6. FINISHED PRODUCT

6.4 Stability

6.4.1 Stability Summary and Conclusion

The following batches of APO-PREGABALIN Capsules 75 mg and 150 mg manufactured at Apotex Research Private Limited, packaged in blisters are placed on stability study.

Summary of Stability Studies Submitted is provided in the table below

Batch Number	Strength	Pack Type	Pack Size	Storage Conditions (°C / % RH)	Completed Test Intervals
PGCF/10240		Blister	10's	25°C/60%RH	24 months
PGCF/10240		Blister	10's	40°C/75%RH	6 months
PGCF/10255	75 ma	Blister	10's	25°C/60%RH	24 months
PGCF/10255	75 mg	Blister	10's	40°C/75%RH	6 months
PGCF/10267*		Blister	10's	25°C/60%RH	24 months
PGCF/10267*		Blister	10's	40°C/75%RH	6 months
PGCD/10238		Blister	10's	25°C/60%RH	24 months
PGCD/10238		Blister	10'S	40°C/75%RH	6 months
PGCD/10253	150 mg	Blister	10's	25°C/60%RH	24 months
PGCD/10253	150 mg	Blister	10'S	40°C/75%RH	6 months
PGCD/10265*		Blister	10's	25°C/60%RH	24 months
PGCD/10265*		Blister	10'S	40°C/75%RH	6 months

Note:

^{*}Batches mentioned above were manufactured and charged for stability study for other market however the formulation and manufacturing process are identical to the proposed formulation and manufacturing process proposed in this application.



STABILITY SUMMARY REPORT



		CONTRO	LLED ROOM TEM	PERATURE CONDI	TIONS STABILITY	SUMMARY REPOR	T			
				Drug Substance Manufacturer: Srini pharmaceuticals Ltd.,			2:		Batch No.: PGCF/10240	
Product Description: Hard gelatin capsules with opaque orange cap and opaque white body. Imprinted APO P75 in black ink. Filled with white powder. Packaging Description: Blister: Forming foil: PVC CLEAR FILM 250 MIC Lidding Foil: Highly heat resistant lacquer on the basis of polyester pure aluminum, hard tempered(0.025 mm) . Carton: Super chrome white duplex board without varnish			Manufacturing Site SRINI PHARMAC Plot No. 10, Road. N	EUTICALS LTD		Batch Size: 1,40,000 Capsules			Pack Size: Blister 10's (Alu-PVC)	
			Jubilee Hills, Hyderabad-500033,			Packaging Date: 15-DEC-10			Stability Start Date: 15-DEC-10	
TIMEPOINT	Initial**	3 months	6 months	9 months	12 months	18 months	24 months	36 months	IDENTIFICATION	
