Apotex Research Pvt. Ltd **STABILITY SUMMARY REPORT** **Product Evaluation and Analytic Support**

PRODUCT NAME	: *Rosuvastatin Calcium Tablets*	*BATCH NO.*	: FD099-93F
ACTIVE INGREDIENT(S)	: *Rosuvastatin Calcium*	*BATCH SIZE*	: 17.51 kg
LABEL CLAIM	: 10 mg	*PACKAGING DATE*	: *21 Jul 08*
PACKAGE TYPE	: Blister PVC clear/foil silver- carton and insert printed	*MFG. SITE*	: *150 Signet Drive*
ACTIVE RM SOURCE	: Apotex Pharmachem Inc.	*MFG. DATE*	: 04 Jul 08
ACTIVE RM BATCH NOS.	: HX6629	*STORAGE CONDITIONS*	: 25 ºC/60%RH
STABILITY PROTOCOL NO.	: ST-rosu119-2009-1		
PRODUCT DESCRIPTION	: Pink, round, biconvex film-coated tablet, engraved "APO" on one side, "ROS" over "10" on the other sice.		

STUDY START DATE: 26 Aug 08	***TIME POINTS*** :	***0 MONTH****	***3 MONTHS****	**6 MONTHS***	**9 MONTHS**	**12 MONTHS**	**18 MONTHS**	**24 MONTHS**	**36 MONTHS**
	DATE PULLED :	N/A	26 Nov 08	26 Feb 09	25 May 09	26 Aug 09	26 Feb 10	26 Aug 10	26 Aug 11
	TESTING START DATE :	17 Sep 08	26 Nov 08	26 Feb 09	26 May 09	28 Aug 09	03 Mar 10	26 Aug 10	26 Aug 11
	TESTING END DATE :	12 Nov 08	08 Jan 09	06 Mar 09	27 Aug 09	12 Apr 10	08 Jun 10	18 Jan 11	19 Sep 11

TEST FOR	*ACCEPTANCE CRITERIA*	*Results*	*Results*	*Results*	*Results*	*Results*	*Results*	*Results*	*Results*
Specification Used: As per Current Version (ROU-TP-ST-FCT-INT-RD)		ROU-TP-ST-FCT-GLOBAL Version 4	ROU-TP-ST-FCT-GLOBAL Version 4	ROU-TP-ST-FCT-AUS-RD Version 2	ROU-TP-ST-FCT-AUS-RD Version 2	ROU-TP-ST-FCT-AUS -RD Version 2	ROU-TP-ST-FCT-AUS-RD Version 2	ROU-TP-ST-FCT-AUS-RD Version 2	ROU-TP-ST-FCT-INT-RD Version 1
Appearance	Refer to the Product Description	Complies*	Complies*	Complies*	Complies*	Complies*	Complies*	Complies*	Complies*
Identification	HPLC Retention Time: Corresponds to stardard	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies
Assay	95.0% - 105.0% of the labelled amount of Rosuvastatin	98.1	99.4	98.4	97.9	100.1	99.6	100.2	99.9
Degradation Product	ROU RC2 : NMT 0.4%	BRT	0.15	0.13	0.2	0.1	0.1	0.1	0.1
	ROU RC3 : NMT 0.4%	BRT	BRT	BRT	BRT	BRT	BRT	BRT	0.1
	ROU RC5 : NMT 0.3%	ND	ND	ND	ND	ND	ND	ND	ND
	ROU RC6 : NMT 0.3%	ND	ND	ND	ND	ND	ND	ND	ND
	ROU RC9 : NMT 1.0%	0.19	0.22	0.17	0.2	0.2	0.2	0.2	0.3
	Unidentified impurity : NMT 0.2% each	BRT	BRT	BRT	BRT	BRT	BRT	BRT	BRT
	Total Impurities : NMT 1.0%	0.19	0.37	0.30	0.4	0.3	0.4	0.3	0.5
Degradation Product	ROU RC 10 : NMT 60 ppm	Not Tested	Not Tested	Not Tested	Not Tested	Not Tested	Not Tested	Not Tested	BRT
Dissolution	As per USP/EP, Q = 80T, Time = 30 minutes Report individual dissolution results	98.4,98.8 101.5, 99.6, 101.1,100.9	97.1, 98.6, 97.8, 97.3, 97.1, 97.1	97.3, 96.8, 98.8, 97.5, 98.4, 98.0	99.7, 101.2, 98.3, 96.8, 101.1, 100.4	97.9, 98,2, 98.9, 97.4, 96.9, 99.0	96, 987, 100 98,98, 98	95, 98, 96 96, 95, 95	100, 99, 95 99, 97, 96
	Mear: (% dissolved)	100.1	97.5	97.8	98	94	97	97	98
	Dissolution Rage: (Min - Max)	98.4 . 101.5	97.1 - 98.6	96.8 - 98.8	96-99	92-96	96-98	96-98	95, 100
	Dissolution Stage: (S1,S2 & S3)	S1	S1	S1	S1	S1	S1	S1	S1
Water	NMT 7.0%	5.87	5.86	5.56	5.6	5.8	5.7	6.1	5.7
Microbial Limits	E. coli : Absent in 1 g	Absent	N/A	N/A	N/A	N /A	N/A	N/A	Absent
	Enterobacteria : Absent in 1 g	Absent							Absent
	Pseudomonas aeruginosa : Absent in 1 g	Absent							Absent
	Staphylococcus aureus : Absent in 1 g	Absent							Absent
	Salmonella species : Absent in 10 g	Absent							Absent
	Total Yeast & Mould Count :NMT 100 cfu/g	< 10cfu/g							<10 cfu/g
	Total Viable Aerobic Microbial Count ; NMT 1000 cfu/g	< 30cfu/g							<100 cfu/g

COMMENTS: * Refer file memo dated 18 Mar-2009 **Refer Protocol No.: ARI/11/PRT/STB/314/B
ND = Not Detected N/A = Not Applicable NMT = Not More Than NLT = Not Less Than cfu = Colony forming units BRT = Below Reporting Threshold (Reporting Threshold = 0.1%)

Verified By:	Date: 13-OCT-11	**Approved By:**	Date: 13-OCT-11 13-OCT-11

Apotex Research Pvt. Ltd **STABILITY SUMMARY REPORT** **Product Evaluation and Analytic Support**

PRODUCT NAME	: *Rosuvastatin Calcium Tablets*	*BATCH NO.*	: FD099-93F
ACTIVE INGREDIENT(S)	: *Rosuvastatin Calcium*	*BATCH SIZE*	: 17.51 kg
LABEL CLAIM	: 10 mg	*PACKAGING DATE*	: *21 Jul 08*
PACKAGE TYPE	: Blister PVC clear/foil silver- carton and insert printed	*MFG. SITE*	: *150 Signet Drive*
ACTIVE RM SOURCE	: Apotex Pharmachem Inc.	*MFG. DATE*	: 04 Jul 08
ACTIVE RM BATCH NOS.	: HX6629	*STORAGE CONDITIONS*	: 30 ºC/65%RH
STABILITY PROTOCOL NO.	: ST-rosu119-2009-2		
PRODUCT DESCRIPTION	: Pink, round, biconvex film-coated tablet, engraved "APO" on one side, "ROS" over "10" on the other sice.		

