



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

## Insulin Injection



### [General Notices](#)

Neutral Insulin

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Soluble Insulin

*(Soluble Insulin Injection, Ph. Eur. monograph 0834)*

### Action and use

Hormone; treatment of diabetes mellitus.

Ph Eur

*Soluble insulin injection complies with the monograph [Insulin preparations, injectable \(0854\)](#) with the amendments prescribed below.*

## DEFINITION

Soluble insulin injection is a neutral, sterile solution of human or porcine insulin.

## CHARACTERS

A colourless liquid, free from turbidity and foreign matter; during storage, traces of a very fine sediment may be deposited.

## 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

Not more than 40.0 µg per 100 IU of insulin.

Determine by the method described in the monograph on [Insulin preparations, injectable \(0854\)](#).

*Use the following test solution.*

**Test solution** Dilute a volume of the gently shaken preparation containing 200 IU to 25.0 mL with [water R](#). Dilute if necessary to a suitable concentration (for example, 0.4 µg to 1.6 µg of Zn per millilitre) with [water R](#).

