

# AUROBINDO PHARMA LIMITED UNIT- XI

Survey No : 61 - 66, IDA, Pydibhimavaram, Srikakulam Dist - 532 409

## PACKING LIST

PRODUCT NAME : ROSUVASTATIN CALCIUM Ph.Eur.

PARTY NAME : METAPIHARMACEUTICAL IND SL

Date : 05.09.2015

Qty : 5.00 Kg

| S.No | BATCH No.  | DRUM No. | GROSS<br>WEIGHT<br>(Kg) | TARE<br>WEIGHT<br>(Kg) | NET<br>WEIGHT<br>(Kg) | SEAL<br>NUMBER | MFG. DATE  | RETEST DATE |
|------|------------|----------|-------------------------|------------------------|-----------------------|----------------|------------|-------------|
| 1    | 1511128062 | 01/01    | 7.19                    | 2.19                   | 5.00                  | 340157         | 18/12/2013 | 17/12/2015  |

|  |          |  |      |      |      |  |  |  |
|--|----------|--|------|------|------|--|--|--|
|  | TOTAL << |  | 7.19 | 2.19 | 5.00 |  |  |  |
|--|----------|--|------|------|------|--|--|--|

Prepared By  
Warehouse Dept :

*De/23*  
*05/09/2015*

Verified By  
Manufacturing Dept :

*Qmm*  
*05/09/2015*

Approved By  
Q.A Dept :

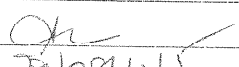
*Qb*  
*05/09/2015*

## CERTIFICATE OF ANALYSIS

|              |                              |                 |            |
|--------------|------------------------------|-----------------|------------|
| PRODUCT NAME | ROSUVASTATIN CALCIUM Ph.Eur. | PAGE No.        | 1 of 3     |
| BATCH NUMBER | 1511128062                   | A.R.No.         | 15FPR0020  |
| MFG. DATE    | 18/12/2013                   | RETEST DATE     | 17/12/2015 |
| QUANTITY     | 5.00 Kg                      | DATE OF RELEASE | 27/04/2015 |

| S No | TEST                                        | RESULT                                                                                                                                                                                   | SPECIFICATION                                                                                                                                                                                  |
|------|---------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 01   | Description                                 | 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 Enantiomeric purity 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 Enantiomeric purity 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) | 2.3                                                                                                                                                                                      | 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      | M.ARUNA DEVI                                                                        | B.V.KISHORE                                                                         | D.SIVA RAMI REDDY                                                                     |
| SIGNATURE |  |  |  |
| DATE      | 27/08/2015                                                                          | 29/08/2015                                                                          | 29/08/2015                                                                            |

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, Pydibhinevaram-532409, Ranasthalam Mandal, Srikakulam Dist, A.P., INDIA, Phone: +91 8942 288292/3



AUROBINDO

## CERTIFICATE OF ANALYSIS

|              |                              |                 |            |
|--------------|------------------------------|-----------------|------------|
| PRODUCT NAME | ROSUVASTATIN CALCIUM Ph.Eur. | PAGE No.        | 2 of 3     |
| BATCH NUMBER | 1511128062                   | A.R.No.         | 15FPR0020  |
| MFG. DATE    | 18/12/2013                   | RETEST DATE     | 17/12/2015 |
| QUANTITY     | 5.00 Kg                      | DATE OF RELEASE | 27/04/2015 |

| S No | TEST                                                                                | RESULT                        | SPECIFICATION                              |
|------|-------------------------------------------------------------------------------------|-------------------------------|--------------------------------------------|
| 06   | Related Substances (By HPLC, % w/w)                                                 |                               |                                            |
|      | Rosuvastatin diastereoisomer (or) Rosuvastatin anti isomer [Pharmeuropa Impurity B] | 0.09                          | Not more than 0.5                          |
|      | 3-Hydroxy-5-keto rosuvastatin [Pharmeuropa Impurity C]                              | 0.34                          | 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                                                                           | 0.07                          | Not more than 0.10                         |
|      | Total                                                                               | 0.54                          | Not more than 1.2                          |
| 07   | Assay (By HPLC, %w/w, as $C_{44}H_{54}F_2N_6O_{12}S_2$ , on anhydrous basis)        | 99.1                          | Not less than 97.0 and Not more than 102.0 |
| 08   | Residual Solvents (By GC, $\mu\text{g/g}$ )                                         |                               |                                            |
|      | Methanol                                                                            | Not detected                  | Not more than 3000                         |
|      | Tetrahydrofuran                                                                     | Not detected                  | Not more than 720                          |
|      | Ethanol                                                                             | Not detected                  | 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                           |

|           |              |             |                   |
|-----------|--------------|-------------|-------------------|
|           | PREPARED BY  | CHECKED BY  | APPROVED BY       |
| NAME      | M.ARUNA DEVI | B.V.KISHORE | D.SIVA RAMI REDDY |
| SIGNATURE |              |             |                   |
| DATE      | 29/08/2015   | 29/08/2015  | 29/08/2015        |

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## CERTIFICATE OF ANALYSIS

| PRODUCT NAME            | ROSUVASTATIN CALCIUM Ph.Eur.                                      | PAGE No.        | 3 of 3                       |
|-------------------------|-------------------------------------------------------------------|-----------------|------------------------------|
| BATCH NUMBER            | 1511128062                                                        | A.R.No.         | 15FPR0020                    |
| MFG. DATE               | 18/12/2013                                                        | RETEST DATE     | 17/12/2015                   |
| QUANTITY                | 5.00 Kg                                                           | DATE OF RELEASE | 27/04/2015                   |
| S No                    | TEST                                                              | RESULT          | SPECIFICATION                |
| <i>Additional Test:</i> |                                                                   |                 |                              |
| 10                      | Particle size (By Malvern Particle size analyzer, $\mu\text{m}$ ) |                 |                              |
|                         | D(v,0.9)                                                          | 33              | Less than 40 $\mu\text{m}$ . |

Remarks: The material Complies as per the above specifications.

|           |                                                                                     |                                                                                     |                                                                                       |
|-----------|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|
|           | PREPARED BY                                                                         | CHECKED BY                                                                          | APPROVED BY                                                                           |
| NAME      | M.ARUNA DEVI                                                                        | B.V.KISHORE                                                                         | D.SIVA RAMI REDDY                                                                     |
| SIGNATURE |  |  |  |
| DATE      | 29/08/2015                                                                          | 29/08/2015                                                                          | 29/08/2015                                                                            |