STUDY START DATE: 26 Aug 08	***TIME POINTS*** :	***0 MONTH****	***1 MONTH****	**2 MONTHS****	**3 MONTHS****	**6 MONTH****	**9 MONTHS**	**12 MONTHS**	**18 MONTHS**	**24 MONTHS**	**36 MONTHS**
	DATE PULLED :	N/A	N/A	N/A	25 Nov 08	26 Feb 09	26 May 09	26 Aug 09	26 Feb 10	26 Aug 10	26 Aug 11
	TESTING START DATE :	17 Sep 08	N/A	N/A	25 Nov 08	26 Feb 09	28 May 09	28 Aug 09	03 Mar 10	26 Aug 10	26 Aug 11
	TESTING END DATE :	12 Nov 08	N/A	N/A	08 Jan 09	06 Mar 09	27 Aug 09	12 Apr 10	08 Jun 10	18 Jan 11	13 Sep 11

TEST FOR	*ACCEPTANCE CRITERIA*	*Results*	*Results*	*Results*	*Results*	*Results*	*Results*	*Results*	*Results*	*Results*	*Results*
Specification Used: As per Current Version (ROU-TP-ST-FCT-INT-RD)		ROU-TP-ST-FCT-GLOBAL Version 4	Not Tested	Not Tested	ROU-TP-ST-FCT-GLOBAL Version 4	ROU-TP-ST-FCT-AUS -RD Version 2	ROU-TP-ST-FCT-AUS-RD Version 2	ROU-TP-ST-FCT-AUS-RD Version 2	ROU-TP-ST-FCT-AUS-RD Version 2	ROU-TP-ST-FCT-AUS-RD Version 2	ROU-TP-ST-FCT-INT-RD Version 1
Appearance	Refer to the Product Description	Complies*			Complies*	Complies*	Complies*	Complies*	Complies*	Complies*	Complies*
Identification	HPLC Retention Time: Corresponds to stardard	Complies			Complies	Complies	Complies	Complies	Complies	Complies	Complies
Assay	95.0% - 102.0% of the labelled amount of Rosuvastatin	98.1			99.8	99.6	98.9	100.7	100.4	100.1	100.4
Degradation Product	ROU RC2 : NMT 0.4%	BRT			0.16	0.14	0.2	0.1	0.1	0.1	0.1
	ROU RC3 : NMT 0.4%	BRT			BRT	BRT	0.1	BRT	0.1	0.1	0.2
	ROU RC5 : NMT 0.3%	ND			ND	ND	ND	ND	ND	ND	ND
	ROU RC6 : NMT 0.3%	ND			ND	ND	ND	ND	ND	ND	ND
	ROU RC9 : NMT 1.0%	0.19			0.23	0.19	0.2	0.2	0.3	0.2	0.3
	Unidentified impurity : NMT 0.2% each	BRT			BRT	BRT	BRT	BRT	BRT	BRT	BRT
	Total Impurities : NMT 1.0%	0.19			0.39	0.32	0.5	0.3	0.6	0.5	0.6
Degradation Product	ROU RC 10 : NMT 60 ppm	Not Tested			Not Tested	Not Tested	Not Tested	Not Tested	Not Tested	Not Tested	15
Dissolution	As per USP/EP, Q = 80T, Time = 30 minutes Report individual dissolution results	98.4,98.8 101.4, 99.6, 101.1,100.9			99.7, 101.2, 98.3, 96.8, 101.1, 100.4	97.9, 98,2, 98.9, 97.4, 96.9, 99.0	96, 987, 100 98,98, 98	95, 98, 96 96, 95, 95	102, 99, 102, 103, 101, 98	101, 101, 98, 100, 99, 101	96, 98, 96 99, 98, 99
	Mear: (% dissolved)	100.1			99,9	98.1	98	96	101	100	98
	Dissolution Rage: (Min - Max)	98.4 . 101.5			98.3 - 101.2	96.9 - 99.0	98 - 100	95- 98	96 - 103	98 - 101	96 - 99
	Dissolution Stage: (S1,S2 & S3)	S1			S1	S1	S1	S1	S1	S1	S1
Water	NMT 7.0%	5.87			5.72	5.67	5.8	5.8	5.7	6.2	6.1
Microbial Limits	E. coli : Absent in 1 g	Absent			N/A	N /A	N/A	N/A	N/A	N/A	N/A
	Enterobacteria : Absent in 1 g	Absent									
	Pseudomonas aeruginosa : Absent in 1 g	Absent									
	Staphylococcus aureus : Absent in 1 g	Absent									
	Salmonella species : Absent in 10 g	Absent									
	Total Yeast & Mould Count :NMT 100 cfu/g	< 10cfu/g									
	Total Viable Aerobic Microbial Count ; NMT 1000 cfu/g	< 30cfu/g									

COMMENTS: * Refer file memo dated 18 Mar-2099 **Refer Protocol No.: ARI/11/PRT/STB/314/B
ND = Not Detected N/A = Not Applicable NMT = Not More Than NLT = Not Less Than cfu = Colony forming units BRT = Below Reporting Threshold (Reporting Threshold = 0.1%)

Verified By:	Date: 13-OCT-11	**Approved By:** TT Boog	Date: 13-OCT-11 13-OCT-11

Apotex Research Pvt. Ltd STABILITY SUMMARY REPORT Product Evaluation and Analytic Support

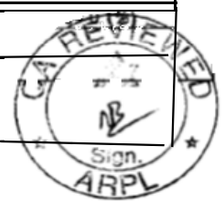
PRODUCT NAME : *Rosuvastatin Calcium Tablets*		*BATCH NO.*	: FD099-93F
ACTIVE INGREDIENT(S) : *Rosuvastatin Calcium*		*BATCH SIZE*	: 17.51 kg
LABEL CLAIM : 10 mg		*PACKAGING DATE*	: *21 Jul 08*
PACKAGE TYPE : Blister PVC clear/foil silver- carton and insert printed		*MFG. SITE*	: *150 Signet Drive*
ACTIVE RM SOURCE : Apotex Pharmachem Inc.		*MFG. DATE*	: Aug 2008
ACTIVE RM BATCH NOS. : HX6629		*STORAGE CONDITIONS*	: 40 ºC/75%RH
STABILITY PROTOCOL NO. : ARI/11/PRT/STB/314/B			
PRODUCT DESCRIPTION : Pink, round, biconvex film-coated tablet, engraved "APO" on one side, "ROS" over "10" on the other sice.			

