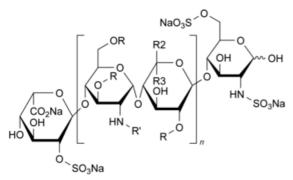
Edition: BP 2025 (Ph. Eur. 11.6 update)

Parnaparin Sodium

General Notices

(Ph. Eur. monograph 1252)



n = 1 to 21 ,R = H or SO_3Na ,R' = SO_3Na or $CO\text{-}CH_3$ R2 = H and R3 = CO_2Na or R2 = CO_2Na and R3 = H

Action and use

Low molecular weight heparin.

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DEFINITION

Sodium salt of a low-molecular-mass heparin that is obtained by radical-catalysed depolymerisation, with hydrogen peroxide and with a cupric salt, of heparin from porcine intestinal mucosa. The majority of the components have a 2-O-sulfo- α -L-idopyranuronic acid structure at the non-reducing end and a 2-N,6-O-disulfo-D-glucosamine structure at the reducing end of their chain.

Parnaparin sodium complies with the monograph <u>Low-molecular-mass heparins (0828)</u>, with the modifications and additional requirements below.

The mass-average relative molecular mass ranges between 4000 and 6000 with a characteristic value of about 5000.

The degree of sulfatation is 2.0 to 2.6 per disaccharide unit.

The potency is not less than 75 IU and not more than 110 IU of anti-factor Xa activity per milligram calculated with reference to the dried substance. The ratio of anti-factor Xa activity to anti-factor IIa activity is between 1.5 and 3.0.

IDENTIFICATION

Carry out identification test A as described in the monograph <u>Low-molecular-mass heparins (0828)</u> using <u>parnaparin sodium CRS</u>.

Carry out identification test C as described in the monograph $\underline{Low-molecular-mass\ heparins\ (0828)}$. In order to verify the suitability of the system in the lower molecular mass ranges (for example M_r 2000), a suitable reference preparation is

used. The following requirements apply.

The mass-average relative molecular mass ranges between 4000 and 6000. The mass percentage of chains lower than 3000 is not more than 30 per cent. The mass percentage of chains between 3000 and 8000 ranges between 50 per cent and 60 per cent.

TESTS

Appearance of solution

The solution is clear (2.2.1) and not more intensely coloured than reference solution Y_5 (2.2.2, Method II).

Dissolve 1.5 g in 10 mL of water R.

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