

Manufacturing Facility: Research & Development:

1389, Trasad Road, Dholka-387 810 Dist: Ahmedabad, Gujarat, India. Phone : +91-2714-221481-83 Fax : +91-2714-220315 (R&D) : +91-2714-221848 Website : www.cadilapharma.com

COMPOSITION CERTIFICATE

1.0 Name and dosage form of product:

Domperidone Tablets

2.0 Active ingredient(s) and amount (s) per unit dose: Each tablets contains:

Domperidone BP......10mg
Excipients.....q.s.
Colour: Brilliant Blue Lake

3.0 Complete qualitative and quantitative composition:

Sr. No.	Ingredients	Specification	Qty.(mg)/tablet
1.	Domperidone	BP	10.00
2.	Lactose	BP	70.00
3.	Maize Starch	BP	19.67
4.	Colour Brilliant Blue Lake	IH	00.03
5.	Sodium Benzoate	ВР	00.20
6.	Gelatin	BP	02.00
7.	Purified Water**	ВР	0.022 ml
8.	Magnesium Stearate	BP	1.10

Theoretical Weight of tablet: 103.00 mg

**This will not be present in the Finished Product.

Dr. Hday Ghorpade

Gen. Manager- Quality Control

Corporate Office : "Cadila Corporate Campus,"

Phone : +91-2718-225001-15

13/3/05/1



STABILITY REPORT

Product Name:	Domperidone Tablets-10mg	Stability commenced on:	24/10/2003
Generic Name:	Domperidone Tablets-10mg	Mfg. Date:	Sep'2003
Batch No.:	E-3009	Batch size:	10,53,000 Tablets
Packing details:	Blister Pack of 50 Tablets		10,00,000 Tablets

Each uncoated tablet contains:

Domperidone	10 mg
Summary of results	10 mg

	iiiiai y	or resurts .	T			· · · · · · · · · · · · · · · · · · ·	T
Conditions & Period		Physical Observations	Assay (90% to 110%) (In %)	DT (NMT 15 minutes) (MinSec.)	Moisture content (NMT 10%w/w) (In %)	Dissolution (NLT 75% (Q+5) in 45 min. (In %)	Related substances NMT 2.0 % w/w
		Light blue coloured, smooth, round, flat, bevelled edged uncoated tablets with a breakline on one side and plain on the other side.	101.10	4-40	5.84	93.78	0.12 %
40°C±2°C/75	3M	Light blue coloured, smooth, round, flat, bevelled edged uncoated tablets with a breakline on one side and plain on the other side.	101.86	3-11	6.19	92.86	0.210 %
40°C	6M	Light blue coloured, smooth, round, flat, bevelled edged uncoated tablets with a breakline on one side and plain on the other side.	101.46	2-30	6.19	92.21	0.451 %
	3М	Light blue coloured, smooth, round, flat, bevelled edged uncoated tablets with a breakline on one side and plain on the other side.	101.80	3-34	6.09	93.42	0.150 %
	6M	Light blue coloured, smooth, round, flat, bevelled edged uncoated tablets with a breakline on one side and plain on the other side.	101.72	2-05	6.16	92.48	0.161 %
%±5%RH	9M	Light blue coloured, smooth, round, flat, bevelled edged uncoated tablets with a breakline on one side and plain on the other side.	100.02	2-13	7.56	91.63	0.180 %
25°C±2°C/60%±5%RH	12M	Light blue coloured, smooth, round, flat, bevelled edged uncoated tablets with a breakline on one side and plain on the other side.	100.62	4-36	7.61	90.15	0.210 %
	18M	Light blue coloured, smooth, round, flat, bevelled edged uncoated tablets with a breakline on one side and plain on the other side.	100.02	4-20	6.25	90.00	0.320 %
	24M	Light blue coloured, smooth, round, flat, bevelled edged uncoated tablets with a breakline on one side and plain on the other side.	100.00	3-40	5.60	91.00	0.370 %
	36M	Light blue coloured, smooth, round, flat, bevelled edged uncoated tablets with a breakline on one side and plain on the other side.	99.89	3-20	6.20	91.20	0.735 %
	48M	Light blue coloured, smooth, round, flat, bevelled edged uncoated tablets with a breakline on one side and plain on the other side.	99.75	4-25	6.25	92.00	0.762 %

Remarks: The product has been found to be stable for a period of 6 months when stored at 40°C±2°C/75±5%RH and 48 months at 25°C±2°C/60±5%RH.Study continue.