STUDY START DATE: 26 Aug 08	***TIME POINTS*** :	***0 MONTH***	***1 MONTH***	**2 MONTHS**	**3 MONTHS**	**6 MONTH**
	DATE PULLED :	N/A	26 Sep 08	29 Oct 08	25 Nov 08	26 Feb 09
	TESTING START DATE :	17 Sep 08	26 Sep 08	29 Oct 08	25 Nov 08	26 Feb 09
	TESTING END DATE :	12 Nov 08	14 Nov 08	07 Jan 09	08 Jan 09	06 Mar 09

TEST FOR	*ACCEPTANCE CRITERIA*	*Results*	*Results*	*Results*	*Results*	*Results*
Specification Used: As per Current Version (ROU-TP-ST-FCT-INT-RD)		ROU-TP-ST-FCT-GLOBAL Version 4	ROU-TP-ST-FCT-GLOBAL Version 4	ROU-TP-ST-FCT-GLOBAL Version 4	ROU-TP-ST-FCT-GLOBAL Version 4	ROU-TP-ST-FCT-AUS -RD Version 2
Appearance	Refer to the Product Description	Complies*	Complies*	Complies*	Complies*	Complies*
Identification	HPLC Retention Time: Corresponds to stardard	Complies	Complies	Complies	Complies	Complies
Assay	95.0% - 102.0% of the labelled amount of Rosuvastatin	98.1	99.0	98.5	99.8	99.6
Degradation Product	ROU RC2 : NMT 0.5%	BRT	BRT	0.10	0.16	0.14
	ROU RC3 : NMT 0.5%	BRT	BRT	0.10	0.10	0.25
	ROU RC5 : NMT 0.5%	ND	ND	ND	ND	ND
	ROU RC6 : NMT 0.5%	ND	ND	ND	ND	ND
	ROU RC9 : NMT 0.5%	0.19	0.18	0.20	0.26	0.25
	Unidentified impurity : NMT 0.2% each	BRT	BRT	BRT	BRT	BRT
	Total Impurities : NMT 1.0%	0.19	0.18	0.39	0.51	0.64
Dissolution	As per USP/EP, Q = 80%, Time = 30 minutes Report individual dissolution results	98.4,98.8 101.5, 99.6, 101.1,100.9	99.8, 100.3, 99.2, 98.8, 101.3, 98.1	98.1, 97.7, 99.9, 96.9, 97.8, 99,7	102.3, 101.6 100.1, 101.5, 97.7, 98.5	97.0, 98.7, 97.1, 97.3, 96.7, 100.0
	Mear: (% dissolved)	100.1	99.6	98.4	100.3	97.8
	Dissolution Rage: (Min - Max)	98.4 . 101.5	98.1 - 101.3	96.9 - 99.9	97.7 - 102.3	96.7 - 100.0
	Dissolution Stage: (S1,S2 & S3)	S1	S1	S1	S1	S1
Water	NMT 7.0%	5.87	5.67	5.70	5.88	5.78
Microbial Limits	E. coli : Absent in 1 g	Absent	N/A	N/A	N/A	N /A
	Enterobacteria : Absent in 1 g	Absent				
	Pseudomonas aeruginosa : Absent in 1 g	Absent				
	Staphylococcus aureus : Absent in 1 g	Absent				
	Salmonella species : Absent in 10 g	Absent				
	Total Yeast & Mould Count :NMT 100 cfu/g	< 10cfu/g				
	Total Viable Aerobic Microbial Count ; NMT 1000 cfu/g	< 30cfu/g				

COMMENTS: * Refer file memo dated 18 Mar-2009
ND = Not Detected N/A = Not Applicable NMT = Not More Than NLT = Not Less Than cfu = Colony forming units BRT = Below Reporting Threshold (Reporting Threshold = 0.1%)

Verified By: M. Sood	Date: 19-Mar-09	**Approved By:** M. Omar Qamar	Date: 19-Mar-09



Apotex Research Pvt. Ltd **STABILITY SUMMARY REPORT** **Product Evaluation and Analytic Support**

PRODUCT NAME	: *Rosuvastatin Calcium Tablets*	*BATCH NO.*	: ROTC/08102
ACTIVE INGREDIENT(S)	: *Rosuvastatin Calcium*	*BATCH SIZE*	: 1.13.333 Tablets
LABEL CLAIM	: 10 mg	*PACKAGING DATE*	: *12 Sep 08*
PACKAGE TYPE	: Blister PVC clear/foil silver- carton and insert printed	*MFG. SITE*	: *150 Signet Drive*
ACTIVE RM SOURCE	: Apotex Pharmachem Inc.	*MFG. DATE*	: Aug 08
ACTIVE RM BATCH NOS.	: HY2445	*STORAGE CONDITIONS*	: 25 ºC/60%RH
STABILITY PROTOCOL NO.	: ST-rosu82-2009-1		
PRODUCT DESCRIPTION	: Pink, round, biconvex film-coated tablet, engraved "APO" on one side, "ROS" over "10" on the other sice.		

STUDY START DATE: 26 Aug 08	***TIME POINTS*** :	***0 MONTH****	***3 MONTHS****	**6 MONTHS***	**9 MONTHS***	**12 MONTHS***	**18 MONTHS**	**24 MONTHS**	**36 MONTHS**
	DATE PULLED :	N/A	12 Dec 08	10-mar-09	12-jun-09	17-sep-09	12-mar-10	14-sep-10	12-sep-11
	TESTING START DATE :	12 Sep 08	12 Dec 08	10-mar-09	12-jun-09	17-sep-09	18-mar-10	15-sep-10	13-sep-11
	TESTING END DATE :	24 Sep 08	19 Jan 09	19-mar-09	18 Aug 09	25 Jan 10	24 Aug 10	04 Jan 11	13-oct-11

