



IP Reference Standard (Est 2010): **Human Insulin: Qty-100mg**

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

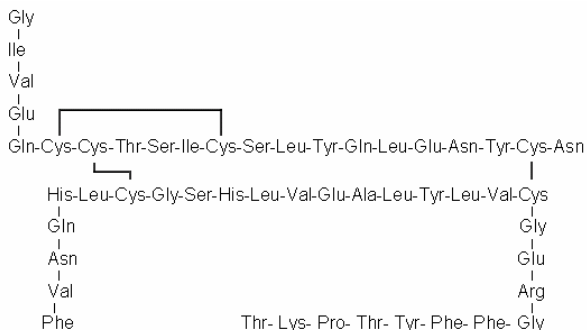
Cat. No. Insulin HI-01
Lot : N10-1

Human Insulin-IP-2010

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

Molecular weight: 5808.0

Structure:



1. INTRODUCTION

Inter Collaborative meetings with participating laboratories, IPC and regulatory authorities held in March & October 2009 agreed on the protocols, modalities and time schedules for the preparation of IP Reference Standard for Human Insulin. The coded API was tested at four laboratories as per the approved protocol. NIB coordinated the study, the data was compiled & Preliminary Report was communicated to the Participants and on 26 August 2010 IPRS for Human Insulin was established.

Further information on IPRS- Human Insulin available on NIB website

1.1 Chromatogram of IPRS- Human Insulin.

1.2 Material Safety Data Sheet dated 26.08.2010(**Caution:** this preparation is not for administration to Humans)

2. VIAL CONTENT

2.1 Each amber colour glass vial contains approx. 100mg of Human Insulin Crystals, and filled under conditions of controlled low humidity and temperature.

2.2 Vials bearing Catalogue No. & Lot are with flip off coloured seal.

3. UNITAGE

Each mg represents an activity of 27.5 IP human insulin units.

3.1 Intended to serve:

3.1.1 Quantitative uses in assays for rh- Insulin Bulk and formulations either by biological methods or by physicochemical techniques such as HPLC.

3.1.2 Qualitative uses such as identification test, system suitability tests chromatographic peak markers.

3.2 Expiry date

The standard remains valid with the assigned potency & status until retested, withdrawn or amended.

4. STORAGE, DISPATCH & DIRECTION FOR USE

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

4.2 The vials will be dispatched at sub-zero temperatures

4.3 Do not dry. Keep container tightly closed. Hygroscopic.

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

4.5 Read Material Safety Data Sheet before use.

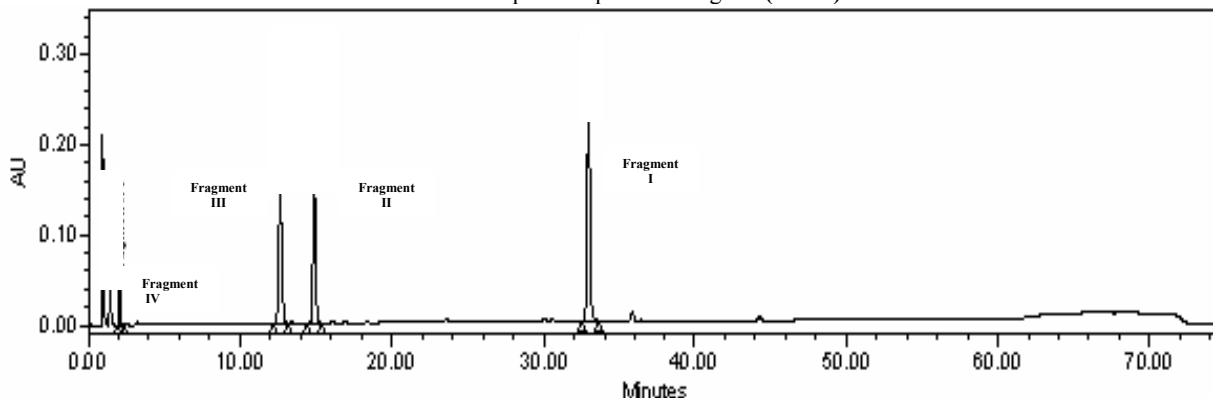
5. PARTICIPANTS

National Institute of Biologicals and manufacturers of Insulin.

6. DISCLAIMER

NIB is not responsible in any case for any misuse & storage of Reference Standard under inappropriate conditions or used for purposes other than those intended

Peptide map Chromatogram (2.3.47)



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