

**EMIL
PHARMACEUTICAL
INDUSTRIES PVT. LTD.**

Reg office: 101
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Borivali East, Mumbai
400066, INDIA.
Tel: +91-22-42090200
Email: info@emilpharma.in



An ISO 9001:2008 Certified Company

ACCELERATED STABILITY STUDY REPORT

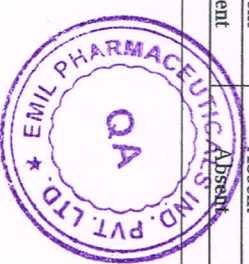
Name of Product	:	Sildenafil Citrate Tablets 50 mg	Batch No	:	MD274
Description of the pack	:	4's blister pack in 0.25 mm thickness PVC foil	Mfg. Date	:	Feb 2008
Parameters and test method monitored	:	Description, Disintegration test, LOD, Dissolution Test, Assay, Related Substances, Microbial count	Expiry Date	:	Jan 2011
Date of Initiation	:	25/02/2008	Storage conditions	:	40° ± 2°C and 75% ± 5% RH
			Date of completion	:	Jul 2008
TEST	LIMITS	RESULTS OF ANALYSIS			
		INITIAL (Feb 2008)	3 Month (Apr 2008)	6 Month (Jul 2008)	
Description	Light blue coloured diamond shaped film coated tablets.	Light blue coloured diamond shaped film coated tablets.	Light blue coloured diamond shaped film coated tablets.	Light blue coloured diamond shaped film coated tablets.	
Disintegration test	N.M.T. 30 min	7 min	8 min	8 min	
LOD	N.M.T. 3% w/w	1.40%	1.48%	1.60%	
Dissolution Test	N.L.T. 70% w/w	1] 96.70% 2] 98.43% 3] 97.57% 4] 99.88% 5] 97.86% 6] 98.72%	1] 95.62% 2] 97.26% 3] 96.20% 4] 97.18% 5] 96.31% 6] 98.22%	1] 96.64% 2] 97.15% 3] 94.05% 4] 95.02% 5] 96.02% 6] 97.18%	
Related Substances	Single Impurity : NMT 1.0 %	0.012%	0.013%	0.014%	
	Total Impurity : NMT 2.0 %	0.012%	0.014%	0.014%	
Assay	90.00% to 110.00%	102.42%	101.98%	101.52%	
Total aerobic microbial count					
Bacterial Counts	NMT 1000 cfu	30	30	35	
Fungi	NMT 100 cfu/g	Absent	Absent	Absent	
Test for specified microorganisms:					
E. Coli	Absent	Absent	Absent	Absent	
Salmonellae	Absent	Absent	Absent	Absent	
Pseudomonas	Absent	Absent	Absent	Absent	
Stap. aureus	Absent	Absent	Absent	Absent	



Smdaptardar
Approved By
Mr. S. Daptardar
(QA Manager)

