



Todo Droga
Química Mayorista

SAINOR PHARMA PVT LTD

Plot No.31, Phase V, IDA, Jeedimetla, Hyderabad 500 055.

Phone # - 040 - 23197772

CERTIFICATE OF ANALYSIS

PRODUCT NAME	: OMEPRAZOLE PELLETS		
CONCENTRATION	: 8.50% w/w	MFG. DATE	: NOV'- 2015
BATCH NO.	: OP-1158 11 15	EXP. DATE	: OCT'- 2019
QUANTITY	: 1000.0 Kg	DATE OF ANALYSIS	: 28.11.2015

S. No.	TEST	SPECIFICATION	RESULT
01.	Description	White to off white color spherical pellets	White color spherical pellets
02.	Identification by HPLC	The retention time of the major peak in the chromatogram of the assay preparation corresponds to that in the chromatogram of the standard solution, as obtained in the assay.	Complies
03.	Water Content by K.F	Not more than 3.0% w/w	1.39% w/w
04.	Particle Size	Between 12 - 16 mesh	Complies
05.	Bulk Density	0.70 to 0.90 g/ml	0.84 g/ml
06.	Uniformity of dosage Units	Meet the requirements	Complies
07.	Dissolution	No individual Value exceeds 15.0 % of the Omeprazole dissolved in 0.1 N HCl after 2 hours. Not less than 75.0% of labeled amount of Omeprazole shall dissolve in pH 6.8 phosphate buffer after 30 minutes.	1.14% w/w
	Acid Resistance		90.45% w/w
	Buffer stage		
08.	Chromatographic Purity		
	a)Thioxopyrido conversion product	Not more than-0.50%	Not detected
	b)5-methoxy-1-h benzimidazole-2-thiol	Not more than-0.50%	Not detected
	c)Any other Individual Impurity	Not more than - 0.50%	0.14%
	d)Total impurities	Not more than - 2.0%	0.37%
09.	Assay of Omeprazole	Not less than 90.0% and Not more than 110.0%	101.18%
10.	Microbial Limits		
	a)Total Microbial count	a)NMT 1000 cfu/g	75 cfu/g
	b)Enterobacteriaceae count	b)NMT 100 cfu/g	Less than 20 cfu/g
	c)Fungal Count	c)NMT 100 cfu/g	Absent
	d)Pathogen test for E.coli, Salmonella, Pseudomonas & S. Aureus	d)Should be absent	Absent in 1.0 g
11.	Residual solvents		
	IPA	NMT 5000 ppm	Not detected
	Acetone	NMT 3000 ppm	60 ppm

REMARKS: The above product complies as per the above Specification of USP -38.

Prepared by *Shayq*
Date 28/11/15

Checked by *[Signature]*
Date 28/11/2015

Approved by *[Signature]*
Date 28/11/15

[Large Signature]