









ACCELERATED STABILITY STUDY REPORT

Name of Product	:	Sildenafil Citra	te Tablets 50 mg	Batch No	:	MD274
Description of the pack	:	4's blister pack PVC foil	in 0.25 mm thickness	Mfg. Date	:	Feb 2008
Parameters and tes method monitored		LOD, Dissolution	sintegration test, on Test, Assay, nces, 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
			R	ESULTS OF A	NA	LYSIS
TEST		LIMITS	INITIAL (Feb 2008)	3 Month (Apr 2008)		6 Month (Jul 2008)
Description	dian	nt blue coloured nond shaped film ed tablets.	Light blue coloured diamond shaped film coated tablets.	Light blue coloured diame shaped film con tablets.	one	Light blue coloured
Disintegration test	N.M	I.T. 30 min	7 min	8 min		8 min
LOD	N.M	I.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		le Impurity : Γ 1.0 %	0.012%	0.013%		0.014%
Substances		l Impurity : Γ2.0 %	0.012%	0.014%		0.014%
Assay	90.0	00% to 110.00%	102.42%	101.98%		101.52%
Total aerobic micro	bial	count				
Bacterial Counts	N	MT 1000 cfu	30	30		35
Fungi	N	MT 100 cfu/g	Absent	Absent		Absent
Test for specified m	icroc	organisms:				
E. Coli		Absent	Absent	Absent		Absent
Salmonellae		Absent	Absent	Absent		Absent
Pseudomonas		Absent	Absent	Absent		Absent
Stap. aureus		Absent	Absent	Absent		Absent



3mpaptaslar Approved By Mr. S. Daptardar (QA Manager)









