



IP Insulin Lispro RS (Est 2017): Qty-5.79 mg

LEAFLET supplements the currently valid Indian Pharmacopoeia Insulin Lispro monographs describing the suitable use of this Reference Standard.

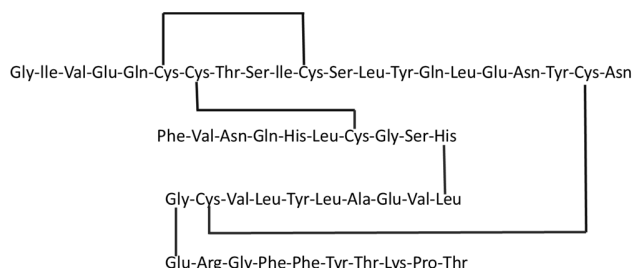
Cat. No. Insulin Lispro HIL-02
Lot : N17-1

Insulin Lispro

Molecular Formula: $C_{257}H_{383}N_{65}O_{77}S_6$

Molecular weight: 5808

Structure:



1. INTRODUCTION

Insulin Lispro is produced by a method based on recombinant DNA (r-DNA) technology. For establishment of National Reference Standard for Insulin Lispro, a collaborative study with participating laboratories, namely manufacturers and regulatory authorities (Pharmacopoeial labs and National Control Laboratory) was conducted after agreeing on the protocol, modalities and time schedules. National Reference Standard serves as Indian Pharmacopoeia Reference Substance (IPRS). The preparation in the vial was tested at six laboratories as per the approved protocol. NIB coordinated the study, the data was compiled & preliminary report was communicated to the

participants and in May 2017 IP Insulin Lispro RS was established.

Additional information inclusive of Safety Data Sheet on IP Insulin Lispro RS available on NIB website

2. VIAL CONTENT

2.1. Each glass vial contains 5.79 mg of Insulin Lispro on as is basis.

2.2. Vials bear Catalogue No. & Lot No. **N17-1**

3. UNITAGE

0.0347 mg Insulin Lispro is equivalent to 1 unit of Insulin Lispro

4. INTENDED USE

Reference standard for laboratory tests as prescribed in Indian Pharmacopoeia monograph only.

5. VALIDITY

The reference standard remains valid with the assigned potency & status until retested, withdrawn or amended.

6. STORAGE, SHIPPING & DIRECTIONS FOR USE

6.1 Store protected from light and moisture, at or below -18°C . When thawed, store at $5\pm 3^{\circ}\text{C}$.

6.2 Allow container to reach from -18°C or below to $5\pm 3^{\circ}\text{C}$ and then to room temperature before use.

6.3 The vials will be shipped at sub-zero temperatures in dry ice.

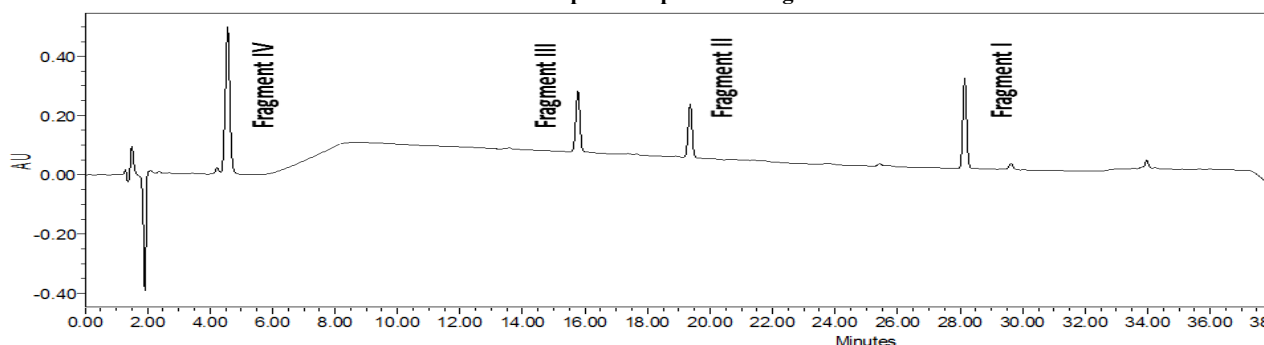
6.4 Do not dry. Keep container tightly closed. Hygroscopic. Read Safety Data Sheet before use.

6.5 Reconstitute contents of entire vial at a time. Do not weigh.

7. DISCLAIMER

User shall take the responsibility for any misuse & storage of Reference Standard under inappropriate conditions or used for purposes other than those intended.

Peptide Map Chromatogram



Peak Identification

Fragment I: Amino acids A5 to A17 & B1 to B13

Fragment II: Amino acids A18 to A21 & B14 to B21

Fragment III: Amino acids B22 to B30

Fragment IV: Amino acids A1 to A4

This chromatogram is for information only to assist in identifying peaks due to digest fragments I, II, III & IV

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Validity: Till further
revision

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