



# CERTIFICATE OF ANALYSIS

Date: 03-09-2026

|                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |               |             |
|--------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|-------------|
| Product Name                   | Tacrolimus EP Impurity E                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |               |             |
| Chemical Name                  | (3S,4R,5S,8R,9E,12S,14S,15R,16S,18R,19R,26aS)-5,19-Dihydroxy-3-[(1E)-1-[(1R,3R,4R)-4-hydroxy-3-methoxycyclohexyl]prop-1-en-2-yl]-14,16-dimethoxy-4,10,12,18-tetramethyl-8-propyl-3,4,5,6,8,11,12,13,14,15,16,17,18,19,24,25,26,26a-Hexadecahydro-7H-15,19-epoxypyrido[2,1-c][1,4]oxaazacyclotricosine-1,7,20,21(23H)-tetrone ;(3S,4R,5S,8R,9E,12S,14S,15R,16S,18R,19R,26aS)-5,6,8,11,12,13,14,15,16,17,18,19,24,25,26,26a-Hexadecahydro-5,19-dihydroxy-3-[(1E)-2-[(1R,3R,4R)-4-hydroxy-3-methoxycyclohexyl]-1-methylvinyl]-14,16-dimethoxy-4,10,12,18-tetramethyl-15,19-epoxy-8-propyl-3H-pyrido[2,1-c][1,4]oxaazacyclotricosine-1,7,20,21(4H,23H)-tetrone (as per USP) |               |             |
| Structure                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |               |             |
| Batch No.                      | -                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | CAS No.       | 104987-30-6 |
| Analysis Date                  | -                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Retest Date   | 2           |
| Mol. Formula                   | C <sub>49</sub> H <sub>76</sub> NO <sub>12</sub>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Molecular Wt. | 806         |
| Long term Storage Condition    | Store at 2-8 °C in well closed container                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |               |             |
| Handling and Transit Condition | 25-30 °C in well closed container                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |               |             |

| Test                                                                                                                                                                                                                            | Result                |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Appearance                                                                                                                                                                                                                      | -                     |
| Solubility                                                                                                                                                                                                                      | -                     |
| <sup>1</sup> H-NMR                                                                                                                                                                                                              | Conforms to structure |
| MASS                                                                                                                                                                                                                            | Conforms to structure |
| Chromatographic Purity                                                                                                                                                                                                          | >90%                  |
| <b>Note: This material should be used for research purpose and not for human or animal consumption. Any patent applicable for this product in any country is not applicable for this analytical standard/research chemical.</b> |                       |

|           | Prepared By | Checked By | Approved By |
|-----------|-------------|------------|-------------|
| Signature |             |            |             |
| Date      |             |            |             |

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