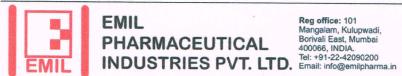


REAL TIME STABILITY STUDY REPORT

Description of the pack	Parameters and	Date of Initiation			Test				Description	A STATE OF THE STA		D. T.	LOD	Dissolution						Related	Substances	Assay	Total aerobic microbial count	Bacteria	Fungi	Test for specified microorganisms:	E. Coli	Salmonellae	Pseudomonas	Stap. aureus
e pack	Parameters and Test methods monitored				Limit		Light blue	coloured diamond	shaped film coated	tablets	and	N.M.T. 30 min	N.M.T. 3% w/w	N.L.T.70 % w/w						Single Impurity NMT 1.0 %	Total Impurity NMT 2.0 %	90.00% to110.00%	robial count	NMT 1000 cfu/g	NMT 100 cfu/g	microorganisms:	Absent	Absent	Absent	Absent
			-		INITIAL	(Feb 2008)	Light blue	coloured	diamond shaped	film coated	tablets.	7 min	1.40%	1] 96.70%	2] 98.43%	3] 97.57%	4] 99.88%	5] 97.86%	6] 98.72%	0.012%	0.012%	102.42%		30	Absent		Absent	Absent	Absent	Absent
4's blister p	Description Substances	25/02/2008						0	aped	-												0,								
4's blister pack in 0.25 mm thic	Description, Disintegration t Substances, Microbial count				3 Month	(Apr 2008)	Light blue	coloured	diamond	shaped film	coated tablets.	7 min	1.42%	1] 96.22%	2]97.58%	3] 97.12%	4] 98.99%	5] 99.31%	6] 98.45%	0.013%	0.014%	102.23%		30	Absent		Absent	Absent	Absent	Absent
4's blister pack in 0.25 mm thickness PVC foil	Description, Disintegration test, LOD, Dissolution Test, Assay, Related Substances, Microbial count				6 Month	(Jul 2008)	Light blue	coloured	diamond shaped	film coated	tablets.	7 min	1.46%	1] 98.60%	2] 99.12%	3] 97.30%	4] 96.20%	5] 96.94%	6] 97.85%	0.015%	0.015%	102.01%		35	Absent		Absent	Absent	Absent	Absent
oil	lution Test, Assay, l			RE	9 Month	(Oct 2008)	Light blue	coloured	diamond	shaped film	coated tablets.	9 min	1.56%	1] 96.48%	2] 97.31%	3] 98.91%	4] 98.25%	5] 97.84%	6] 97.69%	0.020%	0.022%	101.78%		35	Absent		Absent	Absent	Absent	Absent
Mis		Sto		RESULTS OF ANALYSIS	12 Month	(Jan 2009)	Light blue	coloured	diamond shaped	film coated	tablets.	10 min	1.58%	1] 97.32%	2] 97.10%	3] 96.02%	4] 96.30%	5] 95.94%	6] 96.48%	0.024%	0.025%	101.59%		35	Absent		Absent	Absent	Absent	Absent
Mfg. Date	Expiry Date	Storage conditions	Date of completion	YSIS	18 months	(Jul 2009)	Light blue	coloured	diamond shaped	film coated	tablets.	10 min	1.62%	1] 96.33%	2] 95.84%	3] 94.28%	4] 97.66%	5] 96.33%	6] 96.02%	0.025%	0.026%	101.31%		40	Absent		Absent	Absent	Absent	Absent
