HEPARINUM NATRICUM

HEPARIN SODIUM

Additional information. Change the statement to:

**Additional information** Heparin sodium is moderately hygroscopic.

Add the following section after that on **Definition**:

**Manufacture.** Heparin sodium is prepared from the lungs of oxen or from the intestinal mucosa of oxen, pigs or sheep. All stages of production and sourcing are governed by a suitable quality assurance system.

The method of manufacture is designed to minimize or eliminate microbial contamination and substances lowering blood pressure and to ensure freedom from contaminants such as over-sulfated glycosaminoglycans. The method is validated *inter alia* to demonstrate that, if tested, the substance would comply with the following tests.

- **Nuclear magnetic resonance spectrometry.** The $^1$H NMR spectrum obtained with a frequency of at least 300 MHz complies with the specifications approved by the appropriate national or regional regulatory authority.

- **Capillary electrophoresis.** The electrophoretogram obtained complies with the specifications approved by the appropriate national or regional regulatory authority.

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