

Title (en)
DRY HEAT TREATMENT OF PLASMA-DERIVED FACTOR VIII

Title (de)
TROCKENE WÄRMEBEHANDLUNG VON FAKTOR VIII AUS PLASMA

Title (fr)
TRAITEMENT THERMIQUE À SEC DU FACTEUR VIII DÉRIVÉ DU PLASMA

Publication
EP 4387993 A1 20240626 (EN)

Application
EP 22764409 A 20220810

Priority

- EP 21191976 A 20210818
- EP 2022072456 W 20220810

Abstract (en)
[origin: WO2023020914A1] A method of manufacturing a lyophilized plasma-derived Factor VIII product suitable for human administration and a corresponding product is provided. The method comprises: providing a liquid plasma-derived Factor VIII preparation (step a); adjusting the polysorbate 80 content of the preparation to obtain a resulting concentration of 20 to 120 µg polysorbate 80 per mg total protein, preferably 30 to 110 µg per mg total protein, more preferably 40 to 100 µg per mg protein (step b); optionally transferring to one or more suitable container(s) each comprising a dosage unit of Factor VIII (step b1); lyophilization of the preparation obtained in steps b) or b1) (step c); and dry heat treatment of the preparation obtained in step c) to obtain said lyophilized plasma-derived Factor VIII product (step d).

IPC 8 full level
C07K 14/755 (2006.01); **A61K 38/37** (2006.01)

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