					24 Month	(Jan	Light blue	coloured	diamond shaped	film coated	tablets.	11 min	1.69%	1] 93.65%	2] 96.15%	3] 95.60%	4] 95.06%	5]96.03%	6] 97.02%	0.030%	0.030%	101.00%		40	Absent		Absent	Absent	Absent	Absent
Feb 2008	Jan 2011	30°C ± 2	Apr 2011		onth	Jan 2010)	blue	ured	shaped	pated	ets.	nin	%	65%	15%	60%	06%)3%	02%	0%	0%	0%			ent		nt	nt	nt	5
~		30°C ± 2°C and 65%± 5% RH			36 Month	(Jan 2011)	Light blue	coloured	diamond	shaped film	coated tablets.	11 min	1.70%	1]96.21%	2] 95.03%	3] 96.11%	4] 96.85%	5]96.01%	6] 95.84%	0.035%	0.035%	100.84%		45	Absent		Absent	Absent	Absent	Absent
		6 RH			39 Month	(Apr 2011)	Light blue	coloured	diamond	shaped film	coated tablets.	12 min	1.71%	1]94.62%	2] 95.02%	3] 96.88%	4] 95.02%	5] 93.02%	6] 93.32%	0.035%	0.035%	100.68%		50	Absent		Absent	Absent	Absent	Absent

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Approved By
Mr. S. Daptardar
(QA Manager)





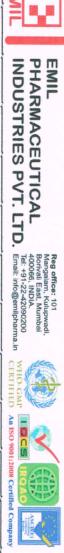






	Τ.					
Name of Product	:		e Tablets 50 mg	Batch No	:	A8006
Description of the pack	:	4's blister pack PVC foil	in 0.25 mm thickness	Mfg. Date	:	Feb 2008
Parameters and test method monitored	t :	Description, Dis LOD, Dissolution Related Substan		Expiry Date	:	Jan 2011
Date of Initiation		20/02/2008		Storage conditions	:	40° ± 2°C and 75% ± 5% RH
			1	Date of completion	:	Jul 2008
			R	ESULTS OF A	NA	LYSIS
TEST		LIMITS	INITIAL (Feb 2008)	3 Month (Apr 2008)		6 Month (Jul 2008)
Description	diam	t blue coloured ond shaped film ed tablets.	Light blue coloured diamond shaped film coated tablets.	Light blue colo	oure	Light blue coloured diamond shaped film
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.	Г. 70% w/w	1] 97.56% 2] 99.59% 3] 99.57% 4] 97.98% 5] 98.72% 6] 95.26%	2] 96.61% 3] 99.26%		1] 96.45% 2] 95.02% 3] 97.66% 4] 98.88% 5] 96.27% 6] 97.18%
Related	NMT	e Impurity :	0.009%	0.010%		0.012%
		Impurity:	0.010%	0.012%		0.013%
Assay	90.0	0% to 110.00%	101.90%	101.21%		100.87%
Total aerobic microl	bial c	ount		Conditions 5% R Date of completion Jul 20		
Bacterial Counts	N	MT 1000 cfu	20	25		35
Fungi		MT 100 cfu/g	Absent			Absent
Test for specified mi	croo	rganisms:	16.			1102011
E. Coli		Absent	Absent	Absent		Absent
Salmonellae		Absent	Absent			Absent
Pseudomonas		Absent	Absent			Absent
Stap. aureus		Absent	Absent	Absent		Absent

