# SHANDONG OCTAGON CHEMICALS LIMITED

## CERTIFICATE OF ANALYSIS

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|---|---|---|---|
| Product name | Tacrolimus (Cas 104987-11-3) | | |
| Batch No. | 21100503 | Mfg. date | 2021.10.15 |
| Rep. Date | 2022.01.03 | Exp. date | 2023.10.14 |
| Packaging | 1kg/Tin | Batch Size | 1.328KG |
| Test Items | Standards: USP42 | | Results |
| Appearance | White crystals or white crystalline powder | | White crystalline powder |
| Identification | A. Infrared Absorption | | Complies |
| | B. The retention time of the major peak of the sample solution corresponds to that of standard solution as obtained in the assay | | Complies |
| Residue on ignition | NMT0.1% | | 0.01% |
| Heavy metals | NMT10ppm | | <10ppm |
| Optical rotation | -110 ~ -115° | | -112° |
| Water | NMT4.0% | | 2.9% |
| Organic impurities | Ascomycin 19-Epimer: NMT0.1%<br>Ascomycin: NMT0.5%<br>Desmethyl Tacrolimus: NMT0.1%<br>Tacrolimus 8-epimer: NMT0.15%<br>Tacrolimus 8-propyl analog: NMT0.15%<br>Any individual unspecified impurity: NMT0.1%<br>Total impurities: NMT1.0% | | ND<br>ND<br>ND<br>ND<br>ND<br>ND<br>ND |
| Residual solvents | Ethanol: NMT0.5%<br>Acetone: NMT0.5%<br>Ethyl acetate: NMT0.5%<br>Isopropyl ether: NMT0.05% | | ND<br>ND<br>0.001%<br>ND |
| Assay | 98.0%~102.0% (on dried basis) | | 101.4% |
| Conclusion | It meets the requirements of USP42 Standards | | |
| Storage | Preserve in a well-closed container. | | |

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