

Atenololum



Kopran

Certificate Of Analysis  
**ATENOLOL EP**

CIN - L 24230 MH 1958 PLC 011078

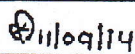
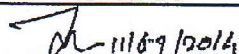
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|-------------------------------|-----------------------|-----------------------|
| BATCH No. <b>ALU/P1408025</b> | ANALYTICAL REPORT No. | MFG. DATE : AUG. 2014 |
| DISPATCH QTY. : 10.00 kg      | FPPA/140704           | EXP. DATE : JUL. 2019 |

| SR. No. | TESTS                                                                                                                                    | RESULTS                                                                            | SPECIFICATIONS                                                                                                                      |
|---------|------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------|
| 1       | APPEARANCE                                                                                                                               | A white powder                                                                     | White or almost white powder                                                                                                        |
| 2       | SOLUBILITY                                                                                                                               | Complies                                                                           | Sparingly soluble in water, soluble in ethanol, slightly soluble in methylene chloride.                                             |
| 3       | IDENTIFICATION                                                                                                                           | A. M. P. : 152.4°C<br>B. UV abs. R : 1.17<br>C. IR : Complies<br>D. TLC : Complies | A) Melting range: 152 to 155°C<br>B) By UV (Ratio of absorbance between 1.15 to 1.20)<br>C) By I.R.<br>D) By TLC                    |
| 4       | APPEARANCE OF SOLUTION                                                                                                                   | Clear and not more intensely coloured than degree 6                                | Solution S is clear & not more intensely coloured than degree 6 of the range of reference solutions of the most appropriate colour. |
| 5       | ANGLE OF OPTICAL ROTATION                                                                                                                | +0.0118°                                                                           | +0.10° TO -0.10°                                                                                                                    |
| 6       | RELATED SUBSTANCES<br>1) Impurity B<br>2) Impurity F<br>3) Impurity G<br>4) Impurity I<br>5) Unspecified Impurity<br>6) Total Impurities | 0.17 %<br>0.08%<br>Not Detected<br>Not Detected<br>0.06 %<br>0.32 %                | NMT 0.2%w/w<br>NMT 0.15%w/w<br>NMT 0.15%w/w<br>NMT 0.15%w/w<br>NMT 0.10%w/w<br>NMT 0.5%w/w                                          |
| 7       | CHLORIDE                                                                                                                                 | Complies                                                                           | NMT 0.1 % w/w                                                                                                                       |
| 8       | SULPHATED ASH                                                                                                                            | 0.08 %                                                                             | NMT 0.1 % w/w                                                                                                                       |
| 9       | LOSS ON DRYING                                                                                                                           | 0.31 %                                                                             | NMT 0.5 % w/w                                                                                                                       |
| 10      | ASSAY ON DRIED BASIS                                                                                                                     | 99.79 %                                                                            | 99.0 % to 101.0 % of C <sub>14</sub> H <sub>22</sub> N <sub>2</sub> O <sub>3</sub>                                                  |

THIS PRODUCT CONFORMS TO EP

DATE: 11/09/2014

This batch is in conformity with Pharm Eur & provisions of certificate of suitability R1-CEP 1998-017-Rev 03 granted to Kopran.

| PREPARED BY                                                                                                           | CHECKED BY                                                                                                               | APPROVED BY                                                                                                                 |
|-----------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------|
| <br>S. D. Kamerkar<br>Officer - QA | <br>M. G. Sutar<br>Asst. Manager - QC | <br>Samir S. Sumbhe<br>Manager - QA/QC |

C. O. A. issued to : M/s. ACETO BV, THE NETHERLAND



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