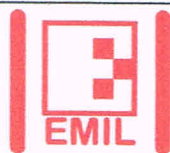
REAL TIME STABILITY STUDY REPORT

Name of Product		:	Sildenafil Citrate Tablets 50 mg					Batch No.	:	MD274
Description of the pack		:	4's blister pack in 0.25 mm thickness PVC foil					Mfg. Date	:	Feb 2008
Parameters and Test methods monitored		:	Description, Disintegration test, LOD, Dissolution Test, Assay, Related Substances, Microbial count					Expiry Date	:	Jan 2011
Date of Initiation		:	25/02/2008					Storage conditions	:	30°C + 2°C and 65%± 5% RH
		:						Date of completion	:	Apr 2011
Test	Limit	RESULTS OF ANALYSIS								
		INITIAL (Feb 2008)	3 Month (Apr 2008)	6 Month (Jul 2008)	9 Month (Oct 2008)	12 Month (Jan 2009)	18 months (Jul 2009)	24 Month (Jan 2010)	36 Month (Jan 2011)	39 Month (Apr 2011)
Description	Light blue coloured diamond shaped film coated tablets.	Light blue coloured diamond shaped film coated tablets.	Light blue coloured diamond shaped film coated tablets.	Light blue coloured diamond shaped film coated tablets.	Light blue coloured diamond shaped film coated tablets.	Light blue coloured diamond shaped film coated tablets.	Light blue coloured diamond shaped film coated tablets.	Light blue coloured diamond shaped film coated tablets.	Light blue coloured diamond shaped film coated tablets.	
D. T.	N.M.T. 30 min	7 min	7 min	7 min	9 min	10 min	10 min	11 min	11 min	12 min
LOD	N.M.T. 3% w/w	1.40%	1.42%	1.46%	1.56%	1.58%	1.62%	1.69%	1.70%	1.71%
Dissolution	N.L.T.70 % w/w	1] 96.70%	1] 96.22%	1] 98.60%	1] 96.48%	1] 97.32%	1] 96.33%	1] 93.65%	1] 96.21%	1] 94.62%
		2] 98.43%	2] 97.58%	2] 99.12%	2] 97.31%	2] 97.10%	2] 95.84%	2] 96.15%	2] 95.03%	2] 95.02%
		3] 97.57%	3] 97.12%	3] 97.30%	3] 98.91%	3] 98.02%	3] 94.28%	3] 95.60%	3] 96.11%	3] 96.88%
		4] 99.88%	4] 98.99%	4] 96.20%	4] 98.25%	4] 96.30%	4] 97.66%	4] 95.06%	4] 96.85%	4] 95.02%
		5] 97.86%	5] 99.31%	5] 96.94%	5] 97.84%	5] 95.94%	5] 96.33%	5] 96.03%	5] 96.01%	5] 93.02%
		6] 98.72%	6] 98.45%	6] 97.85%	6] 97.69%	6] 96.48%	6] 96.02%	6] 97.02%	6] 95.84%	6] 93.32%
Related Substances	Single Impurity NMT 1.0 %	0.012%	0.013%	0.015%	0.020%	0.024%	0.025%	0.030%	0.035%	0.035%
	Total Impurity NMT 2.0 %	0.012%	0.014%	0.015%	0.022%	0.025%	0.026%	0.030%	0.035%	0.035%
Assay	90.00% to 110.00%	102.42%	102.23%	102.01%	101.78%	101.59%	101.31%	101.00%	100.84%	100.68%
Total aerobic microbial count										
Bacteria	NMT 1000 cfu/g	30	30	35	35	35	40	40	45	50
Fungi	NMT 100 cfu/g	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent
Test for specified microorganisms:										
E. Coli	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent
Salmonellae	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent
Pseudomonas	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent
Stap. aureus	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent



Approved By
Mr. S. Dapardar
(QA Manager)

S. Dapardar



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ACCELERATED STABILITY STUDY REPORT

Name of Product	:	Sildenafil Citrate Tablets 50 mg	Batch No	:	A8006
Description of the pack	:	4's blister pack in 0.25 mm thickness PVC foil	Mfg. Date	:	Feb 2008
Parameters and test method monitored	:	Description, Disintegration test, LOD, Dissolution Test, Assay, Related Substances, Microbial count	Expiry Date	:	Jan 2011
Date of Initiation	:	20/02/2008	Storage conditions	:	40° ± 2°C and 75% ± 5% RH
			Date of completion	:	Jul 2008
TEST	LIMITS	RESULTS OF ANALYSIS			
		INITIAL (Feb 2008)	3 Month (Apr 2008)	6 Month (Jul 2008)	
Description	Light blue coloured diamond shaped film coated tablets.	Light blue coloured diamond shaped film coated tablets.	Light blue coloured diamond shaped film coated tablets.	Light blue coloured diamond shaped film coated tablets.	
Disintegration test	N.M.T. 30 mins	5 min	6 min	7 min	
LOD	N.M.T. 3% w/w	1.23%	1.28%	1.40%	
Dissolution Test	N.L.T. 70% w/w	1] 97.56% 2] 99.59% 3] 99.57% 4] 97.98% 5] 98.72% 6] 95.26%	1] 98.12% 2] 96.61% 3] 99.26% 4] 95.02% 5] 95.96% 6] 97.62%	1] 96.45% 2] 95.02% 3] 97.66% 4] 98.88% 5] 96.27% 6] 97.18%	
Related Substances	Single Impurity : NMT 1.0 %	0.009%	0.010%	0.012%	
	Total Impurity : NMT 2.0 %	0.010%	0.012%	0.013%	
Assay	90.00% to 110.00%	101.90%	101.21%	100.87%	
Total aerobic microbial count					
Bacterial Counts	NMT 1000 cfu	20	25	35	
Fungi	NMT 100 cfu/g	Absent	Absent	Absent	
Test for specified microorganisms:					
E. Coli	Absent	Absent	Absent	Absent	
Salmonellae	Absent	Absent	Absent	Absent	
Pseudomonas	Absent	Absent	Absent	Absent	
Stap. aureus	Absent	Absent	Absent	Absent	



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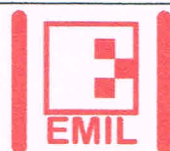


