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Certificate of Analysis

Product 17156 - Azithromycin Dihydrate (AZA), 96% -
[117772-70-0]
Batch No 4456142
Analysis Date 05-Mar-2024
Date of Manufacture March 2024
Expiry Date/Re-Test Date March 2029
Molecular Formula C₃₈H₇₂N₂O₁₂·2H₂O
Molecular Weight 785.02

| Test Parameters | Standards | Actual Results |
|--|--------------------------------|----------------|
| Appearance (Colour) | White | White |
| Appearance (Form) | Powder | Powder |
| Solubility (Turbidity) 1% solution in Ethanol | Clear | Clear |
| Assay | min.96% | 100.2% |
| pH (0.2% in 1:1 Methanol : Water) | 9.0 - 11.0 | 10.1 |
| Specific rotation [α] | - 45° to - 49° (C=1 , Ethanol) | - 45.783° |
| Water (KF) | 4.0 - 5.0% | 4.9% |
| Not for medicinal use | | |

FRM/82/11/4/17156 Rev No. 1 Date 07/25/2017

Prepared by Dnyaneshwar

In compliance with the standard specifications of SRL

Plant Site 2 : H-4, MIDC, Talaja – 410 208, Maharashtra, India

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