

Certificate of Analysis

Structure

Product Name

Gliclazide EP Impurity B

Synonyms

2-Nitrosooctahydrocyclopenta[c]pyrrole

<u>CAS Number</u> <u>Molecular Formula</u>

54786-86-6 C₇H₁₂N₂O

Molecular Weight Mfg. Date Re-Test Date

140.18 g/mol 14-11-2025 13-11-2028

Shipping Condition

All Product are stable to be shipped at room temperature, unless otherwise specified.

Long Term Storage Conditions

 $2^{\circ}C \sim 8^{\circ}C$ Protected from light and Sealed

Analytical Information

| Test | Specifications | Results |
|-------------------------------------|---------------------------|------------------|
| Appearance | Yellow Color Oil | Yellow Color Oil |
| Solubility | Soluble in DMSO, Methanol | Conforms |
| Purity by HPLC | Not less than 90.00% | 99.64% |
| Identification by ¹ HNMR | Conforms to structure | Complies |
| Identification by Mass | Conforms Molecular Weight | Complies |
| Identification by IR | Conform functional groups | Complies |
| Weight Content By TGA | Not specified | 1.644% |
| Residue of Ignition By TGA | Not specified | 0.000% |
| Potency | Not specified | 98.00% |

Prepared by

Muly 1. Makedr Reviewed & Approved by

