



VASUDHA PHARMA CHEM LIMITED
 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	:	DOMPERIDONE	Analyzed on	:	19/03/2018
Batch Number	:	EDOM/1803002-P	Expiry Date	:	FEB'2023
Manufacturing Date	:	MAR'2018	A.R.No.	:	FP/18494, FP/18495
Quantity	:	300.20Kg			

S.No	TEST	RESULT	SPECIFICATION	
1.0	CHARACTERS			
*1.1	Appearance	White crystalline powder	White or almost white crystalline powder.	
1.2	Solubility	Complies	Practically insoluble in water, soluble in dimethylformamide, slightly soluble in ethanol (96 percent) and in methanol.	
*2.0	Identification			
	A	Melting Point	246.8°C	244°C to 248°C
	B	Infrared absorption spectrophotometry	Complies	To match with Reference standard / Working standard.
	C	Test for non-nitrogen substituted barbiturates	Complies	A violet blue color and precipitate should appear.
3.0	TESTS			
*3.1	Color of Solution	Complies	The solution should be clear and not more intensely colored than reference solution Y ₆ .	



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S.No	TEST	RESULT	SPECIFICATION
3.2	Related Substances by HPLC		
	Impurity-A	Below disregard limit	Not more than 0.25%
	Impurity-B	BDL	Not more than 0.25%
	Impurity-C	BDL	Not more than 0.25%
	Impurity-D	0.22%	Not more than 0.25%
	Impurity-E	BRL	Not more than 0.25%
	Impurity-F	0.07%	Not more than 0.25%
	Any major unspecified impurity	Below disregard limit	Not more than 0.10%
	Total impurities	0.37%	Not more than 0.5%
3.3	Loss on drying	0.23%	Not more than 0.5% w/w
3.4	Sulfated Ash	0.04%	Not more than 0.1% w/w
3.5	Assay by titrimetry (On dried substance)	100.2%	Not less than 99.0% w/w and Not more than 101.0% w/w
4.0	ADDITIONAL TESTS		
*4.1	Residual Solvents by GC HS		
	Methanol	424 ppm	Not more than 500 ppm
	Methyl isobutyl ketone	BDL	Not more than 500 ppm
	Toluene	BDL	Not more than 500 ppm
*4.2	Particle size by malvern	2.706 μ m 5.700 μ m 9.95 μ m	50% < 10 μ m 90% < 20 μ m 100% < 30 μ m



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S.No	TEST	RESULT	SPECIFICATION
*4.3	Microbiological Tests		
	Total Aerobic microbial count	Complies	Not more than 100 Cfu/gm
	Total Combined Yeast and Molds count	Complies	Not more than 10 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
*4.4	Clarity of solution	Complies	The solution should be clear or on turbidity degree not to exceed standard-I

Customer reference No: LCP-007836/08-061008, amendment 1.

*As per customer Requirement.

BDL: Below Detection Limit, BRL: Below Reporting Limit (0.005%).

Remarks: The material complies as per BP/Ph.Eur Specification.

	Prepared By	Checked By	Approved By
Signature			
Name	P. GOVARDHAN	N. BHARAT KUMAR	V. BRAHMA CHARY
Designation	Jr. Manager-QC	Asst. Manager-QC	Dy. Manager-QC

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

CQA/002/1705/00

EFFECTIVE DATE: 01/10/2014

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