-HCL/NDMA/001	NMT 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 Aaviya (26/08/2025)	Anita Patel (26/08/2025)	Dr. Kalpesh Patil (26/08/2025)
Sign/Date	Signature valid Digitally signed by Piyush Aaviya Date: 2025.08.26 09:11:45:30 Location: Ahmedabad	Signature valid Digitally signed by Anita Patel Date: 2025.08.26 09:57:40:30 Location: Ahmedabad	Signature valid Digitally signed by Dr. Kalpesh Patil Date: 2025.08.26 10:53:42:05:30 Location: Ahmedabad

END OF REPORT

QUALITY ASSURANCE REVIEW	
SIGN:	TCHB
DATE:	27/08/25
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 I_01	ARL/SOP/QA/047	03/02/2025

Opp. Zydus Pharmez, 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

 24/10/25

Nama: Oc Mar
Jabatan: