



Edition: BP 2025 (Ph. Eur. 11.6 update)

## Insulin Zinc Suspension (Amorphous)



### [General Notices](#)

(*Insulin Zinc Injectable Suspension (Amorphous)*, Ph. Eur. monograph 0835)

### Action and use

Hormone; treatment of diabetes mellitus.

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*Insulin zinc injectable suspension (amorphous) complies with the monograph [Insulin preparations, injectable \(0854\)](#) with the amendments prescribed below.*

## DEFINITION

Insulin zinc injectable suspension (amorphous) 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 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

### 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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