



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

## Hyaluronidase Injection

### [General Notices](#)

#### Action and use

Used to promote absorption of fluid into tissues.

### DEFINITION

Hyaluronidase Injection is a sterile solution of Hyaluronidase in Water for Injections. It is prepared by dissolving Hyaluronidase for Injection in the requisite amount of Water for Injections immediately before use.

*The injection complies with the requirements stated under Parenteral Preparations.*

### STORAGE

Hyaluronidase Injection should be used immediately after preparation.

## HYALURONIDASE FOR INJECTION

### DEFINITION

Hyaluronidase for Injection is a sterile material consisting of Hyaluronidase with or without [excipients](#). It is supplied in a sealed container.

*The contents of the sealed container comply with the requirements for Powders for Injections or Infusions stated under Parenteral Preparations and with the following requirements.*

#### Potency

The estimated potency is not less than 90% and not more than 115% of the stated potency.

### IDENTIFICATION

A solution containing 100 IU in 1 mL of a 0.9% w/v solution of [sodium chloride](#) depolymerises an equal volume of a 1% w/v solution of [sodium hyaluronate EPBRP](#) at 20° in 1 minute, as shown by a pronounced decrease in [viscosity](#). This action is destroyed by heating the initial solution at 100° for 30 minutes.

### TESTS

### Acidity or alkalinity

pH of a 0.3% w/v solution in [carbon dioxide-free water](#), 4.5 to 7.5, [Appendix V L](#).

### Clarity and colour of solution

A 1.0% w/v solution in [carbon dioxide-free water](#) is *clear*, [Appendix IV A](#), and not more than faintly yellow.

### Bacterial endotoxins

Carry out the [test for bacterial endotoxins](#), [Appendix XIV C](#). Dissolve the contents of the sealed container in [water BET](#) to give a solution containing 150 IU of Hyaluronidase per mL (solution A). The endotoxin limit concentration of solution A is 30 IU per mL.

## ASSAY

Carry out the Assay described under Hyaluronidase.

## LABELLING

The label of the sealed container states the total number of IU (Units) contained in it.