WISENT BIOPRODUCTS

CERTIFICATE OF ANALYSIS

RECOMBINANT HUMAN INSULIN-BULK *(rDNA ORIGIN)*

Catalogue No: 511-016-**

Lot No: 511016027

Expiration date: 07/2028

Shipping: On dry ice

Storage: Keep frozen at -20°C.

M.W: 5808g/mol

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

TEST	SPECIFICATION	UNITS	RESULTS
Appearance	White to almost white powder		Complies
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	%	<2.0
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	28.7
Assay (dry basis)	95.0 -105.0	%	100.1
Bioburden	0 -300	CFU/g	< 5
Loss on drying	≤ 10.00 (w/w)	%	4.3
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	%	1.4

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

Glu – Val – Ile – Gly – H
4 3 2 1

Chain A

Gln – Cys – Cys – Thr – Ser – Ile – Cys – Ser – Leu – Tyr – Gln – Leu- Glu – Asn- - Tyr – Cys - Asn – OH
5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21

Gln – His – Leu – Cys – Gly – Ser – His – Leu – Val – Glu – Ala – Leu – Tyr – Leu - Val – Cys –Gly - Glu
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21

Asn – Val – Phe – H *Chain B* HO – Thr – Lys – Pro – Thr – Tyr – Phe – Phe – Gly - Arg
3 2 1 30 29 28 27 26 25 24 23 22