Date due	N/A	15-MAR-11	15-JUN-11	15-SEP-11	15-DEC-11	15-JUN-12	15-DEC-12		Compound Name :	
Date started	15-DEC-10	15-MAR-11	15-JUN-11	15-SEP-11	15-DEC-11	15-JUN-12	15-DEC-12		PRB-II: 3-Isobutyl glutaric acid (Synthetic impurity/	
Date finished	31-DEC-10	26-MAR-11	16-JUL-11	13-OCT-11	27-JAN-12 ^	13-JUL-12	15-JAN-13		Degradation product)	
Specifications used *	PRB-FP-CAP-75MG- GLOBAL-RD, Version 1	PRB-TP-ST-CAP- GLOBAL-RD Version 1	PRB-TP-ST-CAP- GLOBAL-RD Version 1	PRB-TP-ST-CAP- DOM-RD Version 2	PRB-TP-ST-CAP- DOM-RD Version 2	PRB-TP-ST-CAP- DOM-RD Version 2	PRB-TP-ST-CAP- DOM-RD Version 3		PRB-III: 4-Isobutyl -pyrrolidin-2-one (Degradation product) PRB-V: 1-((2S,3R,4R,5R,6R)-4,5-dihydroxy-6-(hydroxymethyl)-	
Appearance	Complies	Complies	Confirms	Complies	Complies	Complies	Complies		2-((2R,3S,4R,5R,6S)-4,5,6-trihydroxy-2- (hydroxymethyl)tetrahydro-2H-pyran-3-yloxy)tetrahydro-2H-	
Identification (HPLC)	Complies	Complies	Confirms	Complies	Complies	Complies	Complies		pyran-3-yl)-4-isobutylpyrrolidin-2-one.	
Assay:90.0 - 110.0% (% of claim)	99.5%	101.1%	100.1%	101.2%	102.3%	100.8%	101.7%		-	
Dissolution: As per USP/EP Q=80% Time = 15 min	99%	99%	101%	91%	100%	102%	99%			
Dissolution range	97%-102%	96%-104%	98%-106%	87% - 94%	97% - 102%	98% - 107%	89% - 105%			
Dissolution-S1/S2/S3	SI	S1	S1	S1	S1	SI	SI			
Degradation products									7	
i.PRB-II:NMT 0.2%	ND	ND	ND	ND	ND	ND	BRT			
ii. PRB-III:NMT 0.2%	ND	BRT	BRT	BRT	BRT	BRT	BRT		1	
iii. PRB-V:NMT 0.2%	-	•	-	•	-	-	BRT		1	
iv. Unidentified Impurity : NMT 0.2% each	BRT(0.06%)	BRT(0.060%)	BRT(0.095%)	0.1%	BRT (0.088%)	0.1%	ND		1	
v. Total Impurities : NMT 1.0%	BRT	BRT	BRT	0.1%	BRT	0.1%	BRT			
Comments: * Specification as per the current test profile PRB-TP-ST-C ^ 12th month analysis performed as per deviation report No	CAP-DOM-RD, Version 4, effec	spiry Date: OCT-2012 tive on 25-Jan-2013		<u> </u>	 	<u> </u>	<u> </u>			
N/A=Not applicable; ND=Not detected; NMT=Not more than; NLT=Not	less than; BRT = Below Reporting Thr	eshold.								
** As per Specification and COA. Reviewed by:	ln				14				In.	
Transfer by.	Date: 22-FCB 13				Approved by:	An			Date: 2.2-feb-13	



