Ciron Drugs & Pharamaceuticals Pvt.Ltd

N-118,119,113 MIDC Tarapur,
Boisar , Maharastra , India

CERTIFICATE OF ANALYSIS

Material / Product	OMEPRAZOLE BP		
Rec. Quantity	7.027 Kg	**Material Code**	C1/RM/A/0583/1
GRN Number	18/IRM/08/0297	**Mfg. Batch No.**	OPFP17077
Retest Date	05/09/2019	**No. of Containers**	1
Mfg. Name	LEE PHARMA LIMITED	**Supplier Name**	CIRON DRUGS & PHARMACEUT

Specification No.	.	**AR Number**	18/IRM/08/297
Sampled Date	01/09/2018	**Sample Number**	RM00955
Analysis Category	Raw Material	**Approved Date**	05/09/2018
Date of Mfg.	01/10/2017	**Expiry Date**	30/09/2022
Sampled by	Mr. Ratish Gaikwad Gaikwad	**Sampled Quantity**	20 gr.
Pharmacopeia Ref	BP		

S No.	Test	Specification Limit	Observation
1	DESCRIPTION	White or almost white powder.	Almost white powder.
2	SOLUBILITY	Very slightly soluble in water, soluble in methylene chloride, sparingly soluble in ethanol (96 per cent) and in methanol. It dissolves in dilute solutions of alkali hydroxides.	Very slightly soluble in water, soluble in methylene chloride, sparingly soluble in ethanol (96 per cent) and in methanol. It dissolves in dilute solutions of alkali hydroxides.
3	IDENTIFICATION BY IR	By IR: The IR spectrum of sample should be concordant with IR spectrum of standard.	The IR spectrum of sample should be concordant with IR spectrum of standard.
4	APPEARANCE OF SOLUTION	Solution S is clear	Solution S is clear
5	IMPURITIES F, G	Maximum 350 ppm for the sum of the contents. The absorbance of solution S determined at 440 nm is not greater than 0.10.	0.094%
6	RELATED SUBSTANCES (BY HPLC)		
6.1	IMPURITIES D, E	NMT 0.15%	Impurity D=0.12%,Impurity E=0.06%
6.2	UNSPECIFIED IMPURITIES	NMT 0.10%	0.07%
6.3	TOTAL	NMT 0.5%	0.31%

Analysed by	:	Mr. Dhananjay Pawar	**Checked by**	:	Mr. Bhavik Solanki	**Approved by**	:	Mr. SanjayWaghmare
Date	:	05/09/2018	**Date**	:	05/09/2018	**Date**	:	05/09/2018
Designation	:	QC Officer	**Designation**	:	QC Sr. Executive	**Designation**	:	Manager-QC

This is an auto generated report. Hence no signatures are required.

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Boisar , Maharastra , India

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Sampled by	Mr. Ratish Gaikwad Gaikwad	**Sampled Quantity**	20 gr.
Pharmacopeia Ref	BP		

S No.	Test	Specification Limit	Observation
7	LOSS ON DRYING	Maximum 0.2%	0.16%
8	SULPHATED ASH	Maximum 0.1%	0.04%
9	ASSAY	99.0% to 101.0% (dried substance).	100.52%(As is basis),100.68% (Dried basis)

Conclusion :The above raw material complies / does not comply as per laid down BP specification.

Analysed by	:	Mr. Dhananjay Pawar	**Checked by**	:	Mr. Bhavik Solanki	**Approved by**	:	Mr. SanjayWaghmare
Date	:	05/09/2018	**Date**	:	05/09/2018	**Date**	:	05/09/2018
Designation	:	QC Officer	**Designation**	:	QC Sr. Executive	**Designation**	:	Manager-QC

This is an auto generated report. Hence no signatures are required.

17/2RM/11/454

Lee Pharma Limited

Factory: Survey No. 10/G-1, Gaddapotharam (Village), Jinnaram (Mandal), Sangareddy (Dist.), Pin code: 502319 Telangana, India.

