AUROBINDO

CERTIFICATE OF ANALYSIS

PRODUCT NAME	**ROSUVASTATIN CALCIUM Ph.Eur.**	**PAGE No.**	**1 of 2**
BATCH NUMBER	**1411117689**	**A.R.No.**	**14FPR0037**
MFG. DATE	**14/12/2013**	**RETEST DATE**	**13/06/2015**
QUANTITY	**5.00 Kg**	**DATE OF RELEASE**	**30/07/2014**

S No	TEST	RESULT	SPECIFICATION
01	Description	Almost white, hygroscopic powder.	White or almost white, hygroscopic powder.
02	Solubility	Slightly soluble in water, freely soluble in methylene chloride, practically insoluble in anhydrous ethanol.	Slightly soluble in water, freely soluble in methylene chloride, practically insoluble in anhydrous ethanol.
03	Identification		
	a) By IR	IR spectrum exhibits maxima at the same wavenumbers as the Rosuvastatin calcium working standard spectrum.	IR spectrum must exhibit maxima at the same wavenumbers as the Rosuvastatin calcium working standard spectrum.
	b) By HPLC	The retention time of the major peak as obtained in the limit of Rosuvastatin Enantiomer test of the sample solution corresponds to that of the Rosuvastatin peak in the system suitability solution.	The retention time of the major peak as obtained in the limit of Rosuvastatin Enantiomer test of the sample solution should correspond to that of the Rosuvastatin peak in the system suitability solution.
	c) Test for Calcium	A white, crystalline precipitate is formed, indicating the presence of calcium ions.	A white, crystalline precipitate should form indicating the presence of calcium ions.
	d) By XRD	X-ray diffraction diagram consists of a very broad, diffuse X-ray reflection; the Rosuvastatin calcium is therefore characterised as amorphous under X-ray.	X-ray diffraction diagram consists essentially of a very broad, diffuse X-ray reflection; the Rosuvastatin calcium is therefore characterised as amorphous under X-ray.
04	Water (% w/w, by KF, determined on 0.100 g)	3.0	Not more than 6.1
05	Enantiomeric Purity (By Chiral HPLC, % w/w)	Not detected	Not more than 0.1

	PREPARED BY	CHECKED BY	APPROVED BY
NAME	K.SILPA	B.V.KISHORE	D.SIVA RAMI REDDY
SIGNATURE			
DATE	12/12/2014	12/12/2014	12/12/2014

Head office: Aurobindo Pharma Ltd , The Water Mark Building , Plot No .11 , Survey No .9 , Kondapur, Hitech City , Hyderabad – 500084, INDIA.
Works: Unit-XI, Survey Nos. 61 – 66, IDA, Pydibhimavaram-532409, Ranasthalam Mandal, Srikakulam Dist, A.P., INDIA, Phone: +91 8942 288292/3.

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S No	TEST	RESULT	SPECIFICATION
06	Related Substances (By HPLC, %w/w)		
	Rosuvastatin diastereoisomer (or) Rosuvastatin anti isomer [Ph.Eur. Impurity B]	0.09	Not more than 0.5
	3-Hydroxy-5-keto rosuvastatin [Ph.Eur. Impurity C]	0.20	Not more than 0.8
	Rosuvastatin Lactone [Ph.Eur. Impurity D]	Below Limit of Quantification	Not more than 0.10
	Diene impurity	Below Limit of Quantification	Not more than 0.10
	Any other	0.06	Not more than 0.10
	Total	0.43	Not more than 1.2
07	Assay (By HPLC, %w/w, as $C_{44}CaH_{54}F_2N_6O_{12}S_2$, on anhydrous basis)	99.2	Not less than 97.0 and Not more than 102.0
08	Residual Solvents (By GC, µg/g)		
	Methanol	Below Limit of Quantification	Not more than 3000
	Tetrahydrofuran	Not detected	Not more than 720
	Ethanol	Below Limit of Quantification	Not more than 5000
	Methyl tert-Butyl ether	Below Limit of Quantification	Not more than 5000
09	Microbiological Quality		
	a) Total aerobic microbial count (TAMC), (cfu/g)	Less than 10	Not more than 1000 (10^3)
	Total combined yeasts / moulds count (TYMC), (cfu/g)	Less than 10	Not more than 100 (10^2)
	b) Escherichia coli	Absent	Should be absent
Additional test:			
10	Particle Size(By Malvern Particle size analyzer, µm)		
	D (v, 0.9)	35	Less than 40 µm

Remarks: The material Complies as per the above specifications.

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