TEST FOR	*ACCEPTANCE CRITERIA*	*Results*	*Results*	*Results*	*Results*	*Results*	*Results*	*Results*	*Results*
Specification Used: As per Current Version (ROU-TP-ST-FCT-INT-RD)		ROU-TP-ST-FCT-GLOBAL Version 4	ROU-ST-FCT-AUS-RD Version 1	ROU-TP-ST-FCT-AUS-RD Version 2	ROU-TP-ST-FCT-AUS-RD Version 2	ROU-TP-ST-FCT-AUS -RD Version 2	ROU-TP-ST-FCT-AUS-RD Version 2	ROU-TP-ST-FCT-AUS-RD Version 2	ROU-TP-ST-FCT-INT-RD Version 1
Appearance	Refer to the Product Description	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies
Identification	HPLC Retention Time: Corresponds to stardard	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies
Assay	95.0% - 105.0% of the labelled amount of Rosuvastatin	96.8	99.2	99.5	98.2	99.0	98.7	99.6	98.4
Degradation Product	ROU RC2 : NMT 0.4%	BRT	0.14	0.15	0.13	BRT	0.1	0.1	0.1
	ROU RC3 : NMT 0.4%	BRT	BRT	BRT	BRT	BRT	BRT	BRT	0.1
	ROU RC5 : NMT 0.3%	ND	ND	ND	ND	ND	ND	ND	ND
	ROU RC6 : NMT 0.3%	ND	ND	ND	ND	ND	ND	ND	BRT
	ROU RC9 : NMT 1.0%	0.17	0.22	0.24	0.23	0.28	0.3	0.3	0.3
	Unidentified impurity : NMT 0.2% each	BRT	BRT	BRT	BRT	BRT	BRT	BRT	BRT
	Total Impurities : NMT 1.0%	0.17	0.36	0.38	0.35	0.28	0.4	0.4	0.6
Degradation Product	ROU RC 10 : NMT 60 ppm	Not Tested	Not Tested	Not Tested	Not Tested	Not Tested	Not Tested	Not Tested	26
Dissolution	As per USP/EP, Q = 80T, Time = 30 minutes Report individual dissolution results	90.5, 91.4, 91.6, 90.7, 91.2, 91.8	97.5, 101.2, 97.1, 97.8, 97.3, 99.9	97.1, 96.8, 97.5, 97.8, 97.2, 97.1	98, 100, 97, 99, 97,98	98, 96, 100, 95, 95, 96	95, 95 94, 97, 95, 96	95, 95 95,94, 94, 95	97, 96, 98, 98, 97,97
	Mear: (% dissolved)	91.2	98.5	97.3	98	97	95	95	97
	Dissolution Range: (Min - Max)	90.5 - 91.8	97.1 - 101,2	96.8 - 97.8	97 - 100	95 - 100	94 - 97	94 - 95	96 - 98
	Dissolution Stage: (S1,S2 & S3)	S1	S1	S1	S1	S1	S1	S1	S1
Water	NMT 7.0%	5.30	5.45	5.51	5.3	5.7	5.8	5.7	5.9
Microbial Limits	E. coli : Absent in 1 g	Absent	N/A	Absent	N/A	N /A	N/A	Absent	Absent
	Enterobacteria : Absent in 1 g	Absent		Absent				Absent	Absent
	Pseudomonas aeruginosa : Absent in 1 g	Absent		Absent				Absent	Absent
	Staphylococcus aureus : Absent in 1 g	Absent		Absent				Absent	Absent
	Salmonella species : Absent in 10 g	Absent		Absent				Absent	Absent
	Total Yeast & Mould Count :NMT 100 cfu/g	10cfu/g		< 10cfu/g				< 10cfu/g	<10 cfu/g
	Total Viable Aerobic Microbial Count ; NMT 1000 cfu/g	25cfu/g		20cfu/g				< 100cfu/g	<100 cfu/g

COMMENTS: * Refer Protocol No.: ARI/11/PRT/STB/120/B
ND = Not Detected N/A = Not Applicable NMT = Not More Than NLT = Not Less Than cfu = Colony forming units BRT = Below Reporting Threshold (Reporting Threshold = 0.1%)

Verified By:	Date: 20-OCT-11	**Approved By:** T. Boody	Date: 20-OCT-11

Apotex Research Pvt. Ltd **STABILITY SUMMARY REPORT** **Product Evaluation and Analytic Support**

PRODUCT NAME	: *Rosuvastatin Calcium Tablets*	*BATCH NO.*	: ROTC/08102
ACTIVE INGREDIENT(S)	: *Rosuvastatin Calcium*	*BATCH SIZE*	: 1.13.333 Tablets
LABEL CLAIM	: 10 mg	*PACKAGING DATE*	: *12 Sep 08*
PACKAGE TYPE	: Blister PVC clear/foil silver- carton and insert printed	*MFG. SITE*	: *150 Signet Drive*
ACTIVE RM SOURCE	: Apotex Pharmachem Inc.	*MFG. DATE*	: Aug 2008
ACTIVE RM BATCH NOS.	: HY2445	*STORAGE CONDITIONS*	: 30 ºC/65%RH
STABILITY PROTOCOL NO.	: ST-rosu082-2009-2		
PRODUCT DESCRIPTION	: Pink, round, biconvex film-coated tablet, engraved "APO" on one side, "ROS" over "10" on the other sice.		

STUDY START DATE:	***TIME POINTS***	***:***	***0 MONTH****	***1 MONTH****	**2 MONTHS***	**3 MONTHS***	**6 MONTH***	**9 MONTHS***	**12 MONTHS***	**18 MONTHS**	**24 MONTHS**	**36 MONTHS**
12-sep-08	*DATE PULLED*	:	N/A	13 Oct 08	12 Nov 08	12 Dec 08	10 Mar 09	12 Jun 09	17 Sep 09	12 Mar 10	14 Sep 10	12 Sep 11
	TESTING START DATE	:	12 Sep 08	13 Oct 08	12 Nov 08	12 Dec 08	10 Mar 09	12 Jun 09	17 Sep 09	18 Mar 10	15 Sep 10	13 Sep 11
	TESTING END DATE	:	24 Sep 08	28 Nov 08	09 Dec 08	19 Jan 09	19 Mar 09	18 Aug 09	25 Jan 10	24 Aug 10	04 Jan 11	13 Oct 11