			In a			114 6			Batch No.:			
Product Name: Pregabalin capsules 75 mg Product Description: Hard gelatin capsules with opaque orange cap and opaque white body. Imprinted APO P75 in black ink. Filled with white powder. Packaging Description: Blister: Forming foil: PVC CLEAR FILM 250 MIC Lidding Foil: Highly heat resistant lacquer on the basis of polyester pure aluminum, hard tempered(0.025 mm) Carton: Super chrome white duplex board without varnish			Drug Substance Manufacturer: Srini pharmaceuticals Ltd.,			Manufacturing Dat NOV-2010	te:		PGCF/10240			
			Manufacturing Site. SRINI PHARMACL Plot No.10, Road. N	EUTICALS LTD		Batch Size: 1,40,000 Capsules			Pack Size: Blister 10's (Alu-PVC)			
			Jubilee Hills, Hyderabad-500033, AP, India. ACTIVE RM BATCH NO.:JN9054, JN9055			Packaging Date: 15-DEC-10			Stability Start Date: 15-DEC-10			
TIMEPOINT	Initial**	1 month	2 months	3 months	6 months	9 months	12 months	18 months	24 months	36 months	IDENTIFICATION	
Date due	N/A	17-JAN-11	15-FEB-11	15-MAR-11	15-JUN-11	N/A	N/A	N/A	N/A	N/A	Compound Name :	
Date started	15-DEC-10	17-JAN-11	15-FEB-11	15-MAR-11	15-JUN-11	N/A	N/A	N/A	N/A	N/A	PRB-II: 3-Isobutyl glutaric acid (Syntheti	
Date finished	31-DEC-10	10-FEB-11	16-MAR-11	26-MAR-11	16-JUL-11	N/A	N/A	N/A	N/A	N/A	impurity/ Degradation product)	
Specifications used *	PRB-FP-CAP-75MG- GLOBAL-RD, Version 1	PRB-TP-ST-CAP- GLOBAL-RD Version 1	PRB-TP-ST-CAP- GLOBAL-RD Version I	PRB-TP-ST-CAP- GLOBAL-RD Version 1	PRB-TP-ST-CAP- GLOBAL-RD Version I	N/A	N/A	N/A	N/A	N/A	PRB-III: 4-Isobutyl -	
Appearance	Complies	Complies	Complies	Complies	Complies	N/A	N/A	N/A	N/A	N/A	(Degradation product)	
Identification (HPLC)	Complies	Complies	Complies	Complies	Complies	N/A	N/A	N/A	N/A	N/A		
Assay:90.0 - 110.0% (% of claim)	99.5%	99.6%	100.2%	99.7%	99.7%	N/A	N/A	N/A	N/A	N/A		
Dissolution : Q=80% Time = 15 min	99%	99%	97%	97%	99%	N/A	N/A	N/A	N/A	N/A		
Dissolution range	97%-102%	96%-102%	94%-100%	94%-100%	95%-103%	N/A	N/A	N/A	N/A	N/A		
Dissolution-S1/S2/S3	SI	S1	S1	S1	SI	N/A	N/A	N/A	N/A	N/A		
Degradation products		1.07				N/A	N/A	N/A	N/A	N/A		
i.PRB-II:NMT 0.2%	ND	ND	ND	ND	ND	N/A	N/A	N/A	N/A	N/A		
ii. PRB-III:NMT 0.2%	ND	BRT	BRT	BRT	BRT	N/A	N/A	N/A	N/A	N/A		
iii. Unidentified Impurity : NMT 0.2% each	BRT(0.06%)	0.1%	0.2%	0.2%	0.3%##	N/A	N/A	N/A	N/A	N/A		
iv. Total Impurities: NMT 1.0%	BRT	0.1%	0.2%	0.2%	0.3%	N/A	N/A	N/A	N/A	N/A		
Comments: * Specification as per the current test profile PRB-TP-, ## Degradation products results reported as per OOS11	ST-CAP-DOM-RD, Version 1, effe 1-25		2					· ·		<u> </u>		
N/A=Not applicable; ND=Not detected; NMT=Not more than; NLT ** As per Specification and COA.	=Not less than; BRT = Below Reporting Ti	nreshold.										
Reviewed by:	Date:				Approved by:				Date:		***************************************	
D. rependes und	29-	Ang -11				A =	seade	7	28	- AUCI	OF REV	

