

# Native Porcine Unfractionated Heparin Reference Standard

**Cat. No.** Unfractionated Heparin-18PRS    **Lot. No.** (See product label)

## SPECIFICATION

### Product Overview

|                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Species</b>   | Porcine                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Source</b>    | Porcine mucosa                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Tag</b>       | Non                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Form</b>      | White freeze-dried solid                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Stability</b> | Accelerated degradation studies, which involves potency estimation of ampoules stored at elevated temperatures relative to ampoules stored at -150°C, have shown that the 6th International Standard is very stable in unopened ampoules stored at -20°C. No loss of activity was observed even when the material has been stored at +45°C for 5 years. The accelerated degradation study and real time monitoring will continue for the lifetime of the standard. |
| <b>Storage</b>   | Unopened ampoules should be stored at or below -20°C.                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>contents</b>  | The bulk starting material consisted of a single batch of porcine mucosal sodium heparin. 275.0 g of dried powder were dissolved in 26 L of sterile distilled water. The solution was distributed at room temperature into 24,000 ampoules.                                                                                                                                                                                                                        |
| <b>Shipping</b>  | Because of the inherent stability of lyophilized material, may ship these materials at ambient temperature.                                                                                                                                                                                                                                                                                                                                                        |

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**UNITAGE**

The potency of 2145 IU/ampoule was assigned by taking the geometric mean of all the valid assay results.

**USE OF MATERIAL**

No attempt should be made to weigh out any portion of the freeze-dried material prior to reconstitution.

Allow ampoules to warm to room temperature. Open ampoule as directed, taking care to ensure that all material is in the lower part of the ampoule. Reconstitue with 1.0 ml of distilled water. Heparin is very stable and aliquots of the reconstituted solution, at a suitable concentration (eg 10 IU/ml) could be stored frozen at - 40°C or below for subsequent use. Storage of reconstituted Standard under different conditions must be validated locally by users.

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