REAL TIME STABILITY STUDY REPORT

Name of Product		:	Sildenafil Citrate Tablets 50 mg					:	Batch No.		:	A 8006	
Description of the pack		:	4's blister pack in 0.25 mm thickness PVC foil					:	Mfg. Date		:	Feb 2008	
Parameters and Test methods monitored		:	Description, Disintegration test, LOD, Dissolution Test, Assay, Related Substances, Microbial count					:	Expiry Date		:	Jan 2011	
Date of Initiation		:	20/02/2008					:	Storage conditions		:	30°C + 2°C and 65%± 5% RH	
		:						:	Date of completion		:	Apr 2011	
RESULTS OF ANALYSIS													
Test	Limit	INITIAL (Feb 2008)	3 Month (Apr 2008)	6 Month (Jul 2008)	9 Month (Oct 2008)	12 Month (Jan 2009)	18 months (Jul 2009)	24 Month (Jan 2010)	36 Month (Jan 2011)	39 Month (Apr 2011)			
Description	Light blue coloured diamond shaped film coated tablets.	Light blue coloured diamond shaped film coated tablets.	Light blue coloured diamond shaped film coated tablets.	Light blue coloured diamond shaped film coated tablets.	Light blue coloured diamond shaped film coated tablets.	Light blue coloured diamond shaped film coated tablets.	Light blue coloured diamond shaped film coated tablets.	Light blue coloured diamond shaped film coated tablets.	Light blue coloured diamond shaped film coated tablets.	Light blue coloured diamond shaped film coated tablets.			
D. T.	N.M.T. 30 mins	5 min	5 min	5 min	6 min	6 min	7 min	8 min	9 min	9 min			
LOD	N.M.T. 3% w/w	1.23%	1.31%	1.36%	1.39%	1.45%	1.48%	1.52%	1.56%	1.60%			
Dissolution	N.L.T.70 % w/w	1] 97.56%	1] 97.20%	1] 95.03%	1] 95.23%	1] 95.12%	1] 95.48%	1] 94.02%	1] 93.02%	1] 93.46%			
		2] 99.59%	2] 98.02%	2] 96.55%	2] 96.45%	2] 96.02%	2] 95.91%	2] 95.12%	2] 94.61%	2] 92.81%			
		3] 99.57%	3] 99.62%	3] 97.02%	3] 97.22%	3] 94.62%	3] 96.02%	3] 96.02%	3] 95.02%	3] 94.05%			
		4] 97.98%	4] 98.16%	4] 99.20%	4] 94.88%	4] 95.03%	4] 96.42%	4] 96.55%	4] 94.31%	4] 93.64%			
		5] 98.72%	5] 97.62%	5] 96.24%	5] 96.02%	5] 96.21%	5] 95.02%	5] 95.08%	5] 93.25%	5] 93.48%			
Related Substances	Single Impurity NMT 1.0 %	0.009%	0.009%	0.011%	0.012%	0.015%	0.016%	0.018%	0.020%	0.025%			
	Total Impurity NMT 2.0 %	0.010%	0.009%	0.011%	0.012%	0.015%	0.016%	0.018%	0.020%	0.025%			
Assay	90.00% to 110.00%	101.90%	101.52%	101.15%	100.98%	100.67%	100.32%	99.97%	99.80%	99.62%			
Total aerobic microbial count													
Bacteria	NMT 1000 cfu/g	20	20	25	30	35	40	40	45	50			
Fungi	NMT 100 cfu/g	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent			
Test for specified microorganisms:													
E. Coli	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent			
Salmonellae	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent			
Pseudomonas	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent			
Step. aureus	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent			



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ACCELERATED STABILITY STUDY REPORT

Name of Product	:	Sildenafil Citrate Tablets 50 mg	Batch No	:	MD286
Description of the pack	:	4's blister pack in 0.25 mm thickness PVC foil	Mfg. Date	:	Mar 2008
Parameters and test method monitored	:	Description, Disintegration test, LOD, Dissolution Test, Assay, Related Substances, Microbial count	Expiry Date	:	Feb 2011
Date of Initiation	:	12/03/2008	Storage conditions	:	40° ± 2°C and 75% ± 5% RH
			Date of completion	:	Aug 2008
TEST	LIMITS	RESULTS OF ANALYSIS			
		INITIAL (Mar 2008)	3 Month (May2008)	6 Month (Aug 2008)	
Description	Light blue coloured diamond shaped film coated tablets.	Light blue coloured diamond shaped film coated tablets.	Light blue coloured diamond shaped film coated tablets.	Light blue coloured diamond shaped film coated tablets.	
Disintegration test	N.M.T. 30 min	7 min	8 min	9 min	
LOD	N.M.T. 3% w/w	1.24%	1.32%	1.38%	
Dissolution Test	N.L.T. 70% w/w	1] 98.05% 2] 99.48% 3] 98.47% 4] 98.02% 5] 97.18% 6] 99.10%	1] 98.45% 2] 97.02% 3] 98.32% 4] 96.07% 5] 96.48% 6] 95.87%	1] 96.48% 2] 95.88% 3] 93.48% 4] 97.84% 5] 98.21% 6] 97.12%	
Related Substances	Single Impurity : NMT 1.0 %	0.009%	0.009%	0.012%	
	Total Impurity : NMT 2.0 %	0.009%	0.010%	0.015%	
Assay	90.00% to 110.00%	100.51%	100.20%	99.64%	
Total aerobic microbial count					
Bacterial Counts	NMT 1000 cfu	20	20	30	
Fungi	NMT 100 cfu/g	Absent	Absent	Absent	
Test for specified microorganisms:					
E. Coli	Absent	Absent	Absent	Absent	
Salmonellae	Absent	Absent	Absent	Absent	
Pseudomonas	Absent	Absent	Absent	Absent	
Stap. aureus	Absent	Absent	Absent	Absent	



