



CERTIFICATE OF ANALYSIS

| PRODUCT : DILTIAZEM HCl (MICRONISED) | | COMPENDIA : Ph.Eur.-7.7 |
|---|--|---|
| BATCH NO. : DIL/M-01214 | | QUANTITY : 500 Kg |
| MFG. DATE : JANUARY.2014 | | EXP. DATE : DECEMBER.2018 |
| QC A.R. No.: FP/016/2014 | | |
| TESTS | RESULTS | SPECIFICATIONS |
| 01. CHARACTERS | | |
| 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. |
| 02. IDENTIFICATION | | |
| 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. |
| 03. APPEARANCE OF SOLUTION | Clear and colorless | Clear and colourless. |
| 04. pH | 4.9 | 4.3 to 5.3 |
| 05. SPECIFIC OPTICAL ROTATION | +117° | + 115° to + 120° |
| 06. RELATED SUBSTANCES | | |
| 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 |
| 07. HEAVY METALS | Less than 10 ppm | Not more than 10 ppm |
| 08. LOSS ON DRYING | 0.27% | Not more than 0.50% w/w |
| 09. SULPHATED ASH | 0.04% | Not more than 0.10% w/w |
| 10. ASSAY (By Titration) | 99.91% | Not less than 98.50% w/w and Not more than 101.00% w/w |
| (On dried basis) | | |
| ADDITIONAL TEST: | | |
| PARTICLE SIZE | | |
| 100% | 40 Microns | 100% Less than 100 Microns |
| Surface Area | 1.75 m ² /gm | For Information |
| RESIDUAL SOLVENTS (BY GC-HS) | | |
| Toluene | 300 ppm | Not more than 750 ppm |
| Methanol | 300 ppm | Not more than 500 ppm |
| Isopropyl Alcohol | 6 ppm | Not more than 1000 ppm |
| Ethyl Acetate | 14 ppm | Not more than 2500 ppm |
| Bulk Density | 0.27 g/ml | For Information |
| Tapped Density | 0.51 g/ml | For Information |

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

Deew
**Prepared by
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