Prepared by



STABILITY REPORT

Product Name:	DOMPERON			
<u> </u>		Stability commenced on:	29/09/1996	
Generic Name:	Domperidone Tablets-10mg	Mfg. Date:	Sep'1996	
Batch No.:	E-6003	5		
Packing details:	Blister Pack		8,00,000 Tablets	

Each film uncoated tablet contains:

Summary of results

	Conditions & Period			Assay (90% to 110%) (In %)	DT (NMT 15 minutes) (MinSec.)	Moisture content (NMT 10%w/w (In %)	Dissolution (NLT 70% (Q) 45 min. (In %)	
(1 1	Initial	Light blue coloured, smooth, round, flat, bevelle edged uncoated tablets with a breakline on or side and plain on the other side.	ed 102.80	2-00	5.41	89.75	
	2°C/75	31 %CH	Light blue coloured, smooth, round, flat, bevelle edged uncoated tablets with a breakline on on side and plain on the other side.	100.50	3-15	5.67	89.27	
	40°C±2°C/75	% 6N	Light blue coloured, smooth, round, flat, bevelle edged uncoaled tablets with a breakline on on side and plain on the other side.	99.15	4-00	6.48	88.53	
		3.	Light blue coloured, smooth, round, flat, beveller edged uncoated tablets with a breakline on one side and plain on the other side.	101.30	2-10	5.47	89.82	
		6M	Light blue coloured, smooth, round, flat, beveiled edged uncoated tablets with a breakline on one side and plain on the other side.	100.60	2-30	5.54	88.67	1
	Ę.	9М	Light blue coloured, smooth, round, flat, beveiled edged uncoated tablets with a breakline on one side and plain on the other side.	99.85	2-45	5.69	87.64	1
1	30°C±2°C/70±5%Rh	12M	Light blue coloured, smooth, round, flat, bevelled edged uncoated tablets with a breakline on one side and plain on the other side.	99.72	3-00	5.58	88.35	
 -	0°C±2°C	18M	Light blue coloured, smooth, round, flat, bevelled edged uncoated tablets with a breakline on one side and plain on the other side.	99.65	3-00	6.07	86.54	
	ю -	24M	Light blue coloured, smooth, round, flat, bevelled edged uncoated tablets with a breakline on one side and plain on the other side.	99.45	3-05	5.88	87.32	Section and Commercial
-	_	36M	Light blue coloured, smooth, round, flat, bevelled edged uncoated tablets with a breakline on one side and plain on the other side.	99.05	3-35	6.37	84.84	
		48M	Light blue coloured, smooth, round, flat, bevelled edged uncoated tablets with a breakline on one side and plain on the other side.	98.20	4-00	6.94	79.67	

Remarks: The product has been found to be stable for a period of 6 months when stored at 40°C±2°C/75±5%RH and 48 months at 30°C±2°C/70±5%RH.

Uffan stolet



STABILITY REPORT

1	Product Name:		DOMPERON	Stability commence		iced on:	04/12/	11000			
(Generic Name: Domperidone Tablets-10mg			mg	Mfg. Date:			Nov'1996			
E	Batch ,	No.:		Batch size:							
		g details:	Blister Pack		241017 3126.			8,00,000 Tablets			
	Each film uncoated tablet contains: Domperidone										
	Conditions & Period		Physical Observations	Assa (90% to 1 (In %	10%)	DT (NMT 15 minutes) (MinSec.)	Moisture content (NMT 10%w/w) (In %)		Dissolution (NLT 70% (Q) 45 min. (In %)		
ا 	Initial edged und		coloured, smooth, round, flat, bevelle coated tablets with a breakline on on lain on the other side.	d e 101.30		3-00	6.46		94.13		
.C.75	31 31	3M Light blue coloured, smooth, round, flat, beveller edged uncoated tablets with a breakline on one side and plain on the other side.		d e 100.49		3-25	6.78		93.86		
40°C+2	% ±5%RH	M edged unc	coloured, smooth, round, flat, bevelled pated tablets with a breakline on one ain on the other side.	99.52		4-10	1-10 7.14		91.37		
	31/	edged unco	coloured, smooth, round, flat, bevelled pated tablets with a breakline on one pain on the other side.	100.66		3-10	6.5	4	94.37		
_	6M	Light blue coloured, smooth, round, flat, bevelled edged uncoated tablets with a breakline on one side and plain on the other side.		velled 100.52		3-20 6.70		,	92.46		
. S.	9М	edged unco:	oloured, smooth, round, flat, bevelled aled tablets with a breakline on one in on the other side.	100.12		3-45	7.03		94.04		
30°C±2°C/70±5%RH	12M	edged uncoa	ploured, smooth, round, flat, bevelled ated tablets with a breakline on one n on the other side.	99.98		3-50	6.84		90.88		
30°C±2%	18M	edged uncoa	loured, smooth, round, flat, bevelled ted tablets with a breakline on one on the other side.	99.75		4-10	7.12		92.54		
	24M	edged uncoa	loured, smooth, round, flat, bevelled ted tablets with a breakline on one on the other side.	99.62		4-15	7.28		89.63		
	36M	edged uncoat	oured, smooth, round, flat, bevelled ed tablets with a breakline on one on the other side.	99.65		4-45	7.60	_	90.84		
	48M	edged uncoate	oured, smooth, round, flat, beveiled ed tablets with a breakline on one on the other side.	98.12		5-10	7.48		86.31		

Remarks: The product has been found to be stable for a period of 6 months when stored at $40^{\circ}\text{C}\pm2^{\circ}\text{C}/75\pm5\%$ RH and 48 months at $30^{\circ}\text{C}\pm2^{\circ}\text{C}/70\pm5\%$ RH.

Prepared by Vikas Gupta

Checked by Dr. Dheerai Gunta

9 c/2/12 mp/10

Approved by