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Insulin Zinc Suspension (Crystalline)

General Notices

(Insulin Zinc Injectable Suspension (Crystalline), Ph. Eur. monograph 0836)

Action and use

Hormone; treatment of diabetes mellitus.

Ph Eur

Insulin zinc injectable suspension (crystalline) complies with the monograph Insulin preparations, injectable (0854) with the amendments prescribed below.

DEFINITION

Insulin zinc injectable suspension (crystalline) is a sterile, neutral suspension of human or porcine insulin, complexed with a suitable zinc salt; the insulin is in a form which is practically insoluble in water.

CHARACTERS

A white or almost white suspension which on standing deposits a white or almost white sediment and leaves a colourless or almost colourless supernatant; the sediment is readily resuspended by gently shaking. When examined under a microscope, the particles are seen to be rhombohedral crystals, the majority having a maximum dimension when measured from corner to corner through the crystal greater than 10 µm but rarely exceeding 40 µm.

IDENTIFICATION

Examine the chromatograms obtained in the assay. The position of the peak due to insulin in the chromatogram obtained with the test solution corresponds to that of the principal peak in the chromatogram obtained with the appropriate reference solution.

TESTS

Insulin not extractable with buffered acetone solution

Not less than 90 per cent of the total insulin content. Centrifuge a volume of the substance to be examined containing 200 IU of insulin and discard the supernatant. Suspend the residue in 1.65 mL of *water R*, add 3.3 mL of *buffered acetone solution R*, stir for 3 min, again centrifuge, discard the supernatant and repeat all the operations with the residue. Dissolve the residue using a suitable procedure, for example dissolve in *0.1 M hydrochloric acid* to give a final volume of 2.0 mL. Determine the insulin content of the residue (*R*) and determine the total insulin content (*T*) of an equal volume of the suspension by a suitable method. Calculate the percentage of insulin not extractable with buffered acetone solution from the expression:

Total zinc

0.12 mg to 0.25 mg per 100 IU of insulin, determined as described in the monograph *Insulin preparations, injectable (0854)*.

Zinc in solution

20 per cent to 65 per cent of the total zinc is in the form of zinc in solution. Determine by the method described in the monograph *Insulin preparations, injectable (0854)*.

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