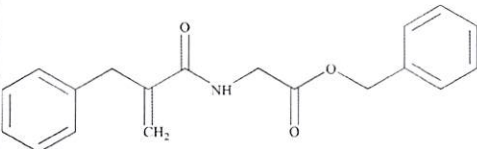


Certificate of Analysis



Certificate No.: 20250509011

Date: May 9, 2025

Retest date: May 8, 2028

| | | |
|------------------------------|---|--|
| Compound Name: | Racecadotril EP Impurity F | |
| Synonyms: | benzyl (2-benzylacryloyl)glycinate | |
| TLC Catalogue Number: | R-734 |  |
| CAS Number: | 87428-99-7 | |
| Alternate CAS Number: | N/A | |
| Molecular Weight: | 309.37 | |
| Molecular Formula: | C ₁₉ H ₁₉ NO ₃ | |
| Source: | TLC Pharmaceutical Standards | |
| Source Lot No.: | 1573-013A5 | |
| Storage Conditions: | Store at 2-8 °C | |
| Solubility: | Methanol | |

| Test Description | Specifications | Results |
|--------------------------------|--------------------------------|-----------------|
| Visual Description | White to off-white solid | Conforms |
| Identification | | |
| IR | Conforms to structure | Conforms |
| MS | Conforms to structure | Conforms |
| ¹ H NMR | Conforms to structure | Conforms |
| Purity (HPLC) | Not less than 95.0% | 99.5% |
| Impurity (HPLC) | RT 2.26, 0.31%; RT 6.61, 0.12% | |
| Water Content (KF) | N/A | 0.2% |
| Residual Solvents (NMR) | 0.1% <i>n</i> -hexane | |
| Assay (%) | Not less than 90.0% | 99.2% |
| Recommendation: | Release. | |

| Name | Department | Signature | Date |
|---------------------------|-------------------|--|------------|
| Reviewed and approved by: | Quality Control |  | 05/09/2025 |
| Approved by: | Quality Assurance |  | 05/09/2025 |

Attachments: Peak Attribution Table, HPLC, IR, MS and NMR spectra.