

## RECOMBINANT HUMAN INSULIN-BULK (*RDNA ORIGIN*)

**Catalogue No:** 511-016-\*\*

**Shipping:** On dry ice

**Lot No:** 511016023

**Storage:** Keep frozen at -20°C.

**Expiration date:** 11/2026

**M.W:** 5808g/mol

This recombinant insulin is produced in *Saccharomyces Cerevisiae* (Yeast).

| TEST                                                             | SPECIFICATION                                                                                                                                          | UNITS | RESULTS  |
|------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------|-------|----------|
| Appearance                                                       | Almost white powder                                                                                                                                    |       | Complies |
| Endotoxin                                                        | ≤ 10                                                                                                                                                   | EU/mg | < 5      |
| Solubility                                                       | Dissolve with distilled water and adjust pH with HCl (0.1 or 0.01N). The solution becomes clear as it approaches the isoelectric point of the product. |       | Complies |
| Related compounds:                                               |                                                                                                                                                        |       |          |
| A21 Desamido Human insulin                                       | ≤ 2.0                                                                                                                                                  | %     | 0.3      |
| Other related proteins                                           | ≤ 2.0                                                                                                                                                  | %     | 0.4      |
| Bioidentity                                                      | ≥ 15                                                                                                                                                   | U/mg  | Complies |
| Zinc (on dried basis)                                            | ≤ 1.0 (w/w)                                                                                                                                            | %     | 0.4      |
| Assay (by HPLC): Content of Insulin + A21 Desamido Human insulin | ≥ 27.5 Human Insulin                                                                                                                                   | U/mg  | 28.6     |
| Assay (dry basis)                                                | 95.0 -105.0                                                                                                                                            | %     | 100.2    |
| Bioburden                                                        | 0 -300                                                                                                                                                 | CFU/g | < 5      |
| Loss on drying                                                   | ≤ 10.00 (w/w)                                                                                                                                          | %     | 3.2      |
| Host Cell derived proteins                                       | ≤ 10                                                                                                                                                   | ppm   | <10.00   |
| Limit of high molecular weight proteins                          | ≤ 1.0 (w/w)                                                                                                                                            | %     | 0.2      |
| Sulfated Ash (NMT)                                               | ≤ 2.5                                                                                                                                                  | %     | 1.2      |

### Identification:

a) RT Comparison: Retention time of sample and standard in assay chromatogram should be comparable.

b) Peptide mapping: the chromatographic profile of the test digest solution should correspond to that of the standard digest solution

Insulin is made in India by Biocon

**AVOID INHALATION AND SKIN CONTACT!**

**KEEP TIGHTLY CLOSED. AVOID MOISTURE.**

## Primary Structure