STABILITY SUMMARY REPORT



		CONTRO	OLLED ROOM TEM	PERATURE CONDI	ITIONS STABILITY	'SUMMARY REPO	RT				
Product Name: Pregabalin capsules 75 mg	Drug Substance Ma Srini pharmaceutic			Manufacturing Date DEC-2010	e:		Batch No.: PGCF/10255				
Product Description: Hard gelatin capsules with opaque orange cap and opaque whil with white powder.	Manufacturing Site SRINI PHARMAC Plot No.10, Road. N	EUTICALS LTD		Batch Size: 1,40,000 Capsules			Pack Size: Blister 10's (Alu-PVC)				
Packaging Description: Blister: Forming foil: PVC CLEAR FILM 250 MIC			Jubilee Hills, Hyder AP, India.	rabad-500033,	0.474	Packaging Date: 21-JAN-11			Stability Start Date: 03-FEB-11		
Lidding Foil: Highly heat resistant lacquer on the basis hard tempered(0.025 mm) Carton: Super chrome white duplex board without varn		<i>t</i> ,	ACTIVE RM BATCH NO.:JR9473, JR9474								
TIMEPOINT	Initial**	3 months	6 months	9 months	12 months	18 months	24 months	36 months	IDENTIFICATION		
Date due	N/A	03-MAY-11	03-AUG-11	03-NOV-11	03-FEB-12	03-AUG-12	04-FEB-13		Compound Name :		
Date started	22-JAN-11	03-MAY-11	03-AUG-11	03-NOV-11	03-FEB-12	03-AUG-12	04-FEB-13		PRB-II: 3-Isobutyl glutaric acid (Synthetic impurity/		
Date finished	31-JAN-11	03-JUN-11	23-AUG-11	06-DEC-11	08-MAR-12	30-AUG-12	06-MAR-13		Degradation product)		
Specifications used *	PRB-FP-CAP-75MG- GLOBAL-RD,	PRB-TP-ST-CAP- GLOBAL-RD	PRB-TP-ST-CAP- GLOBAL-RD	PRB-TP-ST-CAP- DOM-RD,	DOM-RD,	PRB-TP-ST-CAP- DOM-RD,	PRB-TP-ST-CAP- DOM-RD,		PRB-III: 4-Isobutyl -pyrrolidin-2-one (Degradation product)		
	Version 1	Version.1	Version.1	Version.2	Version.2	Version.3	Version.4	· · · · · · · · · · · · · · · · · · ·	PRB-V:1-((2S,3R,4R,5R,6R)-4,5-dihydroxy-6-(hydromethyl)-2- ((2R,3S,4R,5R,6S)-4,5,6-trihydroxy-2-		
Appearance	Complies	Complies	Complies	Complies	Complies	Complies	Complies		(hydroxymethyl)tetrahydro-2H-pyran-3-yloxy)tetrahydro-2H-		
Identification (HPLC)	Complies	Complies	Complies	Complies	Complies	Complies	Complies		pyran-3-yl)-4-isobutylpyrrolidin-2-one.		
Assay: 90.0 - 110.0% (% of claim)	99.7%	99.6%	99.7%	98.1%	99.5%	102.1%	101.3%				
Dissolution: As per USP/EP Q=80% Time = 15 min	101%	101%	101%	98%	98%	99%	100%				
Dissolution range	100% - 102%	97% - 106%	100% - 104%	96% - 100%	96% - 101%	97% - 100%	99% - 102%		1		
Dissolution-S1/S2/S3	SI	S1	S1	S1	S1	S1	S1		1		
Degradation products									7		
i. PRB-V:NMT 0.2%	-	-	-	-	-	0.1%	BRT		7		
ii.PRB-II:NMT 0.2%	ND	ND	ND	ND	ND	ND	BRT		7		
iii. PRB-III:NMT 0.2%	ND	BRT	BRT	BRT	BRT	BRT	BRT		1		
iv. Unidentified Impurity : NMT 0.2% each	BRT	BRT(0.064%)	BRT (0.087%)	0.1%	BRT (0.070%)	ND	ND		-		
v. Total Impurities: NMT 1.0%	BRT	BRT	BRT	0.1%	BRT	0.1%	BRT		1		
Comments: * Specification as per the current test profile PRB-TP-ST-CAP		Expiry Date: NOV-2012 tive on 25-Jan-2013									
N/A=Not applicable; ND=Not detected; NMT=Not more than; NLT=Not less	than; BRT = Below Reporting Thr	eshold.									
** As per Specification and COA.	- In .		-		T						
Reviewed by:	Date: 12-MAR 13				Approved by:			Date:			



