Residual Solvents - Statement

Product group: Biopharma

Brand name: BioHale®
Trehalose Dihydrate

Document No.: PD-0822

Dear Customer,

Herewith we certify the following:

For manufacturing of our products BioHale® Trehalose Dihydrate no other solvents than purified water and Acetone are used.

This is certified with reference to the solvents listed in ICH guidance Q3C <Residual Solvent>, USP general chapter <467> as well as any other non-ICH solvents in the raw materials, manufacturing process and product.

Acetone is classified as a Class 3 solvent with low toxic potential and 5000 ppm limit.

Acetone is fully removed from the product through evaporation during the process, and the absence of this solvent in the finished product is tested against the specified max. residue (max. 900 ppm) in each individual batch. The result is reported on each Certificate of Analysis for every batch produced.

No other Class 1, Class 2 and Class 3 (other than Acetone) solvents are likely to be present in BioHale® Trehalose Dihydrate.

This statement substitutes all previous versions issued for the brand names mentioned above.
We trust this information, which is made up to the best of our knowledge, will be helpful to you.

Name : Wilbert van de Rakt
Job title : Quality Director
Signature :

This document is controlled by a validated, electronic system and is valid without signature.
The above facsimile signature is only for display.

DFE Pharma GmbH & Co. KG
Klever Strasse 187, 47574 Goch, Germany, P.O. Box 20 21 20, 47568 Goch, Germany, T. +49 2823 9288 770, F. +49 2823 9288 7799

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