



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/1901032
Batch Number	:	B264E9004	Pack Style	:	N/A
Mfg. Date	:	Feb. 2019	Exp. Date	:	Jan. 2022
Specification Number	:	REL-D-004-10	STP No.	:	STP-D-004-01
Date of Analysis	:	07/03/2019	Date of Report	:	22/03/2019

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 Domperidone BP(By UV)	The light absorption of the sample solution, prepared during the estimation of assay exhibit maxima at the same wavelength as that of standard solution.	(A) The light absorption of the sample solution, prepared during the estimation of assay should exhibit maxima at the same wavelength as that of standard solution.
	Colour Brilliant Blue Lake (By Thin Layer chromatography)	A dark blue spot obtained with solution (2), the colour and R_f value corresponds to that obtained with solution (1).	(B) A dark blue spot obtained with solution (2), the colour and R_f value should correspond to that obtained with solution (1).
3	Average weight	103.82 mg	$103.00 \pm 3\%$ (99.91 mg to 106.09 mg)
4	Uniformity of weight	-1.5 % to +1.7%	Not more than two of the individual weight deviate from the average weight by more than $\pm 7.5\%$ and none deviates by more than $\pm 15\%$.
5	Hardness	2.7 to 3kg/cm ²	Between 2 to 6 kg/cm ² or 20-60 N
6	Friability	0.03 % w/w	Not more than 1.0% w/w
7	Disintegration time	28 Seconds	Not more than 15 minutes
8	Dissolution (By UV)	Min.97%, Max.101%, Mean 99%	Not less than 70% (Q) of the labeled amount of Domperidone should dissolve in 45 minutes

Prepared By :

Date :

(Executive-Q.C) : 22/04/19

Checked By :

Date :

(Manager-Q.C) : 22/04/19

Approved By :

Date :

(Head-Q.C) : 22/04/19

FORM No. : FQC214-04/00

Reprint Date : 22/04/2019



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9	Uniformity of dosage unit (By Content uniformity)(By UV)	3.8	The acceptance value of the first 10 dosage units should be less than or equal to L1%, where L1 is 15.0 -If the acceptance value is greater than L1%, test the next 20 units and calculate the acceptance value. The final acceptance value of the 30 dosage units should be less than or equal to L1%, and no individual content of any dosage unit should be less than $[1 - (0.01)(L2)]M$ nor more than $[1 + (0.01)(L2)]M$, where L1 is 15.0 and L2 is 25.0.
10	Related Substances(By HPLC)	0.19 %	Not more than 2.0% w/w
11	Assay - Each uncoated tablet contains :		
	Domperidone	10.0 mg 100.2%	NLT 9.0mg/Tab and NMT 11.0mg/Tab NLT 90.0% and NMT 110.0% of label claimed
	Sodium benzoate	0.193 mg 101.5%	NLT 0.152% and NMT 0.228% NLT 80.0% and NMT 120.0% of label claimed
12	Microbial limit test		
	(A) Microbial Enumeration Tests :		
	Total aerobic microbial count (TAMC)	20 cfu/g	Not more than 1000 cfu/g
	Total yeasts and molds count (TYMC)	< 10 cfu/g	Not more than 100 cfu/g

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S.No.	TESTS	RESULTS	SPECIFICATION
	(B) Tests for Specified Microorganisms		
	Pseudomonas aeruginosa	Absent	Should be absent/g
	Salmonella	Absent	Should be absent/10g
	Escherichia Coli	Absent	Should be absent/g
	Staphylococcus Aureus	Absent	Should be absent/g
	Additional tests		
13	Diameter	6.4 to 6.48mm	6.15 mm to 6.55 mm
14	Thickness	2.4 to 2.5mm	2.3 mm to 2.9 mm

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

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