

METROCHEM API PRIVATE LIMITED

Flat No. 302, Bhanu Enclave, Sunder Nagar,
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**CERTIFICATE OF ANALYSIS**

Product	: Omeprazole Pellets 7.5% w/w	Reference	: Customer
Batch No.	: OMP/P/2/2018081161	License No.	: 18/RR/AP/2006/F/R
Batch Qty.	: 500.30 kg	Date of Mfg.	: August 2018
Dispatch Qty.	: 500.00 kg	Date of Expiry	: July 2021
Customer	: M/s. Medibios Laboratories Pvt. Ltd.		

S.No.	Test	Specification	Result
1.	Description	A white to an off white spherical pellets	An off white spherical pellets
2.	Identification by HPLC	The retention time of the major peak in the chromatogram of the assay preparation corresponds to that of the standard preparation obtained as directed in the assay.	Conforms
3.	Dissolution (% w/w)		
	a) Drug Release in 0.1M HCL (Test 2 as per USP)	NMT 10.0% of labeled amount of Omeprazole should be released in 0.1M HCL after 2 hours	0.2
	b) Buffer stage (Test 2 as per USP)	NLT 75.0% (Q) of labeled amount of Omeprazole should be dissolved in pH 6.8 buffer within 45 minutes	96.2
4.	Organic Impurities (%)		
	a) Thioxopyrido conversion product ^a	NMT 0.5	Not detected
	b) 5-methoxy -1H-benzimidazole-2-thiol	NMT 0.5	Not detected
	c) Any other individual impurity	NMT 0.5	0.10
	d) Total impurities	NMT 2.0	0.10
5.	Assay (% w/w) (Content of Omeprazole)	NLT 7.2% to NMT 7.8%	7.65
Additional Tests			
6.	Pellets size (ASTM)	100% pass through 12 ASTM and Not Less than 90% retained on 16 ASTM	Conforms
7.	Moisture Content by KF (% w/w)	NMT 2.0	1.66
8.	Bulk Density (g/ml)	0.70 to 0.90	0.84
9.	Colour of pellets in 0.1 N HCL	Colour should not be change after 2 hours	No Pellets are colour changed.

Remarks: The material conforms to above specifications.

Storage: Preserve in tight, light-resistant containers. Stored at 25°C (excursions allowed between 15° and 30°C)

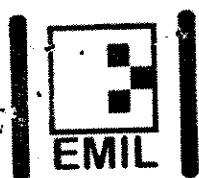
Prepared by Sign & Dt:	Reviewed by Sign & Dt:	Approved by Sign & Dt:
 21/08/18	 31/08/2018	 31/08/2018

UNIT-II

Works: Plot No. D-69/A (Part) & D-69, Phase – I, IDA, Jeedimetla, Quthbullapur (M),
Medchal (District)-500055 T.S, INDIA. Ph: +91-40-32435802. Fax: +91-40-23140277.



VOLUME • QUALITY



**EMIL
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An ISO 9001:2008 Certified Company



Analytical Report For Raw Material

Item Code : R0825		
Item Name : Omeprazole pellets 7.5%		G.R.N. No.: MEMR8/232
Mfg. by : Metrochem API Pvt. Ltd. (Unit-II)	Sup. By : Metrochem API Pvt. Ltd. (Unit-II)	A.R. No. (QC) : MEMR8/232 A
Mfg. Date : 08/2018	Exp. Date : 07/2021	Mfg. B.No.: OMP/P/2/2018081161
Qty Recd.: 10 x 50 kg	Date of Sampling : 04/09/2018	Sampled Qty : 1 x 17 gm 1 x 33 gm
	Date of Analysis : 05/09/2018	
Sampled by : Mr. Sambhaji	Date of Completion : 06/09/2018	Analyst : Mr. Akash

Test	Specification	Result
Description	White to off white spherical pellets.	White to off white spherical pellets.
Identification (By HPLC)	The retention time of the major peak in the chromatogram of the assay preparation corresponds to that of the Standard preparation obtained as directed in the assay.	The retention time of the major peak in the chromatogram of the assay preparation corresponds to that of the Standard preparation obtained as directed in the assay.
Water Content (BY KF)	Not more than 2.0% w/w	1.7% w/w
Drug Release in 0.1 N HCl	Not more than 10% of released in 0.1 M HCL after 2 hours	1) Nil 2) Nil 3) Nil 4) Nil 5) Nil 6) Nil
Dissolution In Buffer pH 6.8	Not less than 75% (Q) of released in Buffer pH 6.8 after in 45 minutes.	1) 94% 2) 94% 3) 93% 4) 92% 5) 93% 6) 94%
Organic Impurities		
Thioxopyrido conversion Product ^a	Not more than 0.5%	Not detected
5-Methoxy-1H-benzimidazole-2-thiol	Not more than 0.5%	Not detected
Any other individual impurity	Not more than 0.5%	0.094%
Total Impurities	Not more than 2.0%	0.350%
Assay	7.2% to 7.8%	7.69%

Additional Test :

Bulk Density	0.7 gm/ml to 0.9 gm/ml	0.80 g/ml
Sieve Analysis (Particle Size)	100% passes through 12 ASTM and Not less than 90% retained by 16 ASTM.	100% Passes through 12 ASTM# 95.45% Retained on 16 ASTM#
Colour of pellets in 0.1 N HCL	Colour should not be change after 2 hours.	Colour not change after 2 hours.

AK951

Analysed by :
Date : 06/09/18

Amir

Checked By :
Date : 06/09/18

Amir

Approved by :
Date : 06/09/18



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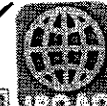
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Mfg. Date : 08/2018	Exp. Date : 07/2021	Mfg.B.No.: OMP/P/2/2018081161
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	Date of Analysis : 05/09/2018	
Sampled by : Mr. Sambhaji	Date of Completion : 06/09/2018	Analyst : Mr. Akash

Test	Specification	Result
Assay on individual containers		
Container 1/10	7.2% to 7.8%	7.70%
Container 2/10		7.79%
Container 3/10		7.68%
Container 4/10		7.61%
Container 5/10		7.60%
Container 6/10		7.64%
Container 7/10		7.71%
Container 8/10		7.75%
Container 9/10		7.61%
Container 10/10		7.76%

Above sample **Complies** as per standard specification No. STP-RM-O-R0825.

Working Standard Reference No. : SP-007-138 Valid up to Jan-2019

As defined in the Act & the rules made under in the above respect.

Retest Date : 05/03/2019

AKAS

Analysed by :
Date : 06/09/18

Aur

Checked By :
Date : 06/09/18

Rh

Approved by :
Date : 06/09/18