



Certificate of Analysis

Page 1 of 2

GEM-700-112P

Bovine Insulin Powder

Catalogue no:	GEM-700-112P
Product Name	Insulin from bovine pancreas ≥27 USP units/mg (HPLC), powder
CAS Number	11070-73-8
Molecular Weight	5733.49

Description	Insulin is purified from an ethanol/phosphoric acid extract of bovine pancreas by multiple ammonium sulphate and isoelectric precipitations. It is then crystallized without zinc followed by crystallization with zinc. The zinc content of the final product is approximately 0.5%. Zinc can be removed by solubilizing the insulin in dilute acetic acid, adding excess EDTA to chelate the zinc and then precipitating the insulin at its pI.7.
Solubility/Stability	Insulin has low solubility at neutral pH. It can be solubilized at 2mg/mL in dilute acetic or hydrochloric acid, pH 2-3. Insulin solutions cannot be autoclaved. Insulin can also be solubilised in 125 mM NaHCO ₃ however; alkaline stock solutions are not recommended since high pH increases the rate of deamidation and aggregation.
Physical Appearance	White to off-white powder
Source	Bovine pancreas
Storage	Insulin should be stored, protected from light, in a desiccator at -20°C. A stock solution can be stored frozen at 20°C in single-use aliquots. Freeze-thaw cycles should be avoided. Alternatively, it can be stored for up to 12 months at 2-8°C if it is sterile-filtered through a low protein binding membrane or if it contains a suitable bacteriostat, such as 0.1% thimerosal or sodium azide.

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Test	Specification
Appearance	White to off white powder
Solubility	Clear colourless solution at 2mg plus 1ml water (pH adjusted to 20.0 with Hydrochloric Acid)
Elemental Analysis	14.5 to 16.0% Nitrogen approx 0.5% Zinc
Loss on drying	NMT 10%
HPLC Potency	NLT 27 USP units/mg

For further manufacturing or laboratory use. Not for human or animal consumption.

Signed:



for SLI Ltd.

the serum and antibody specialists

Date: 7 October 2011

Gentaur Molecular Products
Voortstraat 49
1910 Kampenhout, Belgium