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REAL TIME STABILITY STUDY REPORT

Name of Product		:	Sildenafil Citrate Tablets 50 mg					Batch No.	:	MD286
Description of the pack		:	4's blister pack in 0.25 mm thickness PVC foil					Mfg. Date	:	Mar 2008
Parameters and Test methods monitored		:	Description, Disintegration test, LOD, Dissolution Test, Assay, Related Substances, Microbial count					Expiry Date	:	Feb 2011
Date of Initiation		:	12/03/2008					Storage conditions	:	30°C + 2°C and 65%+ 5% RH
		:	12/03/2008					Date of completion	:	May 2012
RESULTS OF ANALYSIS										
Test	Limit	INITIAL (Jan.2009)	3 Month (Mar.2009)	6 Month (Jun.2009)	9 Month (Sep.2009)	12 Month (Dec.2009)	18 months (Jun. 2010)	24 Month (Dec.2010)	36 Month (Dec.2011)	39 Month (Mar.2012)
Description	Light blue coloured diamond shaped film coated tablets.	Light blue coloured diamond shaped film coated tablets.	Light blue coloured diamond shaped film coated tablets.	Light blue coloured diamond shaped film coated tablets.	Light blue coloured diamond shaped film coated tablets.	Light blue coloured diamond shaped film coated tablets.	Light blue coloured diamond shaped film coated tablets.	Light blue coloured diamond shaped film coated tablets.	Light blue coloured diamond shaped film coated tablets.	Light blue coloured diamond shaped film coated tablets.
D. T.	N.M.T. 30 mins	7 mins	8 mins	8 mins	9 mins	9 mins	10 mins	10 mins	11 mins	12 mins
LOD	N.M.T. 3% w/w	1.24%	1.27%	1.30%	1.32%	1.38%	1.45%	1.50%	1.56%	1.61%
Dissolution	N.L.T. 70 % w/w	1] 98.05%	1] 98.22%	1] 98.61%	1] 97.02%	1] 97.10%	1] 98.00%	1] 97.66%	1] 96.25%	1] 94.32%
		2] 99.48%	2] 99.02%	2] 97.02%	2] 98.55%	2] 98.05%	2] 97.50%	2] 97.02%	2] 95.93%	2] 95.25%
		3] 98.47%	3] 97.62%	3] 98.37%	3] 98.21%	3] 98.32%	3] 98.15%	3] 96.66%	3] 96.15%	3] 96.30%
		4] 98.02%	4] 98.82%	4] 97.94%	4] 97.45%	4] 97.82%	4] 97.02%	4] 96.22%	4] 95.40%	4] 93.02%
		5] 97.18%	5] 97.15%	5] 98.02%	5] 97.62%	5] 97.48%	5] 96.88%	5] 97.02%	5] 96.22%	5] 95.40%
		6] 99.10%	6] 97.84%	6] 97.66%	6] 97.20%	6] 96.90%	6] 97.51%	6] 97.16%	6] 95.02%	6] 96.03%
Related Substances	Single Impurity NMT 1.0 %	0.009%	0.009%	0.010%	0.011%	0.012%	0.013%	0.015%	0.021%	0.025%
	Total Impurity NMT 2.0 %	0.009%	0.009%	0.011%	0.012%	0.015%	0.015%	0.017%	0.025%	0.031
Assay	90.00% to 110.00%	100.51%	100.22%	99.98%	99.82%	99.61%	99.12%	98.88%	98.42%	98.21%
Total aerobic microbial count										
Bacteria	NMT 1000 cfu/g	20	20	25	30	30	35	40	40	45
Fungi	NMT 100 cfu/g	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent
Test for specified microorganisms:										
E. Coli	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent
Salmonellae	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent
Pseudomonas	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent
Stap. aureus	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent



Approved By
Mr. S. Dapardar
(QA Manager)