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REAL TIME STABILITY STUDY REPORT

East methods monitored I. 4 Subiser pack in 20 mm biochases PVC foll Expire pack in 20 mm biochases PVC foll Expiry Date I. Absont I. Account follows I. Acco	Name of Product	4	\neg	nafil Citrato Tahlete	בח שימ		Rat	-L NI.	-		
Intitiation	Description of th	ie pack	-	ister pack in 0.25 m	m thickness PVC for	oil	Mfg	Date	+	08	
Test Limit Limit Limit Light blue	Parameters and	Test methods monitor		ription, Disintegration ances, Microbial co	on test, LOD, Disso unt	lution Test, Assay, l	ď	iry Date	-	11	
Test Limit Light blue L	Date of Initiation	n	_	/2008			Stor	age conditions	+	+ 2°C and 65%+ 5%	% RH
Test Limit INITIAL 3 Month 6 Month 9 Month 12 Month						RE	SULTS OF ANAL	YSIS	-		
Light blue Lig	Test	Limit	TVILINI	3 Month	6 Month	9 Month	12 Month	1	24 Month	36 Month	39 Month
			(Feb 2008)	(Apr 2008)	(Jul 2008)	(Oct 2008)	(Jan 2009)	(Jul 2009)	(Jan 2010)	(Jan 2011)	(Apr 20
Pytion Salaged film coated Salaged film coated Salaged film Salaged fil		Light blue	Light blue	Light blue	Light blue	Light blue	Light blue	Light blue	Light blue	Light blue	Light blue
		coloured diamond	diamond shaped	diamond	diamond shaped	diamond	diamond shaped	diamond shaped	diamond shaped	diamond	diamon
N.M.T. 300 mins Smin Smi	Description	shaped film coated	film coated	shaped film	film coated	shaped film	film coated	film coated	film coated	shaped film	shaped fi
N.M.T. 30 mins		ranzers.	tablets.	coated tablets.	tablets.	coated tablets.	tablets.	tablets.	tablets.	coated tablets.	coated tabl
N.M.T. 39% w/w 1.23% 1.31% 1.36% 1.39% 1.45% 1.48% 1.52% 1.195.02% 1.195.129	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
Inition N.I.T.70 % w/w 2197.59% 2195.23% 2195.23% 2195.23% 2195.23% 2195.23% 2195.48% 2195.49% 2195.29% 2195	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%
			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] 93.469
			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] 92.819
Algority	Dissolution	NI.T 70 % w/w	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%
Single Impurity Sign.72% Si		2 11 12 12 12 12 12 12 12 12 12 12 12 12	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%
Single Impurity Di 95-10% Di 97-45%			5] 98.72%	5] 97.62%	5] 96.24%	5] 96.02%		5] 95.02%	5]95.08%	5] 93.25%	5] 93.48%
ed NMT 1.0 % NMT 1.0 % 0.009% 0.011% 0.012% 0.015% 0.016% 0.018% 0.020% aarcesic Total Impurity NMT 2.0 % 0.010% 0.009% 0.011% 0.012% 0.015% 0.016% 0.018% 0.020% aerobic microbial count 50.00% to110.00% 101.52% 101.15% 100.98% 100.67% 100.32% 99.97% 99.80% ria NMT 1000 cfu/g Absent Abse			0] 22.20/0	0/ 07.70%	0/2/.43/0	07.77.70		0] 34.00%	0%aT*C6.fa	0%T0.CE [0	TO.SE
ances Total Impurity 0.010% 0.009% 0.011% 0.012% 0.015% 0.016% 0.018% 0.020%	Related	Single Impurity NMT 1.0 %	0.009%	0.009%	0.011%	0.012%	0.015%	0.016%	0.018%	0.020%	0.025%
aerobic microbial count aerobic microbial count 101.52% 101.15% 100.98% 100.98% 100.67% 100.32% 99.97% 99.80% ria NMT 1000 cfu/g 20 20 25 30 35 40 40 45 Absent or specified microorganisms: NABSENT Absent Abs	Substances	Total Impurity NMT 2.0 %	0.010%	0.009%	0.011%	0.012%	0.015%	0.016%	0.018%	0.020%	0.025%
ria NMT 1000 cfu/g 20 20 25 30 35 40 40 40 45 Absent or specified microorganisms: I Absent A	Assay	90.00% to 110.00%	101.90%	101.52%	101.15%	100.98%	100.67%	100.32%	99.97%	99.80%	99.62%
ria NMT 1000 cfu/g 20 20 25 30 35 40 40 40 45 Absent NMT 100 cfu/g Absent Absen	Total aerobic mi	crobial count									
or specified microorganisms: Absent Absent Absent Absent Absent Absent Absent Absent ii Absent Absent Absent Absent Absent Absent Absent Absent inellae Absent Absent Absent Absent Absent Absent Absent Absent omonas Absent Absent Absent Absent Absent Absent Absent Absent aureus Absent Absent Absent Absent Absent Absent Absent Absent	Bacteria	NMT 1000 cfu/g	20	20	25	30	35	40	40	45	50
i Absent	Fungi	NMT 100 cfu/g	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent
Absent Ab	Test for specified	l microorganisms:									
Absent Ab	E. Coli	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent
Absent Ab	Salmonellae	Absent	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

