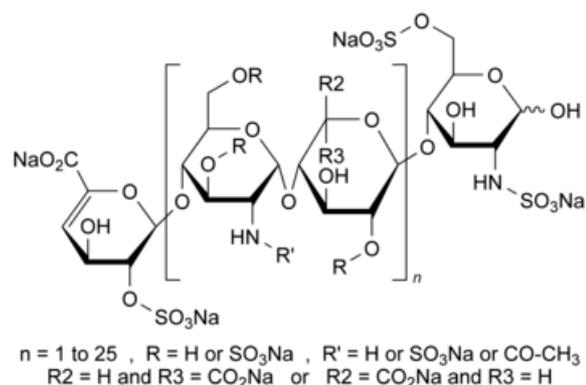


Edition: BP 2025 (Ph. Eur. 11.6 update)

## Tinzaparin Sodium

### [General Notices](#)

(Ph. Eur. monograph 1271)



### Action and use

Low molecular weight heparin.

### Preparation

[Tinzaparin Sodium Injection](#)

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## DEFINITION

Tinzaparin sodium is the sodium salt of a low-molecular-mass heparin that is obtained by controlled enzymatic depolymerisation of heparin from porcine intestinal mucosa using heparinase from *Flavobacterium heparinum*. The majority of the components have a 2-O-sulfo-4-enopyranosuronic acid structure at the non-reducing end and a 2-N,6-O-disulfo-D-glucosamine structure at the reducing end of their chain.

*Tinzaparin sodium complies with the monograph on [Low-molecular-mass heparins \(0828\)](#) with the modifications and additional requirements below.*

The mass-average relative molecular mass ranges between 5500 and 7500 with a characteristic value of about 6500.

The degree of sulfatation is 1.8 to 2.5 per disaccharide unit.

The potency is not less than 70 IU and not more than 120 IU of anti-factor Xa activity per milligram calculated with reference to the dried substance. The ratio of the anti-factor Xa activity to anti-factor IIa activity is between 1.5 and 2.5.

## IDENTIFICATION

Carry out identification test A as described in the monograph [Low-molecular-mass heparins \(0828\)](#) using [tinzaparin sodium CRS](#).

Carry out identification test C as described in the monograph [Low-molecular-mass heparins \(0828\)](#). The following requirements apply.

The mass-average relative molecular mass ranges between 5500 and 7500. The mass percentage of chains lower than 2000 is not more than 10.0 per cent. The mass percentage of chains between 2000 and 8000 ranges between 60.0 and 72.0 per cent. The mass percentage of chains above 8000 ranges between 22.0 and 36.0 per cent.

## TESTS

### Appearance of solution

Dissolve 1.0 g in 10 mL of [water R](#). The solution is clear ([2.2.1](#)) and not more intensely coloured than intensity 5 of the range of reference solutions of the most appropriate colour ([2.2.2, Method II](#))

### Absorbance ([2.2.25](#))

Dissolve 50.0 mg in 100 mL of [0.01 M hydrochloric acid](#). The specific absorbance, measured at 231 nm and calculated with reference to the dried substance, is 8.0 to 12.5.

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