



Sri Krishna Pharma
Trusted partners for life's journey

CERTIFICATE OF ANALYSIS

Q.C.DEPARTMENT
DATE: 23.09.2021

PRODUCT	DOMPERIDONE Ph.Eur		
BATCH NO.	034DN21-22	DATE OF ANALYSIS	21.09.2021
BATCH QTY.	205.175 Kg.	MANUFACTURING DATE	AUGUST, 2021
AR.No:	FPC/DOM/0081/21-22	EXPIRY DATE	JULY, 2026
SAMPLED BY : K. CHOUDARI			
DATE : 15.09.2021		SIGNATURE OF CHEMIST <i>Sdr</i>	
Sr. No.	TESTS	SPECIFICATIONS	RESULTS
1	Characters		
	A) Appearance	A white or almost white powder	White powder
	B) Solubility	Practically insoluble in water, soluble in Dimethyl formamide, slightly soluble in methanol and in ethanol (96%).	Complies
2	Identification tests		
	A) Melting point	244°C – 248°C	244.2°C – 245.3°C
	B) By Infrared Absorption Spectrophotometry	Sample spectrum should be concordant with the Domperidone Working standard spectrum/ CRS spectrum.	Complies
	C) TLC Method	The principal spot in the chromatogram obtained with the test solution is similar in position and size to the principal spot in the chromatogram obtained with reference solution (a)	Complies
	D) Non-nitrogen Substituted Barbiturates	It gives reaction of non-nitrogen substituted Barbiturates.	Complies
3	Appearance of solution	The solution is clear and not more intensely coloured than reference solution Y ₆ .	Complies
4	Loss on Drying	Not more than 0.50%	0.16%
5	Sulphated ash	Not more than 0.10%	0.05%
6	Assay (on dried basis)	Not less than 99.0% and Not more than 101.0% w/ w	99.7%
PREPARED BY QC DATE: <i>Coel</i> 23.09.2021			
CHECKED BY QA <i>Aphok</i> DATE: 23.09.2021			
APPROVED BY <i>Hy</i> Sr.MANAGER-QC/DESIGNATE DATE: 23/09/21			
ISSUED TO: M/s. GEMINI EXPORTS.		QTY: 25.0 Kg	
REPORT NO: 034DN (C)		ISSUED ON: 23.09.2021	

Page 1 of 2

Sri Krishna Pharmaceuticals Limited
Corporate Office : C-4, Industrial Area, Uppal Khalsa (V), Uppal (M),
Medchal-Malkajgiri (Dist.), Hyderabad - 500 039, Telangana, India.
Tel : +91 40 2720 1101-02/2720 0103-04/2720 4471-72
Fax : +91 40 2720 4470
Email : skg@srikrishnapharma.com

Unit-I

Factory : C-4, Industrial Area, Uppal Khalsa (V), Uppal (M),
Medchal-Malkajgiri (Dist.), Hyderabad - 500 039, Telangana, India.
Tel : +91 40 2720 1101-02/2720 0103-04/2720 4471-72
Fax : +91 40 2720 4470
website : www.srikrishnapharma.com
CIN No. : U24230 TG1974 PLC001790



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SAMPLED BY : K. CHOUDARI			
DATE	: 15.09.2021		
		SIGNATURE OF CHEMIST	
Sr. No.	TESTS	SPECIFICATIONS	RESULTS
7	Related substances (by HPLC)		
	i) Individual impurities	Not more than 0.25%	BDRL (<0.05%)
	Known Impurity A		
	Impurity B	Not more than 0.25%	BDRL (<0.05%)
	Impurity C	Not more than 0.25%	BDRL (<0.05%)
	Impurity D	Not more than 0.25%	0.14%
	Impurity E	Not more than 0.25%	BDRL (<0.05%)
	Impurity F	Not more than 0.25%	BDRL (<0.05%)
	Unspecified impurities	Not more than 0.10%	0.05%, 0.06%
	ii) Total Impurities	Not more than 0.50%	0.25%
8	Residual solvents (By HSGC)		
	A) Methanol	Not more than 3000 ppm	BQL (<87 ppm)
	B) Chloroform	Not more than 60 ppm	BDL (<3 ppm)
	C) Methyl Isobutyl Ketone	Not more than 4500 ppm	BDL (<46 ppm)
	D) Toluene	Not more than 890 ppm	BDL (<10 ppm)
	E) O-Xylene	Not more than 2170 ppm	BDL (<20 ppm)
Remarks: BDRL: Below Disregard Limit, BDL: Below detection limit, BQL: Below Quantitation Limit. The above product complies With specifications of Ph.Eur 9.0			
PREPARED BY QC DATE: 23.09.2021		CHECKED BY QA DATE: 23.09.2021	APPROVED BY Sr.MANAGER-QC/DESIGNATE DATE: 23/09/21
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PRESHIPMENT COA

Page 2 of 2

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