Factory: +91-08458-277149/250 Office: +91-40-66170335/336

CERTIFICATE OF ANALYSIS

Product	:	Omeprazole EP	Customer name	:	M/s. Ciron drugs & Pharmaceuticals pvt ltd
Batch No.	:	OPFP17077	Date of Manufacture	:	Oct .2017
Batch Size	:	370.0 kg	Date of Retest	:	Sep .2022
A.R.No.	:	CB17698	Date Analyzed	:	31.10.2017
Reference	:	EP	Specification No.	:	SOPFP01
Storage	:	Store in airtight container, protected from light, at a temp. of 2°C to 8°C	Dispatch Quantity	:	10.0 kg

QUALITY ASSURANCE RELEASED Sign Date 14/11/2017

S. No.	TEST	RESULT	SPECIFICATION
1.0	Appearance	Almost white powder.	White or almost white powder.
2.0	Solubility	Very slightly soluble in water, soluble in methylene chloride, sparingly soluble in ethanol (96%) and in methanol. It dissolves in dilute solutions of alkali hydroxides.	Very slightly soluble in water, soluble in methylene chloride, sparingly soluble in ethanol (96%) and in methanol. It dissolves in dilute solutions of alkali hydroxides.
3.0	Identification by IR	IR spectrum of sample is concordant to that of Working standard of Omeprazole.	IR spectrum of sample should be concordant to that of EP CRS/ Working standard of Omeprazole.
4.0	Appearance of solution (2 % w/v solution in MDC)	Solution S is clear	Solution S should be clear
5.0	Absorbance at 440 nm Impurity F and G (Abs.)	0.056	Not more than 0.10 (This limit corresponds to 350 ppm of impurity – F and G)
6.0	Related substances by HPLC (%) a. Impurity – D b. Impurity – E c. Unspecified impurity d. Total impurities	 0.02 0.01 0.01 0.04	 Not more than 0.15 Not more than 0.15 Not more than 0.10 Not more than 0.5
7.0	Loss on drying (%, w/w) (At 60°C for 4 hr)	0.11	Not more than 0.2
8.0	Sulphated ash (%, w/w)	0.08	Not more than 0.1

Prepared by: Date: 14/11/17

Reviewed by: Date: 14/11/2017

Head Quality Control: Date: 14/11/17

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Lee Pharma Limited
Factory: Survey No. 10/G-1, Gaddapotharam (Village), Jinnaram (Mandal), Sangareddy (Dist.), Pin code: 502319
Telangana, India.
Factory: +91-08458-277149/250 Office: +91-40-66170335/336

CERTIFICATE OF ANALYSIS

Product	:	Omeprazole EP	Customer name	:	M/s. Ciron drugs & Pharmaceuticals pvt ltd
Batch No.	:	OPFP17077	Date of Manufacture	:	Oct .2017
Batch Size	:	370.0 kg	Date of Retest	:	Sep .2022
A.R.No.	:	CB17698	Date Analyzed	:	31.10.2017
Reference	:	EP	Specification No.	:	SOPFP01
Storage	:	Store in airtight container, protected from light, at a temp. of 2°C to 8°C	Dispatch Quantity	:	10.0 kg

QUALITY ASSURANCE Sign Date 14/11/2017 RELEASED

S. No.	TEST	RESULT	SPECIFICATION
9.0	Assay by potentiometry (%, w/w) (On dried basis)	100.0	Not less than 99.0 and Not more than 101.0
10.0	Residual solvents by GC HS (ppm)		
	10.1 Methanol	15	Not more than 3000
	10.2 Acetone	154	Not more than 3000
	10.3 Toluene	6	Not more than 300
	10.4 Triethylamine	Not detected	Not more than 200

The product CONFORMS to above specifications.

Prepared by: Date: 14/11/17

Reviewed by: Date: 14/11/2017

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