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Certificate of Analysis

| Property | Specification | Batch 481AUV |
|-------------------------------------|------------------------------|---------------------|
| Physical Description | White or almost white powder | Almost white powder |
| Identification (IR) | To conform to test A | Conforms |
| Identification (TLC) | To conform to test B | Conforms |
| Specific Optical Rotation ([α]20/D) | +63 - +70 ° (c=1, dioxane) | 66.6° |
| Loss on Drying | ≤ 1.0% (105°C, 3h) | 0.9% |
| Residue on Ignition | ≤ 0.2% | 0.04% |
| Any Individual Impurity | ≤ 1.0% | 0.1% |
| Total Impurities | ≤ 2.0% | 0.3% |
| Assay | 97.0 - 103.0 % (dried basis) | 98.3% |
| Pharmacopoeia Specification(s) | USP | Conforms |
| | | |
| Specification Varsian v1.0 | | |

| v1.0 |
|------------|
| 2023-11-16 |
| 2032-02-26 |
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