			ACCELERATED	CONDITIONS STAI	BILITY SUMMARY	REPORT						
Product Name: Pregabalin capsules 75 mg				nufacturer: als Ltd.,		Manufacturing Date: DEC-2010			Batch No.: PGCF/10255			
Product Description: Hard gelatin capsules with opaque orange cap and opaque white body. Imprinted APO P75 in black ink. Filled with white powder. Packaging Description: Blister: Forming foil: PVC CLEAR FILM 250 MIC Lidding Foil: Highly heat resistant lacquer on the basis of polyester pure aluminum, hard tempered(0.025 mm) Carton: Super chrome white duplex board without varnish			Manufacturing Site SRINI PHARMACI Plot No. 10, Road. N	EUTICALS LTD		Batch Size: 1,40,000 Capsules			Pack Size: Blister 10's (Alu-PVC)			
			rioi: No.10, Kosa. No.5, Jim nagar Jubilee Hills, Hyderabad-500033, AP, India. ACTIVE RM BATCH NO.:JR9473, JR9474			Packaging Date: 21-JAN-11			Stability Start Date: 03-FEB-11			
TIMEPOINT	Initial**	1 month	2 months	3 months	6 months	9 months	12 months	18 months	24 months	36 months	IDENTIFICATION	
Date due	N/A	03-MAR-11	05-APR-11	03-MAY-11	03-AUG-11	N/A	N/A	N/A	N/A	N/A	Compound Name	
Da.2 started	22-JAN-11	03-MAR-11	05-APR-11	03-MAY-11	03-AUG-11	N/A	N/A	N/A	N/A	N/A	PRB-II. 3-Isobutyl glutaric acid (Synthetic	
Date finished	31-JAN-11	01-APR-11	03-MAY-11	03-JUN-11	23-AUG-11	N/A	N/A	N/A	N/A	N/A	impurity/ Degradation product)	
Specifications used *	PRB-FP-CAP-75MG- GLOBAL-RD, Version I	PRB-TP-ST-CAP- GLOBAL-RD Version. I	PRB-TP-ST-CAP- GLOBAL-RD Version. 1	PRB-TP-ST-CAP- GLOBAL-RD Version.1	PRB-TP-ST-CAP- GLOBAL-RD Version I	N/A	N/A	N/A	N/A	N/A	PRB-III. 4-Isobutyl - pyrrolidin-2-one	
Арреагансе	Complies	Complies	Complies	Complies	Complies	N/A	N/A	N/A	N/A	N/A	(Degradation product)	
Identification (HPLC)	Complies	Complies	Complies	Complies	Complies	N/A	N/A	N/A	N/A	N/A		
Assay:90.0 - 110.0% (% of claim)	99.7%	100.2%	100.7%	100.4%	98.6%	N/A	N/A	N/A	N/A	N/A		
Dissolution : Q=80% Time = 15 min	101%	97%	98%	96%	99%	N/A	N/A	N/A	N/A	N/A		
Dissolution range	100% - 102%	95% - 100%	94% - 104%	85% - 99%	95% - 100%	N/A	N/A	N/A	N/A	N/A		
Dissolution-S1/S2/S3	\$1	SI	SI	SI	SI	N/A	N/A	N/A	N/A	N/A		
Degradation products						N/A	N/A	N/A	N/A	N/A	EVIEW	
i.PRB-II:NMT 0.2%	ND	ND	ND	BRT	BRT	N/A	N/A	N/A	N/A	N/A		
ii. PRB-III:NMT 0.2%	ND	BRT	BRT	BRT	BRT	N/A	N/A	N/A	N/A	N/A	<u> </u>	
iii. Unidentified Impurity : NMT 0.2% each	BRT	BRT(0.074%)	0.1%	0.2%	0.2%	N/A	N/A	N/A	N/A	N/A	APOI	
iv. Total Impurities : NMT 1.0%	BRT	BRT	0.1%	0.2%	0.2%	N/A	N/A	N/A	N/A	NA	ADVATOCING GENE	
Comments: * Specification as per the current test profile PRB-TP-ST-C N/A=Not applicable: ND=Not detected; NMT=Not more than; NLT=Not	CAP-DOM-RD, Version 2, effec		2							**	Sign.	
** As per Specification and COA.	See See Reporting II										ARPL	
Reviewed by: D. upendy my	Date:	1 Ang 1,	i		Approved by:	AS,	leddy	-	Date:	9-AU4.	- / 1	



