

 $C_{256}H_{381}N_{65}O_{76}S_6$ (pork)

 $C_{254}H_{377}N_{65}O_{75}S_6$ (beef)

Definition. Insulin is the natural antidiabetic hormone obtained from pork or beef pancreas and purified.

Chemical name. [Pork] Insulin; porcine insulin; CAS Reg. No. 12584-58-6.

[Beef] Insulin; bovine insulin; CAS Reg. No. 11070-73-8.

Description. A white or almost white powder; odourless.

Solubility. Practically insoluble in water, ethanol (~750 g/l) TS, and ether R; dissolves in dilute solutions of mineral acids and alkali hydroxides.

Category. Antidiabetic agent.

Storage. Insulin should be kept in a tightly closed container, protected from light, and stored at a temperature not below -20 °C.

Labelling. The designation on the container should state the animal source of the insulin; expiry date.

Additional information. Insulin is hygroscopic; it degrades in solutions of alkali hydroxides. Attention should be paid to the microbiological quality since Insulin is of natural origin.

The quality of insulin, which represents a unique case among preparations in the WHO Model List of Essential Drugs, cannot be adequately controlled by methods adopted for *The International Pharmacopoeia*. Therefore, it is advised to refer to methods described in other pharmacopoeias, such as those of China, Europe, Japan, UK, and USA.