

### CERTIFICATE OF ANALYSIS

| <b>PRODUCT : DILTIAZEM HCl</b><br>(MICRONISED)      |  | <b>COMPENDIA : Ph.Eur.-7.7</b>  |
|---|--|---|
| <b>BATCH NO. : DIL/M-15213</b>                      |  | <b>QUANTITY : 500 Kg</b>  |
| <b>MFG. DATE : AUGUST.2013</b>                      |  | <b>EXP. DATE : JULY.2018</b>  |
| <b>QC A.R. No.: FP/184/2013</b>                     |  |   |
| TESTS   | RESULTS  | SPECIFICATIONS  |
| <b>01. CHARACTERS</b>                               |  |   |
| i. Appearance                                       | A white, crystalline powder.   | White or almost white, crystalline powder.  |
| ii. Solubility                                      | Freely soluble in water, in methanol and in methylene chloride, slightly soluble in anhydrous ethanol. | Freely soluble in water, in methanol and in methylene chloride, slightly soluble in anhydrous ethanol.              |
| iii. Melting point                                  | Melted at 213°C with decomposition   | Melts at about 213° C with decomposition.   |
| <b>02. IDENTIFICATION</b>                           |  |   |
| IR Absorption                                       | Concordant with working standard   | IR Absorption spectrum of the sample is concordant with that of the Diltiazem hydrochloride CRS / working standard. |
| CHLORIDES   | Positive   | It gives reaction to chlorides.   |
| <b>03. APPEARANCE OF SOLUTION</b>                   | Clear and colorless  | Clear and colourless.   |
| <b>04. pH</b>                                       | 4.9  | 4.3 to 5.3  |
| <b>05. SPECIFIC OPTICAL ROTATION</b>                | +117°  | + 115° to + 120°  |
| <b>06. RELATED SUBSTANCES</b>                       |  |   |
| i. Impurity F                                       | Not Quantified   | Not more than 0.3% w/w  |
| ii. Unspecified Impurities                          | Not Quantified   | Not more than 0.10% w/w each  |
| iii. Total Impurities                               | Not Quantified   | Not more than 0.30% w/w   |
| <b>07. HEAVY METALS</b>                             | Less than 10 ppm   | Not more than 10 ppm  |
| <b>08. LOSS ON DRYING</b>                           | 0.20%  | Not more than 0.50% w/w   |
| <b>09. SULPHATED ASH</b>                            | 0.03%  | Not more than 0.10% w/w   |
| <b>10. ASSAY (By Titration)</b><br>(On dried basis) | 100.00%  | Not less than 98.50% w/w and Not more than 101.00% w/w  |
| <b>ADDITIONAL TEST:</b>                             |  |   |
| <b>PARTICLE SIZE</b>                                |  |   |
| 100%  | 24 Microns   | 100% Less than 100 Microns  |
| <b>Surface Area</b>                                 |  |   |
|   | 1.84 m <sup>2</sup> /gm  | For Information   |
| <b>RESIDUAL SOLVENTS</b>                            |  |   |
| Toluene   | 249 ppm  | Not more than 750 ppm   |
| Methanol  | 86 ppm   | Not more than 500 ppm   |
| Isopropyl Alcohol                                   | 2 ppm  | Not more than 1000 ppm  |
| Ethyl Acetate                                       | 1 ppm  | Not more than 2500 ppm  |
| Bulk Density  | 0.26 g/ml  | For Information   |
| Tapped Density                                      | 0.48 g/ml  | For Information   |

**REMARKS:** The product conforms to Ph.Eur.-7.7 & Customer's Specifications

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