PRODUCT NAME:	Pregabalin Capsules 75mg	BATCH NO.:		PGCF/10267	PACKAGING DESCR	UPTION:	V 18/18/2-10			
ACTIVE INGREDIENT(S):	Pregabalin	BATCH SIZE:		70,000 Capsules	FORMING FOIL:		PVC CLEAR FILM 250 MIC			
LABEL CLAIM:	75mg P				10 X 10 Capsules	LIDDING FOIL:		Highly heat resistant lacquer on the basis of polyester pure aluminum, hard tempered(0.025mm)		
PACKAGE TYPE:	Blister(Alu-PVC)		MFG. SITE:		ARPL, Bangalore	UNIT DOSAGE CAR	TONS:	Super chrome white duplex board without		
ACTIVE RM SOURCE:	Srini pharmaceuticals Ltd.,		MFG. DATE:		DEC-2010	PACKAGING DATE:		varnish 21-JAN-11		
ACTIVE RM BATCH NOS.:	JR9475, JR9476		STORAGE CONDITION	ONS:	25°C / 60%RH	PACKAGING SITE:		ARPL, Bangalore		
STABILITY PROTOCOL NO.:	ARI/01/PRT/STB/277/A		·			1		711d E, Dangalore		
PRODUCT DESCRIPTION:	Hard gelatin capsules with opaque orange cap and opaq	ue white body. Imprinte	d APO P75 in black ink.	Filled with white powde	er.				****	
STUDY START DATE:	TIME POINTS:	INITIAL	3 MONTHS	6 MONTHS	9 MONTHS	12 MONTHS	18 MONTHS	24 MONTHS	36 MONTHS	
03-FEB-11	DATE PULLED:	N/A	03-MAY-11	03-AUG-11	03-NOV-11	03-FEB-12	03-AUG-12	04-FEB-13	36 MUNTHS	
	TESTING START DATE:	22-JAN-11	03-MAY-11	03-AUG-11	03-NOV-11	03-FEB-12	03-AUG-12	04-FEB-13		
	TESTING END DATE:	31-JAN-11	03-JUN-11	23-AUG-11	06-DEC-11	08-MAR-12	31-AUG-12	06-MAR-13		
TEST	ACCEPTANCE CRITERIA							1 00 MM 15		
Specifications used *		PRB-FP-CAP-75MG- GLOBAL-RD, Version 1	PRB-TP-ST-CAP- GLOBAL-RD Version, 1	PRB-TP-ST-CAP- GLOBAL-RD	PRB-TP-ST-CAP-AUS	AUS-RD,	PRB-TP-ST-CAP- AUS-RD,	PRB-TP-ST-CAP- AUS-RD,		
Appearance	Refer to product description	Confirms	Confirms	Version.1 Confirms	Version 3 Confirms	Version 3 Confirms	Version 4	Version 4		
Identification	HPLC Retention Time: Corresponds to standard	Confirms	Confirms	Confirms	Confirms	Confirms	Confirms Confirms	Confirms		
Assav	92.5 - 107.5% (% of claim)	101.8%	100.6%	100.5%				Confirms		
Dissolution	As per USP/EP	104%, 104%	100.6%	99%, 100%	101.6% 96%, 97%	98.6%	99.5%	100.0%		
	Q=80%, Time = 15 min	101%, 100%	107%, 100%	99%, 100%	1 '	97%, 96%	99%, 99%	101%, 102%		
	2 5575, 1 Mile 15 Mili	102%, 101%	100%, 99%	99%, 100%	100%, 95% 98%, 95%	95%, 98%	100%, 102%	97%, 99%		
	Mean (% dissolved)	102%	101%	100%	97%	96%, 101% 97%	99%, 99%	101%, 99%		
	Dissolution range (min-max)	100% - 104%	99% - 107%	99% - 100%	95% - 100%	95% - 101%	100% 99% - 102%	100%		
	Dissolution stage	SI	S1	S1	SI	S1	99% - 102% S1	97% - 102% S1		
Degradation Products	PRB-II: NMT 0.2%	ND	ND	ND ND	ND ND	ND	ND	BRT	***************************************	
	PRB-III: NMT 0.2%	ND	BRT	BRT	BRT	BRT	BRT	BRT		
	Unidentified Impurity :NMT 0.2% each	BRT	BRT(0.062%)	BRT (0.096%)	0.1%	BRT (0.068%)	0.1%	BRT		
	Total Impurities : NMT 1.0%	BRT	BRT	BRT	0.1%	BRT	0.1%	BRT		
Microbial Limits	a) Total Aerobic Microbial Count : NMT 1000 cfu/g	20 cfu/g	N/A	20 cfu/g	N/A	20 cfu/g	N/A	20 cfu/g	***	
	b) Total Yeast and Mould Count : NMT 100 cfu/g	Less than 10 cfu/g	N/A	Less than 10 cfu/g	N/A	Less than 10 cfu/g	N/A	Less than 10 cfu/g		
	c) E.coli : Absent in 1 g	Absent/g	N/A	Absent/g	N/A	Absent/g	N/A	Absent/g		
Water Content	NMT 5.0% (200 mg of sample)	-	-	-	-		1.55%	1.78%		
* As per Specification and COA Specification as per the current test profi	ile PRB-TP-ST-CAP-AUS-RD , Version. 4, effective on 14-Jun-2012			L				1.7070		
ND = Not Detected	N/A = Not Applicable	NLT = Not Less Than			cfu = Colony forming units		par p.l. p m. l. III			
Verified by:	The state of the s		3	Approved by:	ou - Coony forming units			BRT = Below Reporting Threshold Date:		
	Thomas	Date:				Dr.		12-Mar-13		