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ACCELERATED STABILITY STUDY REPORT

Name of Product		:	Sildenafil Citrate	e Tablets 50 mg	Batch No	:	MD286
Description of the pack		:	4's blister pack i PVC foil	in 0.25 mm thickness	Mfg. Date	:	Mar 2008
Parameters and tes method monitored	st	:	Description, Dis LOD, Dissolutio Related Substan		Expiry Date	:	Feb 2011
Date of Initiation		:	12/03/2008		Storage conditions	:	40° ± 2°C and 75% ± 5% RH
					Date of completion	:	Aug 2008
TOTAL CO. MILITARY				R	ESULTS OF A	NA	LYSIS
TEST			LIMITS	INITIAL (Mar 2008)	3 Month (May2008)		6 Month (Aug 2008)
Description	dia	am	t blue coloured ond shaped film ed tablets.	Light blue coloured diamond shaped film coated tablets.			Light blue coloured
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.	Γ. 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%		1] 96.48% 2] 95.88% 3] 93.48% 4] 97.84% 5] 98.21% 6] 97.12%
Related			e Impurity :	0.009%	0.009%		0.012%
Substances			Impurity : 2.0 %	0.009%	0.010%		0.015%
Assay	90	0.0	0% to 110.00%	100.51%	100.20%		99.64%
Total aerobic micro	bia	ıl c	ount				
Bacterial Counts		N	MT 1000 cfu	20	20	alloured diamond diaped film coated tablets. 8 min 1.32% 1] 98.45% 2] 97.02% 3] 98.32% 4] 96.07% 5] 96.48% 6] 95.87% 0.009% 100.20% 20 Absent Absent	30
Fungi		NI	MT 100 cfu/g	Absent			Absent
Test for specified m	icr	00	rganisms:				
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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Stap. aureus	Pseudomonas	Salmonellae	E. Coli	Test for specified microorganisms:	Fungi	Bacteria	Total aerobic microbial count	Assay 9	Substances T	Related N			Dissolution			LOD	-	D.T.			Description	I			Test		TO ME OF THE PROPERTY.	Date of Initiation	Parameters and Tes	Description of the pack	Name of Product
Absent	Absent	Absent	Absent	croorganisms:	NMT 100 cfu/g	NMT 1000 cfu/g	bial count	90.00% to110.00%	Total Impurity NMT 2.0 %	Single Impurity NMT 1.0 %			N.L.1./0 % W/W	77 77 77 77 77		N.M.1. 3% W/W	TAT 20/	N.M.T. 30 mins		coated tablets.	diamond shaped film	Light blue coloured			Limit				Parameters and Test methods monitored	ack	
Absent	Absent	Absent	Absent		Absent	20		100.51%	0.009%	0.009%	6] 99.10%	5] 97.18%	4] 98.02%	3] 98.47%	21 99.48%	1.24%	1 740/	7 mins	tablets.	coated min	shaned film	diamond	Light blue	(Jan 2009)	INITIAL		\vdash	12/03/2008	: Descri	: 4's bli	: Silden
Absent	Absent	Absent	Absent		Absent	20		100.22%	0.009%	0.009%	6] 97.84%	5] 97.15%	4] 98.82%	3] 97.62%	21 99.02%	11.27%	4 270	8 mins	coated tablets.	shaped film	diamond	coloured	Light blue	(Mar.2009)	3 Month		1000	2008	Description, Disintegration t Substances, Microbial count	ster pack in 0.25 m	Sildenafil Citrate Tablets 50 mg
Absent	Absent	Absent	Absent		Absent	25		99.98%	0.011%	0.010%	6] 97.66%	5] 98.02%	4] 97.94%	3] 98.37%	2] 97.02%	11.30%	4 2007	8 mins	tablets.	film coated	diamond shaped	coloured	Light blue	(Jun2009)	6 Month				on test, LOD, Disso	4's blister pack in 0.25 mm thickness PVC foil	50 mg
Absent	Absent	Absent	Absent		Absent	30		99.82%	0.012%	0.011%	6] 97.20%	5] 97.62%	4] 97.45%	3] 98.21%	2] 98.55%	1.32%	2 220	9 mins	coated tablets.	shaped film	diamond	coloured	Light blue	(Sep.2009)	9 Month	7			Description, Disintegration test, LOD, Dissolution Test, Assay, Related Substances, Microbial count	oil	
Absent	Absent	Absent	Absent		Absent	30		99.61%	0.015%	0.012%	6] 96.90%	5] 97.48%	4] 97.82%	3] 98.32%	2198.05%	1.38%	4 200/	9 mins	tablets.	film coated	diamond shaped	coloured	Light blue	(Dec.2009)	12 Month	RESULTS OF ANALYSIS	Dat	Sto		Mí	Bat
Absent	Absent	Absent	Absent		Absent	35		99.12%	0.015%	0.013%	6] 97.51%	5] 96.88%	4] 97.02%	3] 98.15%	2] 97.50%	1.45%	TO MINIS	10 mins	tablets.	film coated	diamond shaped	coloured	Light blue	(Jun. 2010)	18 months	ALYSIS	Date of completion	Storage conditions	Expiry Date	Mfg. Date	Batch No.
Absent	Absent	Absent	Absent		Absent	40		98.88%	0.017%	0.015%	6] 97.16%	5]96.15%	4] 96.22%	3] 96.66%	21 97.02%	1.50%	TO THIE	10 mins	tablets.	film coated	diamond shaped	coloured	Light blue	(Dec.2010)	24 Month		: May 2012	: 30°C	: Feb 2011	: Mar 2008	: MD286
Absent	Absent	Absent	Absent		Absent	40		98.42%	0.025%	0.021%	6] 95.02%	5] 96.22%	4] 95.40%	3] 96.15%	2195.93%	1.56%	TT IIII	11 mins	coated tablets.	shaped film	diamond	coloured	Light blue	(Dec.2011)	36 Month		2012	30°C ± 2°C and 65%± 5% RH	011	800	36
Absent	Absent	Absent	Absent		Absent	45		98.21%	0.031	0.025%	6] 96.03%	5] 95.40%	4] 93.02%	3] 96.30%	2] 95.25%	1.61%	1 C10/	12 mins	tablets.	film coated	diamond shaped	coloured	Light blue	(Mar.2012)	39 Month	,		% RH			

* EMIL Approved By

(QA Manager)

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