TEST FOR	*ACCEPTANCE CRITERIA*		*Results*	*Results*	*Results*	*Results*	*Results*	*Results*	*Results*	*Results*	*Results*	*Results*
Specification Used: As per Current Version (ROU-TP-ST-FCT-INT-RD)			ROU-TP-ST-FCT-GLOBAL Version 4	ROU-TP-ST-FCT-GLOBAL Version 4	ROU-TP-ST-FCT-GLOBAL Version 4	ROU-ST-FCT-AUS-RD Version 1	ROU-TP-ST-FCT-AUS -RD Version 2	ROU-TP-ST-FCT-AUS-RD Version 2	ROU-TP-ST-FCT-AUS-RD Version 2	ROU-TP-ST-FCT-AUS-RD Version 2	ROU-TP-ST-FCT-AUS-RD Version 2	ROU-TP-ST-FCT-INT-RD Version 1
Appearance	Refer to the Product Description		Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies
Identification	HPLC Retention Time: Corresponds to stardard		Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies
Assay	95.0% - 102.0% of the labelled amount of Rosuvastatin		96.8	99.7	99.5	100.3	99.3	100.2	99.8	99.1	99.6	98.9
Degradation Product	ROU RC2	: NMT 0.4%	BRT	BRT	BRT	0.14	0.15	0.13	BRT	0.1	0.1	0.1
	ROU RC3	: NMT 0.4%	BRT	BRT	BRT	BRT	BRT	BRT	BRT	0.1	BRT	0.2
	ROU RC5	: NMT 0.3%	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
	ROU RC6	: NMT 0.3%	ND	ND	ND	ND	ND	ND	ND	ND	ND	BRT
	ROU RC9	: NMT 1.0%	0.17	0.18	0.19	0.23	0.25	0.25	0.30	0.3	0.3	0.4
	Unidentified impurity	: NMT 0.2% each	BRT	BRT	BRT	BRT	BRT	BRT	BRT	BRT	BRT	BRT
	Total Impurities	: NMT 1.0%	0.19	0.18	0.19	0.36	0.40	0.38	0.3	0.6	0.4	0.7
Degradation Product	ROU RC 10	: NMT 60 ppm	Not Tested	Not Tested	Not Tested	Not Tested	Not Tested	Not Tested	Not Tested	Not Tested	Not Tested	31
Dissolution	As per USP/EP, Q = 80T, Time = 30 minutes Report individual dissolution results		90.5, 94.4 91.6, 90.7, 91.2, 91.8	97.1, 97.1, 99.0, 97.6, 99.4, 97.0	94.4, 98.3, 98.9, 97.7, 98.8, 96.6	98.6, 96.9, 99.4, 98.3, 98.6, 99.1	96.4, 98.5, 97.5, 97.4, 96.6, 98.0	99, 98, 101, 98 97, 97	96, 99, 96, 94 98,95	96, 93, 94, 97, 94, 94	95, 92, 97, 96 94, 95	99, 94 97, 101, 98, 98
	Mear: (% dissolved)		91.2	97.9	97.5	98.5	97.4	98	96	95	95	98
	Dissolution Rage: (Min - Max)		90.5- 91.8	97.0- 99.4	94.4 - 93.9	96.9 - 99.4	96.4 - 98.5	97 - 101	94 - 99	93 - 97	92 - 97	94 - 101
	Dissolution Stage: (S1,S2 & S3)		S1	S1	S1	S1	S1	S1	S1	S1	S1	S1
Water	NMT 7.0%		5.30	5.46	5.06	5.41	5.66	5.2	5.3	5.3	5.8	5.7
Microbial Limits	E. coli	: Absent in 1 g	Absent	N/A	N/A	N/A	Absent	N/A	N/A	N/A	Absent	Absent
	Enterobacteria	: Absent in 1 g	Absent				Absent				Absent	Absent
	Pseudomonas aeruginosa	: Absent in 1 g	Absent				Absent				Absent	Absent
	Staphylococcus aureus	: Absent in 1 g	Absent				Absent				Absent	Absent
	Salmonella species	: Absent in 10 g	Absent				Absent				Absent	Absent
	Total Yeast & Mould Count	:NMT 100 cfu/g	10cfu/g				< 10cfu/g				< 10cfu/g	< 10cfu/g
	Total Viable Aerobic Microbial Count	; NMT 1000 cfu/g	25cfu/g				15cfu/g				<100cfu/g	<100cfu/g

COMMENTS: * Refer Protocol No.: ARI/11/PRT/STB/120/B
ND = Not Detected N/A = Not Applicable NMT = Not More Than NLT = Not Less Than cfu = Colony forming units BRT = Below Reporting Threshold (Reporting Threshold = 0.1%)

Verified By:		Date:	20-Oct-11	**Approved By:**	T. Boddy
Date:	20-Oct-11				

Apotex Research Pvt. Ltd **STABILITY SUMMARY REPORT** **Product Evaluation and Analytic Support**

PRODUCT NAME : *Rosuvastatin Calcium Tablets*		*BATCH NO.*	: ROTC/08102
ACTIVE INGREDIENT(S) : *Rosuvastatin Calcium*		*BATCH SIZE*	: 1, 13, 333 Tablets
LABEL CLAIM : 10 mg		*PACKAGING DATE*	: *12 Sep 08*
PACKAGE TYPE : Blister PVC clear/foil silver- carton and insert printed		*MFG. SITE*	: *150 Signet Drive*
ACTIVE RM SOURCE : Apotex Pharmachem Inc.		*MFG. DATE*	: Aug 2008
ACTIVE RM BATCH NOS. : HY2445		*STORAGE CONDITIONS*	: 40 ºC/75%RH
STABILITY PROTOCOL NO. : ARI/01/PRT/STB/120/B			
PRODUCT DESCRIPTION : Pink, round, biconvex film-coated tablet, engraved "APO" on one side, "ROS" over "10" on the other sice.			

STUDY START DATE: 12-sep-08	***TIME POINTS*** :	***0 MONTH***	***1 MONTH***	**2 MONTHS**	**3 MONTHS**	**6 MONTH**
	DATE PULLED :	N/A	13 Oct 08	12 Nov 08	12 Dec 08	10 Mar 09
	TESTING START DATE :	12 Sep 08	13 Oct 08	12 Nov 08	12 Dec 08	10 Mar 09
	TESTING END DATE :	24 Sep 08	28 Nov 08	09 Dec 08	19 Jan 09	19 Mar 09

