

Code No.09-0647

SPECIFICATION

Insulin, Human, recombinant for Cell Culture

REQUIREMENT	SPECIFICATION
Appearance	White ~ nearly white, crystals ~ powder
Solubility in dil.hydrochloric acid	to pass test
Loss on drying at 105°C	max.10.0%
Bacterial endotoxins	max.10EU/mg
Zinc (Zn) (after drying)	max.1.0%
Total nitrogen (N) (calculated on the dried basis)	13.0~17.0%
Mass spectrometry (MALDI-TOF)	to pass test
Potency (calculated on the dried basis)	min.27.5units/mg

Source:Pichia pastoris expressed human insulin