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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	BP	00.20
6.	Gelatin	BP	02.00
7.	Purified Water**	BP	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

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		

Each uncoated tablet contains:

Domperidone.....10 mg

Summary of results

Conditions & Period	Physical Observations	Assay (90% to 110%) (In %)	DT (NMT 15 minutes) (Min.-Sec.)	Moisture content (NMT 10%w/w) (In %)	Dissolution (NLT 75% (Q+5) in 45 min. (In %)	Related substances NMT 2.0 % w/w
Initial	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%±5%RH	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 %
	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 %
25°C±2°C/60%±5%RH	3M 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 %
	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 %
	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



Checked by



Approved by

STABILITY REPORT

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

Each film uncoated tablet contains:

Domperidone.....

10 mg

Summary of results

Summary of Results						
Conditions & Period		Physical Observations	Assay (90% to 110%) (In %)	DT (NMT 15 minutes) (Min.-Sec.)	Moisture content (NMT 10%w/w) (In %)	Dissolution (NLT 70% (Q) in 45 min. (In %)
Initial		Light blue coloured, smooth, round, flat, bevelled edged uncoated tablets with a breakline on one side and plain on the other side.	102.80	2-00	5.41	89.75
40°C±2°C/75 % ±5%RH	3M	Light blue coloured, smooth, round, flat, bevelled edged uncoated tablets with a breakline on one side and plain on the other side.	100.50	3-15	5.67	89.27
	6M	Light blue coloured, smooth, round, flat, bevelled edged uncoated tablets with a breakline on one side and plain on the other side.	99.15	4-00	6.48	88.53
30°C±2°C/70±5%RH	3M	Light blue coloured, smooth, round, flat, bevelled 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, bevelled edged uncoated tablets with a breakline on one side and plain on the other side.	100.60	2-30	5.54	88.67
	9M	Light blue coloured, smooth, round, flat, bevelled edged uncoated tablets with a breakline on one side and plain on the other side.	99.85	2-45	5.69	87.64
	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
	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
	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
	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.

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24/10/06

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STABILITY REPORT

Product Name:	DOMPERON	Stability commenced on:	04/12/1996
Generic Name:	Domperidone Tablets-10mg	Mfg. Date:	Nov'1996
Batch No.:	E-6004	Batch size:	8,00,000 Tablets
Packing details:	Blister Pack		

Each film uncoated tablet contains:

Domperidone.....

Summary of results10 mg

Conditions & Period	Physical Observations	Assay (90% to 110%) (In %)	DT (NMT 15 minutes) (Min.-Sec.)	Moisture content (NMT 10%w/w) (In %)	Dissolution (NLT 70% (Q) in 45 min. (In %)
Initial	Light blue coloured, smooth, round, flat, bevelled edged uncoated tablets with a breakline on one side and plain on the other side.	101.30	3-00	6.46	94.13
40°C±2°C/75%±5%RH	3M	100.49	3-25	6.78	93.86
	6M	99.52	4-10	7.14	91.37
30°C±2°C/70±5%RH	3M	100.66	3-10	6.54	94.37
	6M	100.52	3-20	6.70	92.46
	9M	100.12	3-45	7.03	94.04
	12M	99.98	3-50	6.84	90.88
	18M	99.75	4-10	7.12	92.54
	24M	99.62	4-15	7.28	89.63
	36M	99.65	4-45	7.60	90.84
	48M	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°C±2°C/75±5%RH and 48 months at 30°C±2°C/70±5%RH.

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