PRODUCT NAME:	Pregabalin Capsules 75mg	BATCH NO.:		PGCF/10267	PACKAGING DESCRIPTION:		
ACTIVE INGREDIENT(S):	Pregabalin	BATCH SIZE:	BATCH SIZE: 7		FORMING FOIL:	PVC CLEAR FILM 250 MIC	
LABEL CLAIM:	75mg P.		PACKAGING SIZE:		10 X 10 Capsules	LIDDING FOIL:	Highly heat resistant lacquer on the basis of polyester pure aluminum, hard tempered(0.025mm)
PACKAGE TYPE:	Blister(Alu-PVC)		MFG. SITE:		ARPL, Bangalore	UNIT DOSAGE CARTONS:	Super chrome white duplex board without varnish
ACTIVE RM SOURCE:	Srini pharmaceuticals Ltd.,		MFG. DATE:		DEC-2010	PACKAGING DATE:	21-JAN-11
ACTIVE RM BATCH NOS	JR9475, JR9476		STORAGE CONDIT	IONS:	40°C / 75%RH	PACKAGING SITE:	ARPL, Bangalore
STABILITY PROTOCOL NO.:	ARI/01/PRT/STB/277/A						
PRODUCT DESCRIPTION:	Hard gelatin capsules with opaque orange cap and opaq.	ue white body. Imprinted A	PO P75 in black ink.	Filled with white powe	der.		
STUDY START DATE	TIME POINTS:	INITIAL	1 MONTH	2 MONTHS	3 MONTHS	6 MONTHS	
03-FEB-11	DATE PULLED:	N/A	03-MAR-11	05-APR-11	03-MAY-11	03-AUG-11	Company of the State of the Sta
03 120 11	TESTING START DATE:	22-JAN-11	03-MAR-11	05-APR-11	03-MAY-11	03-AUG-11	
	TESTING END DATE:	31-JAN-11	01-APR-11	03-MAY-11	03-JUN-11	23-AUG-11	
TEST	ACCEPTANCE CRITERIA						
Specifications used *		PRB-FP-CAP-75MG-	PRB-TP-ST-CAP-	PRB-TP-ST-CAP-	PRB-TP-ST-CAP-	PRB-TP-ST-CAP-	
		GLOBAL-RD, Version	GLOBAL-RD	GLOBAL-RD	GLOBAL-RD	GLOBAL-RD	
		1	Version.1	Version.1	Version.1	Version, 1	
Appearance	Refer to product description	Confirms	Confirms	Confirms	Confirms	Confirms	
Identification	HPLC Retention Time: Corresponds to standard	Confirms	Confirms	Confirms	Confirms	Confirms	
Assav	90.0 to 110.0% (% of claim)	101.8%	100.6%	101.4%	100.5%	102.6%	
Dissolution	As per USP/EP	104%, 104%	98%, 98%	99%, 93%	99%, 100%	98%, 94%	
	Q=80%, Time = 15 min	101%, 100%	100%, 99%	96%, 97%	96%, 96%	92%, 91%	
		102%, 101%	101%, 99%	97%, 100%	96%, 97%	96%, 97%	
	Mean (% dissolved)	102%	99%	97%	97%	95%	16-242-16-20 PM-15-2
	Dissolution range (min-max)	100% - 104%	98% - 101%	93% - 100%	96% - 100%	91% - 98%	
	Dissolution stage	S1	S1	S1	S1	S1	
Degradation Products	PRB-II: NMT 0.2%	ND	ND	ND	BRT	BRT	
	PRB-III: NMT 0.2%	ND	BRT	BRT	BRT	BRT	
	Unidentified Impurity :NMT 0.2% each	BRT	BRT(0.075%)	0.2%	0.2%	0.2%	
	Total Impurities : NMT 1.0%	BRT	BRT	0.2%	0.2%	0.3%	And the state of t
Microbial Limits	a) Total Aerobic Microbial Count : NMT 1000 cfu/g	20 cfu/g	N/A	N/A	40 cfu/g	10 cfu/g	
	b) Total Yeast and Mould Count: NMT 100 cfu/g	Less than 10 cfu/g	N/A	N/A	Less than 10 cfu/g	Less than 10 cfu/g	
	c) E.coli : Absent in 1 g	Absent/g	N/A	N/A	Absent/g	Absent/g	
** As per Specification and COA * Specification as per the current test pro	offle PRB-TP-ST-CAP-AUS-RD , Version.2, effective on 25-Aug-2011						
ND = Not Detected	N/A = Not Applicable	NMT = Not More Than			ot Less Than	cfu = Colony forming units	BRT = Below Reporting Threshold
Verified by:		Date:		Approved by:		_	Date:
D. spens	dis mul	30-A	ng-11		A.S.	leady_	30-AVU-11

