

Native Human C1-Inhibitor Reference Standard

Cat. No. C1-Inhibitor-20HRS **Lot. No.** (See product label)

SPECIFICATION

Product Overview

Species	Human
Source	Human Plasma
Tag	Non
Form	White powder
Stability	To provide predictions on the long term stability of the C1-inhibitor potency of ampoules stored under accelerated degradation conditions is being monitored over time. After one year little or no potency loss was observed for samples stored up to +56°C. Based on the results of a stability test, it is advised that samples are stored on wet ice following reconstitution, and potency assays should be completed within 4 hours of reconstitution.
Usage	The intended use of this preparation is to calibrate the measurement of functional C1-inhibitor in products derived from human plasma used in replacement therapy.
Storage	Upon receipt unopened ampoules should be stored in the dark at or below -20°C.
contents	One manufacturer generously provided 100,000 U (200 vials) of their C1-inhibitor product as the source material. Each vial contained 500 U of a freeze-dried preparation, purified from pooled human plasma. The material was reconstituted and

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diluted to a final concentration of 10 U/ml (based on the labelled potency) in 10 mM HEPES buffer (pH 7.4) containing 0.15 M sodium chloride and 5 mg/ml human albumin. A total of 9890 5 ml DIN ampoules were filled with 1 ml aliquots of the diluted material, with a mean filling weight of 1.0053 g (cv = 0.15%).

Shipping

Because of the inherent stability of lyophilized material, may ship these materials at ambient temperature.

UNITAGE

The assigned potency of this preparation is: 9.6 IU/ ampoule

USE OF MATERIAL

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

Allow the ampoule to reach ambient temperature before opening and reconstitute with 1.0 ml distilled water.

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