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Insulin Zinc Suspension

General Notices

Insulin Zinc Suspension, Mixed

(Insulin Zinc Injectable Suspension, Ph. Eur. monograph 0837)

Action and use

Hormone; treatment of diabetes mellitus.

Ph Eur

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

DEFINITION

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

PRODUCTION

Insulin zinc injectable suspension is prepared by carrying out the procedures described in the monograph *Insulin preparations, injectable (0854)*.

Insulin zinc injectable suspension is produced by mixing insulin zinc injectable suspension (crystalline) and insulin zinc injectable suspension (amorphous) in a ratio of 7 to 3.

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 majority of the particles are seen to be rhombohedral crystals with a maximum dimension when measured from corner to corner through the crystal greater than 10 µm but rarely exceeding 40 µm; a considerable proportion of the particles are seen to have no uniform shape and a maximum dimension rarely exceeding 2 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

63 per cent to 77 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:

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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)*.

Ph Eur