TEST FOR	*ACCEPTANCE CRITERIA*	*Results*	*Results*	*Results*	*Results*	*Results*
Specification Used: As per Current Version (ROU-TP-ST-FCT-AUS-RD)		ROU-TP-ST-FCT-GLOBAL Version 4	ROU-TP-ST-FCT-GLOBAL Version 4	ROU-TP-ST-FCT-GLOBAL Version 4	ROU-ST-FCT-AUS-RD Version 1	ROU-TP-ST-FCT-AUS -RD Version 2
Appearance	Refer to the Product Description	Complies	Complies	Complies	Complies	Complies
Identification	HPLC Retention Time: Corresponds to stardard	Complies	Complies	Complies	Complies	Complies
Assay	95.0% - 102.0% of the labelled amount of Rosuvastatin	96.8	99.3	99.1	97.9	99.1
Degradation Product	ROU RC2 : NMT 0.5%	BRT	BRT	BRT	0.14	0.15
	ROU RC3 : NMT 0.5%	BRT	BRT	BRT	0.10	0.21
	ROU RC5 : NMT 0.5%	ND	ND	ND	ND	ND
	ROU RC6 : NMT 0.5%	ND	ND	ND	ND	ND
	ROU RC9 : NMT 0.5%	0.17	0.21	0.23	0.31	0.36
	Unidentified impurity : NMT 0.2% each	BRT	BRT	BRT	BRT	BRT
	Total Impurities : NMT 1.0%	0.17	0.21	0.23	0.55	0.71
Dissolution	As per USP/EP, Q = 80%, Time = 30 minutes Report individual dissolution results	90.5, 91.4, 91.6, 90.7, 91.2, 91.8	97.9, 97.4, 98.9, 99.0, 95.4, 96.8	95.7, 97.1 98.0, 96.5, 96.7, 97.8	97.7, 96.8, 97.6, 97.4, 97.0, 99,8	97.1, 97.7 96.4, 97.1 98.5, 96.8
	Mear: (% dissolved)	91.2	97.6	97.0	97.7	97.3
	Dissolution Rage: (Min - Max)	90.5-91.8	95.4-99.0	95.7-98.0	96.8-99.8	96.4-98.5
	Dissolution Stage: (S1,S2 & S3)	S1	S1	S1	S1	S1
Water	NMT 7.0%	5.30	5.48	5.71	5.42	5.83
Microbial Limits	E. coli : Absent in 1 g	Absent	N/A	N/A	N/A	Absent
	Enterobacteria : Absent in 1 g	Absent				Absent
	Pseudomonas aeruginosa : Absent in 1 g	Absent				Absent
	Staphylococcus aureus : Absent in 1 g	Absent				Absent
	Salmonella species : Absent in 10 g	Absent				Absent
	Total Yeast & Mould Count :NMT 100 cfu/g	10cfu/g				< 10cfu/g
	Total Viable Aerobic Microbial Count ; NMT 1000 cfu/g	25cfu/g				10cfu/g

COMMENTS:
ND = Not Detected N/A = Not Applicable NMT = Not More Than NLT = Not Less Than cfu = Colony forming units BRT = Below Reporting Threshold (Reporting Threshold = 0.1%)

Verified By: M. Sood	Date: 20-Nov-08	**Approved By:** M. Omar Qamar	Date: 20-Nov-08

Apotex Research Pvt. Ltd **STABILITY SUMMARY REPORT** **Product Evaluation and Analytic Support**

PRODUCT NAME : *Rosuvastatin Calcium Tablets*							*BATCH NO.* : ROTC/08103			
ACTIVE INGREDIENT(S) : *Rosuvastatin Calcium*							*BATCH SIZE* : 1.13.333 Tablets			
LABEL CLAIM : 10 mg							*PACKAGING DATE* : *12 Sep 08*			
PACKAGE TYPE : Blister PVC clear/foil silver- carton and insert printed							*MFG. SITE* : *150 Signet Drive*			
ACTIVE RM SOURCE : Apotex Pharmachem Inc.							*MFG. DATE* : Aug 08			
ACTIVE RM BATCH NOS. : HY2446							*STORAGE CONDITIONS* : 25 ºC/60%RH			
STABILITY PROTOCOL NO. : ST-rosu82-2009-1										
PRODUCT DESCRIPTION : Pink, round, biconvex film-coated tablet, engraved "APO" on one side, "ROS" over "10" on the other sice.										
STUDY START DATE: 13 Sep. 08	***TIME POINTS*** :	***0 MONTH****	***3 MONTHS****	**6 MONTHS***	**9 MONTHS***	**12 MONTHS***	**18 MONTHS**	**24 MONTHS**	**36 MONTHS**	
	DATE PULLED :	N/A	16 Dec 08	11 Mar 08	15-jun-09	17 Sep 09	15 Mar 10	14 Sep 10	13 Sep 11	
	TESTING START DATE :	15 Sep 08	16 Dec 08	11 Mar 09	15 Jun 09	17 Sep 09	18 Mar 10	15 Sep 10	13 Sep 11	
	TESTING END DATE :	24 Sep 08	19 Jan 09	19 Mar 09	18 Aug 09	25 Jan 10	24 Aug 10	04 Jan 11	05 Oct 11	
TEST FOR	*ACCEPTANCE CRITERIA*	*Results*	*Results*	*Results*	*Results*	*Results*	*Results*	*Results*	*Results*	
Specification Used: As per Current Version (ROU-TP-ST-FCT-INT-RD)		ROU-TP-ST-FCT-GLOBAL Version 4	ROU-ST-FCT-AUS-RD Version 1	ROU-TP-ST-FCT-AUS-RD Version 2	ROU-TP-ST-FCT-AUS-RD Version 2	ROU-TP-ST-FCT-AUS -RD Version 2	ROU-TP-ST-FCT-AUS-RD Version 2	ROU-TP-ST-FCT-AUS-RD Version 2	ROU-TP-ST-FCT-INT-RD Version 1	
Appearance	Refer to the Product Description	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies	
Identification	HPLC Retention Time: Corresponds to stardard	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies	
Assay	95.0% - 105.0% of the labelled amount of Rosuvastatin	98.8	99.9	99.3	98.8	100.2	99.1	98.9	98.9	
Degradation Product	ROU RC2 : NMT 0.4%	BRT	0.16	0.17	0.15	BRT	0.2	0.1	0.1	
	ROU RC3 : NMT 0.4%	BRT	BRT	BRT	BRT	BRT	BRT	BRT	0.1	
	ROU RC5 : NMT 0.3%	ND	ND	ND	ND	ND	ND	ND	ND	
	ROU RC6 : NMT 0.3%	ND	ND	ND	ND	ND	ND	ND	ND	
	ROU RC9 : NMT 1.0%	BRT	0.10	0.11	0.12	0.15	0.2	0.1	0.2	
	Unidentified impurity : NMT 0.2% each	BRT	BRT	BRT	BRT	BRT	BRT	BRT	BRT	
	Total Impurities : NMT 1.0%	BRT	0.26	0.28	0.26	0.15	0.3	0.3	0.4	
Degradation Product	ROU RC 10 : NMT 60 ppm	Not Tested	Not Tested	Not Tested	Not Tested	Not Tested	Not Tested	Not Tested	BRT	
Dissolution	As per USP/EP, Q = 80T, Time = 30 minutes Report individual dissolution results	95.7, 93.7, 98.7, 95,0 95.0, 95.2	99.4, 100.0, 97.8, 98.2, 97.8, 99.5	97.1, 96.4, 97.1, 98.3, 96.6, 97.2	99, 98, 99, 98 98, 97	95, 95 97, 95, 95, 95	95, 92 93, 94 91,95	97, 92, 96, 97, 94, 96	100, 100, 96, 97, 97, 95	
	Mear: (% dissolved)	95.6	98.8	97.1	98	95	93	95	98	
	Dissolution Range: (Min - Max)	93.7-98.7	97.8-100.0	96.4-98.2	97-99	95-97	91-95	92-97	95-100	
	Dissolution Stage: (S1,S2 & S3)	S1	S1	S1	S1	S1	S1	S1	S1	
Water	NMT 7.0%	5.53	5.35	5.62	5.5	5.6	6.2	5.6	5.5	
Microbial Limits	E. coli : Absent in 1 g	Absent	N/A	Absent	N/A	N /A	N/A	Absent	Absent	
	Enterobacteria : Absent in 1 g	Absent		Absent				Absent	Absent	
	Pseudomonas aeruginosa : Absent in 1 g	Absent		Absent				Absent	Absent	
	Staphylococcus aureus : Absent in 1 g	Absent		Absent				Absent	Absent	
	Salmonella species : Absent in 10 g	Absent		Absent				Absent	Absent	
	Total Yeast & Mould Count :NMT 100 cfu/g	< 10cfu/g		< 10cfu/g				< 10cfu/g	<10 cfu/g	
	Total Viable Aerobic Microbial Count ; NMT 1000 cfu/g	< 25cfu/g		25cfu/g				< 100cfu/g	<100 cfu/g	

