Process Flow Sheet

Product group: Biopharma

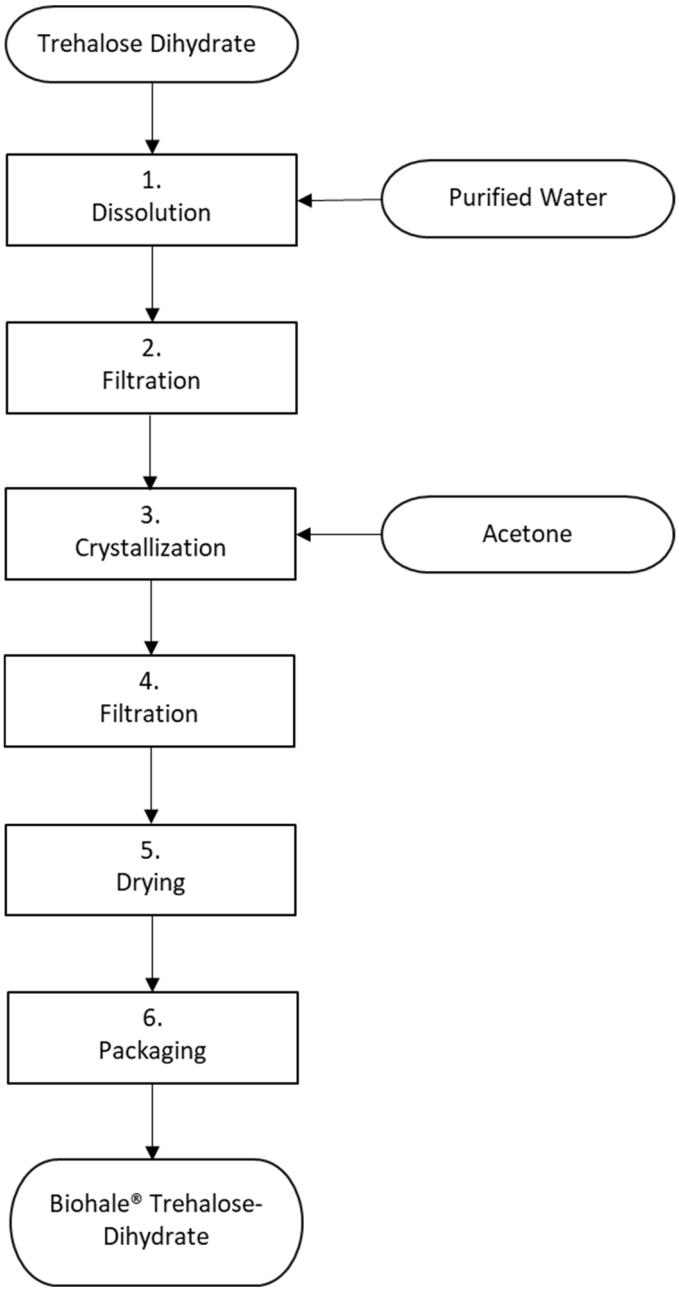
Brand name: BioHale® Trehalose Dihydrate

Article code: SAP 1182228, 1181599

Product description: Trehalose dihydrate, low endotoxin grade

Document No.: PD-0859

Process steps **Raw materials**



1. Raw Trehalose Dihydrate is fully dissolved in purified water
2. The solution is filtered (pore size <1.0 µm) to the crystallization section to remove un-dissolved impurities
3. By adding Acetone to the solution and by cooling the Trehalose Dihydrate crystallises from the solution
4. The crystals are separated from the solvent.
5. The obtained crystals are dried and subsequently cooled to <30 °C before packaging.
6. The product is packed into HDPE drums with a LDPE inner liner

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

The document is an uncontrolled copy and is valid only at the time of distribution. Timestamp: 11-11-2026; 07:00 UTC

Release date: 28-07-2021

Process Flow Sheet

Product group: Biopharma

Brand name: BioHale® Trehalose Dihydrate

Article code: SAP 1182228, 1181599

Product description: Trehalose dihydrate, low endotoxin grade

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 : Teun Heijnen
Job title : Operations & Supply Chain 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

The document is an uncontrolled copy and is valid only at the time of distribution. Timestamp: 11-11-2026; 07:00 UTC

Release date: 28-07-2021