

1602000010

 VASUDHA PHARMA CHEM LTD	<b>VASUDHA PHARMA CHEM LIMITED</b> 78/A, VENGALRAO NAGAR, HYDERABAD – 38 TELANGANA, INDIA PHONE: 91-40-2381 2046, 2371 1717, FAX: 91-40-2381 1576 E-MAIL: vasudha@vasudhapharma.com, Website: www.vasudhapharma.com	

**CERTIFICATE OF ANALYSIS**

Name of the Product	:	LOPERAMIDE HYDROCHLORIDE			
Batch Number	:	LPD/1512009-M	Analyzed on	:	08/12/2015
Manufacturing Date	:	NOV'2015	Expiry Date	:	OCT'2020
Quantity	:	100.20Kg	A.R.No.	:	FP/152057

S.No	TEST	RESULT	SPECIFICATION
1.0	Description	White powder	White to slightly yellow powder.
2.0	Solubility	Complies	Freely soluble in methanol and in chloroform; slightly soluble in water and in dilute acids; very slightly soluble in isopropyl alcohol.
3.0	Melting point	225.8°C	Melts at about 225°C, with some decomposition.
4.0	IDENTIFICATION		
	A By Infrared Absorption	Complies	To match with working / Reference standard.
	B By Ultraviolet absorption	Complies	The UV absorption spectrum between 250 and 300 nm of the test solution and the Standard solution should exhibit maxima and minima at the same wavelengths.
5.0	Loss on drying	0.25%	Not more than 0.5% w/w
6.0	Residue on Ignition	0.04%	Not more than 0.2% w/w
7.0	Heavy metals	Complies	Not more than 0.002% w/w
8.0	Chromatographic purity by TLC %	Complies	The R <sub>f</sub> value of the test sample concordant with that of Loperamide HCl RS/WS and any secondary spots should not appear.
9.0	Chloride content	13.92%	Between 13.52% and 14.20% w/w
10.0	Assay by titrimetry (On dried basis)	99.8%	Not less than 98.0% and Not more than 102.0% w/w
11.0	ADDITIONAL TESTS		
11.1	Residual Solvents by GC HS		
	Methanol	BDL	Not more than 3000 ppm
	Acetone	479 ppm	Not more than 5000 ppm
	Methylene dichloride	76 ppm	Not more than 600 ppm
	Isopropyl alcohol	BDL	Not more than 5000 ppm
	Chloroform	BDL	Not more than 60 ppm
	Toluene	BDL	Not more than 890 ppm

Manufactured at: Vasudha Pharma Chem Ltd. Unit-I, Plot No.39, A&B, Phase-I, J.D.A., Jeedimetla, Hyderabad-500 055, TELANGANA, India.  
 CQA/002/F05/00

EFFECTIVE DATE: 01/10/2014

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S.No	TEST	RESULT	SPECIFICATION
11.2	Related Substances by HPLC		
	Impurity-A	Not detected	Not more than 0.20%
	Impurity-B	Not detected	Not more than 0.20%
	Impurity-C	Below disregard limit	Not more than 0.20%
	Impurity-D	0.15%	Not more than 0.20%
	Impurity-E	BDL	Not more than 0.20%
	Impurity-F	BDL	Not more than 0.20%
	Impurity-G	Not detected	Not more than 0.20%
	Impurity-H	Below disregard limit	Not more than 0.20%
	Single maximum unspecified impurity	Below disregard limit	Not more than 0.10%
	Total impurities	0.21%	Not more than 0.30%
*11.3	Particle size	11.105 µm 20.83 µm	90% < 20 µm 100% < 40 µm

**Manufactured at:** Vasudha Pharma Chem Ltd. Unit-I, Plot No.39, A&B, Phase-I, LD A, Jeedimetla, Hyderabad-500 055, TELANGANA, India.  
**CQA/002/F05/00**

**EFFECTIVE DATE:** 01/10/2014

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VASUDHA PHARMA CHEM LTD  
 CUSTODY: Chemo AG  
 Qty: 12kg  
 Signature: *[Signature]*  
 Date: 09/12/15

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S.No.	TEST	RESULT	SPECIFICATION
*11.4	Microbiology Tests		
	Total Aerobic microbial count	Complies	Not more than 1000 cfu/gm
	Total combined Yeast and Molds count	Complies	Not more than 100 cfu/gm
	PATHOGENS		
	Bile-Tolerant Gram-negative Bacteria	Absent	Should be absent
	Escherichia coli	Absent	Should be absent
	Salmonella species	Absent	Should be absent
	Pseudomonas aeruginosa	Absent	Should be absent
	Staphylococcus aureus	Absent	Should be absent

\*As per customer Requirement.

BDL: Below Detection Limit.

Remarks: The material complies as per USP-38 Specification.

	Prepared By	Checked By	Approved By
Signature	<i>[Signature]</i> 09/12/15	<i>[Signature]</i> 09/12/15	<i>[Signature]</i> 09/12/15
Name	I. VIJAY RAJU	V. BRAHMA CHARY	P.V. RAMESH BABU
Designation	Sr.Chemist-QC	Asst.Manager-QC	Manager-QC

Manufactured at: Vasudha Pharma Chem Ltd, Unit-I, Plot No.39, A&B, Phase-I, I.D.A, Jeelimetla, Hyderabad-500 055, TELANGANA, India.  
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