COMMENTS: * Refer Protocol No.: ARI/01/PRT/STB/120/B
ND = Not Detected N/A = Not Applicable NMT = Not More Than NLT = Not Less Than cfu = Colony forming units BRT = Below Reporting Threshold (Reporting Threshold = 0.1%)

Verified By:	Date: 20-Oct-11	**Approved By:**	Date: 20-Oct-11

Apotex Research Pvt. Ltd **STABILITY SUMMARY REPORT** **Product Evaluation and Analytic Support**

PRODUCT NAME	: *Rosuvastatin Calcium Tablets*	*BATCH NO.*	: ROTC/08103
ACTIVE INGREDIENT(S)	: *Rosuvastatin Calcium*	*BATCH SIZE*	: 1.13.333 Tablets
LABEL CLAIM	: 10 mg	*PACKAGING DATE*	: *12 Sep 08*
PACKAGE TYPE	: Blister PVC clear/foil silver- carton and insert printed	*MFG. SITE*	: *150 Signet Drive*
ACTIVE RM SOURCE	: Apotex Pharmachem Inc.	*MFG. DATE*	: Aug 2008
ACTIVE RM BATCH NOS.	: HY2446	*STORAGE CONDITIONS*	: 30 ºC/65%RH
STABILITY PROTOCOL NO.	: ST-rosu082-2009-2		
PRODUCT DESCRIPTION	: Pink, round, biconvex film-coated tablet, engraved "APO" on one side, "ROS" over "10" on the other sice.		

STUDY START DATE: 13 Sep 08	***TIME POINTS*** :	***0 MONTH****	***1 MONTH****	**2 MONTHS***	**3 MONTHS***	**6 MONTH***	**9 MONTHS***	**12 MONTHS***	**18 MONTHS**	**24 MONTHS**	**36 MONTHS**
	DATE PULLED :	N/A	13 Oct 08	13 Nov 08	16 Dec 08	11 Mar 09	15 Jun 09	17 Sep 09	15 Mar 10	14 Sep 10	13 Sep 11
	TESTING START DATE :	15 Sep 08	13 Oct 08	13 Nov 08	16 Dec 08	11 Mar 09	15 Jun 09	17 Sep 09	18 Mar 10	15 Sep 10	13 Sep 11
	TESTING END DATE :	24 Sep 08	28 Nov 08	09 Dec 08	19 Jan 09	19 Mar 09	18 Aug 09	25 Jan 10	24 Aug 10	04 Jan 11	05 Oct 11

TEST FOR	*ACCEPTANCE CRITERIA*	*Results*	*Results*	*Results*	*Results*	*Results*	*Results*	*Results*	*Results*	*Results*	*Results*
Specification Used: As per Current Version (ROU-TP-ST-FCT-INT-RD)		ROU-TP-ST-FCT-GLOBAL Version 4	ROU-TP-ST-FCT-GLOBAL Version 4	ROU-TP-ST-FCT-GLOBAL Version 4	ROU-ST-FCT-AUS-RD Version 1	ROU-TP-ST-FCT-AUS -RD Version 2	ROU-TP-ST-FCT-AUS-RD Version 2	ROU-TP-ST-FCT-AUS-RD Version 2	ROU-TP-ST-FCT-AUS-RD Version 2	ROU-TP-ST-FCT-AUS-RD Version 2	ROU-TP-ST-FCT-INT-RD Version 1
Appearance	Refer to the Product Description	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies
Identification	HPLC Retention Time: Corresponds to stardard	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies
Assay	95.0% - 102.0% of the labelled amount of Rosuvastatin	98.8	99.9	98.8	102.0	98.8	98.4	99.3	98.9	99.1	97.9
Degradation Product	ROU RC2 : NMT 0.4%	BRT	BRT	BRT	0.16	0.17	0.16	BRT	0.2	0.2	0.1
	ROU RC3 : NMT 0.4%	BRT	BRT	BRT	BRT	BRT	BRT	BRT	0.1	BRT	0.2
	ROU RC5 : NMT 0.3%	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
	ROU RC6 : NMT 0.3%	ND	ND	ND	ND	ND	ND	ND	ND	ND	BRT
	ROU RC9 : NMT 1.0%	BRT	BRT	BRT	0.11	0.13	0.14	0.19	0.2	0.2	0.2
	Unidentified impurity : NMT 0.2% each	BRT	BRT	BRT	BRT	BRT	BRT	BRT	BRT	BRT	BRT
	Total Impurities : NMT 1.0%	BRT	BRT	BRT	0.26	0.30	0.30	0.19	0.5	0.3	0.6
Degradation Product	ROU RC 10 : NMT 60 ppm	Not Tested	Not Tested	Not Tested	Not Tested	Not Tested	Not Tested	Not Tested	Not Tested	Not Tested	16
Dissolution	As per USP/EP, Q = 80T, Time = 30 minutes Report individual dissolution results	95.7, 93.7 98.7, 95.0, 95.0, 95.2	98.5, 98.3 96.9, 98.8, 100.0, 98.5	97.1, 97,0, 99.6, 96.3, 100.0, 99.6	99.2, 98.5, 98.3, 98.1, 97.0, 97.9	99.0, 96.9, 97.0, 96.9, 97.1, 98.5	98, 98, 99, 99, 100,96	98, 97 97, 95 97, 98	99, 100, 100, 96, 95,94	92, 92, 92, 96, 94, 99	94, 91 97, 94 98, 97
	Mear: (% dissolved)	95.6	98.6	98.3	97.8	97.6	98	97	97	94	95
	Dissolution Rage: (Min - Max)	93.7-98.7	96.9-100.0	96.3-100.0	96.5-99.2	96.9-99.0	96-100	95-98	94-100	92-99	91-98
	Dissolution Stage: (S1,S2 & S3)	S1	S1	S1	S1	S1	S1	S1	S1	S1	S1
Water	NMT 7.0%	5.53	5.65	5.43	5.24	5.59	5.1	5.6	6.1	5.3	5.5
Microbial Limits	E. coli : Absent in 1 g	Absent	N/A	N/A	N/A	Absent	N/A	N/A	N/A	Absent	Absent
	Enterobacteria : Absent in 1 g	Absent				Absent				Absent	Absent
	Pseudomonas aeruginosa : Absent in 1 g	Absent				Absent				Absent	Absent
	Staphylococcus aureus : Absent in 1 g	Absent				Absent				Absent	Absent
	Salmonella species : Absent in 10 g	Absent				Absent				Absent	Absent
	Total Yeast & Mould Count :NMT 100 cfu/g	< 10cfu/g				< 10cfu/g				< 10cfu/g	< 10cfu/g
	Total Viable Aerobic Microbial Count ; NMT 1000 cfu/g	< 25cfu/g				20cfu/g				<100cfu/g	<100cfu/g

