



CADILA PHARMACEUTICALS LIMITED

1389, Trasad Road, Dholka, Dist. Ahmedabad, Gujarat, India.

Phone: +91-2714-221481/83/84, Fax: +91-2714-221848

CERTIFICATE OF ANALYSIS
QUALITY CONTROL DEPARTMENT

Product Name		:	DOMPERIDONA			
Generic Name		:	DOMPERIDONE TABLETS (10 mg)			
Batch Size		:	2500000 TAB	A.R. Number	:	FG/DHLK/1704824
Batch Number		:	B264E7009	Pack Style	:	N/A
Mfg. Date		:	Oct. 2017	Exp. Date	:	Sep. 2020
Specification Number		:	REL-D-004-09	STP No.	:	STP-D-004-10
Date of Analysis		:	28/10/2017	Date of Report	:	31/10/2017
S.No.	TESTS		RESULTS		SPECIFICATION	
1	Description		Light blue coloured, smooth, round, flat, beveled edged, uncoated tablets with breakline on one side and plain on other side.		Light blue coloured, smooth, round, flat, beveled edged, uncoated tablets with breakline on one side and plain on other side.	
2	Identification		Positive		(A) It should comply with the identification test for (a) Domperidone BP : The light absorption of the sample preparation, prepared during the estimation of assay should exhibit maxima at the same wavelength as that of standard preparation.	
			Positive		(B) Colour Brilliant Blue Lake : A dark blue spot obtained with solution (2), the colour and Rf value shouldcorrespond to that obtained with solution (1).	
3	Average weight		103.60 mg		103.00 ± 3% (99.91 mg to 106.09 mg)	
4	Uniformity of weight		-3.2 % to +1.4%		Not more than two of the individual weight deviate from the average weight by more than ± 7.5% and none deviates by more than ± 15%.	
5	Hardness		2.82 to 3.72kg/cm ²		Between 2 to 6 kg/cm ² or 20-60 N	
6	Friability		0.13 % w/w		Not more than 1.0% w/w	

Prepared By :

Date :

(Executive-Q.C) :

15/11/17

Checked By :

Date :

(Manager-Q.C) :

15/11/17

Approved By :

Date :

(Head-Q.C) :

15/11/17

FORM No. : FQC214-04/00

Reprint Date : 15/11/2017



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S.No.	TESTS	RESULTS	SPECIFICATION
7	Disintegration time	04 Minutes 24 Seconds	Not more than 15 minutes
8	Dissolution	Min.98%, Max.101%, Mean 99%	Not less than 70% (Q) in 45 minutes
9	Uniformity of dosage unit	99% to 101%	85% to 115% of the labeled amount
10	Related Substances(By HPLC)	0.31 %	Not more than 2.0% w/w
11	Assay - Each uncoated tablet contains :		
	Domperidone	9.92 mg 99.2%	NLT 9.00mg/Tab and NMT 11.00mg/Tab NLT 90.0% and NMT110.0% of label claimed
	Sodium benzoate	0.20 mg 104.1%	NLT 0.15% and NMT 0.23% NLT 80.0% and NMT120.0% of label claimed
12	Microbial limit test		
	Total microbial count		
	Bacteria	10 cfu/g	Not more than 1000 cfu/g
	Yeast / Mould	< 10 cfu/g	Not more than 100 cfu/g
	Pathogens		
	Pseudomonas aeruginosa	Absent	Should be absent
	Salmonella	Absent	Should be absent

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S.No.	TESTS		RESULTS		SPECIFICATION	
	Escherichia Coli		Absent		Should be absent	
	Staphylococcus Aureus		Absent		Should be absent	
	Additional tests					
13	Diameter		6.31 to 6.49mm		6.15 mm to 6.55 mm	
	Thickness		2.42 to 2.67mm		2.3 mm to 2.9 mm	

Conclusion: The Product is standard quality in respect of above specification.

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