COMMENTS: * Refer Protocol No.: ARI/01/PRT/STB/120/B
ND = Not Detected N/A = Not Applicable NMT = Not More Than NLT = Not Less Than cfu = Colony forming units BRT = Below Reporting Threshold (Reporting Threshold = 0.1%)

Verified By:	Date: 20-Oct-11	**Approved By:** T. Boddy	Date: 20-Oct-11 20 OCT 11

Apotex Research Pvt. Ltd **STABILITY SUMMARY REPORT** **Product Evaluation and Analytic Support**

PRODUCT NAME : *Rosuvastatin Calcium Tablets*		*BATCH NO.*	: ROTC/08103
ACTIVE INGREDIENT(S) : *Rosuvastatin Calcium*		*BATCH SIZE*	: 1, 13, 333 Tablets
LABEL CLAIM : 10 mg		*PACKAGING DATE*	: *12 Sep 08*
PACKAGE TYPE : Blister PVC clear/foil silver- carton and insert printed		*MFG. SITE*	: *150 Signet Drive*
ACTIVE RM SOURCE : Apotex Pharmachem Inc.		*MFG. DATE*	: Aug 2008
ACTIVE RM BATCH NOS. : HY2446		*STORAGE CONDITIONS*	: 40 ºC/75%RH
STABILITY PROTOCOL NO. : ARI/01/PRT/STB/120/B			
PRODUCT DESCRIPTION : Pink, round, biconvex film-coated tablet, engraved "APO" on one side, "ROS" over "10" on the other sice.			

STUDY START DATE: 13 Sep 08	***TIME POINTS*** :	***0 MONTH***	***1 MONTH***	**2 MONTHS**	**3 MONTHS**	**6 MONTH**
	DATE PULLED :	N/A	13 Oct 08	13 Nov 08	16 Dec 08	11 Mar 09
	TESTING START DATE :	15 Sep 08	13 Oct 08	13 Nov 08	16 Dec 08	11 Mar 09
	TESTING END DATE :	24 Sep 08	28 Nov 08	09 Dec 08	19 Jan 09	19 Mar 09

TEST FOR	*ACCEPTANCE CRITERIA*	*Results*	*Results*	*Results*	*Results*	*Results*
Specification Used: As per Current Version (ROU-TP-ST-FCT-AUS-RD)		ROU-TP-ST-FCT-GLOBAL Version 4	ROU-TP-ST-FCT-GLOBAL Version 4	ROU-TP-ST-FCT-GLOBAL Version 4	ROU-ST-FCT-AUS-RD Version 1	ROU-TP-ST-FCT-AUS -RD Version 2
Appearance	Refer to the Product Description	Complies	Complies	Complies	Complies	Complies
Identification	HPLC Retention Time: Corresponds to stardard	Complies	Complies	Complies	Complies	Complies
Assay	95.0% - 102.0% of the labelled amount of Rosuvastatin	98.8	98.5	98.1	99.5	98.4
Degradation Product	ROU RC2 : NMT 0.5%	BRT	BRT	BRT	0.17	0.17
	ROU RC3 : NMT 0.5%	BRT	BRT	BRT	0.12	0.22
	ROU RC5 : NMT 0.5%	ND	ND	ND	ND	ND
	ROU RC6 : NMT 0.5%	ND	ND	ND	ND	ND
	ROU RC9 : NMT 0.5%	BRT	BRT	0.12	0.18	0.22
	Unidentified impurity : NMT 0.2% each	BRT	BRT	BRT	BRT	BRT
	Total Impurities : NMT 1.0%	BRT	BRT	0.12	0.47	0.61
Dissolution	As per USP/EP, Q = 80%, Time = 30 minutes Report individual dissolution results	95.7, 93.7, 98.7, 95.0, 95.0, 95.2	94.5, 96.6 97.1, 95.5 95.4, 96.6	96.6, 98.3, 94.7, 94.9, 96.0, 98.5	99.4, 97.1, 98.6, 97.5, 95.9, 98.2	98.9, 97.3, 98.0, 99.7, 99.4, 97.7
	Mear: (% dissolved)	95.6	96.0	96.5	97.8	98.5
	Dissolution Rage: (Min - Max)	93.7-98.7	94.5-97.1	94.7-98.5	95.9-99.4	97.3-99.7
	Dissolution Stage: (S1,S2 & S3)	S1	S1	S1	S1	S1
Water	NMT 7.0%	5.53	5.67	5.60	5.43	5.66
Microbial Limits	E. coli : Absent in 1 g	Absent	N/A	N/A	N/A	Absent
	Enterobacteria : Absent in 1 g	Absent				Absent
	Pseudomonas aeruginosa : Absent in 1 g	Absent				Absent
	Staphylococcus aureus : Absent in 1 g	Absent				Absent
	Salmonella species : Absent in 10 g	Absent				Absent
	Total Yeast & Mould Count :NMT 100 cfu/g	<10cfu/g				< 10cfu/g
	Total Viable Aerobic Microbial Count ; NMT 1000 cfu/g	< 25cfu/g				20cfu/g

COMMENTS:
ND = Not Detected N/A = Not Applicable NMT = Not More Than NLT = Not Less Than cfu = Colony forming units BRT = Below Reporting Threshold (Reporting Threshold = 0.1%)

Verified By: M. Sood	Date: 20-Nov-08	**Approved By:** M. Omar Qamar	Date: 20-Nov-08		