

Trehalose Dihydrate, Injectable Grade — Technical Data Sheet

海藻糖二水合物（注射级）—— 技术数据表

Injectable-grade specification, lyoprotectant rationale and marketed biologics.

注射级规格、冻干保护机理与已上市生物制品应用。

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Product 产品	Trehalose Dihydrate, injectable grade 海藻糖二水合物（注射级）
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1 Product profile 产品概况

Chemical name 化学名称	α -D-Glucopyranosyl- α -D-glucopyranoside dihydrate α -D-吡喃葡萄糖基- α -D-吡喃葡萄糖苷二水合物
Formula / MW 分子式 / 分子量	$C_{12}H_{22}O_{11} \cdot 2H_2O$ / 378.33
CAS No.	6138-23-4 (二水合物)
Function 功能	Non-reducing disaccharide — no Maillard reaction with proteins. Protects proteins, lipids and cell membranes during lyophilisation, freeze-thaw and storage. 非还原性二糖，不与蛋白发生美拉德反应。在冻干、冻融与贮存过程中保护蛋白、脂质与细胞膜。
Appearance 性状	White crystalline powder 白色结晶性粉末
Solubility 溶解性	Freely soluble in water, approximately 689 g/L 易溶于水，约 689 g/L
Standards 质量标准	Current USP-NF · EP · JP · ChP
Grade 级别	Injectable grade, high purity and low endotoxin 注射级，高纯度、低内毒素

2 Specification 质量标准

Test 检测项目	Typical specification 典型规格	Reference 依据
Appearance 性状	White crystalline powder; clear and colourless in solution 白色结晶性粉末；溶液澄清无色	ChP / USP-NF / EP / JP
Assay (HPLC, anhydrous basis) 含量（液相，无水基）	NLT 99.0%	ChP / USP-NF / EP / JP
Water content (Karl Fischer) 水分（卡尔费休法）	9.0% – 11.0%	ChP / USP-NF / EP / JP
Specific optical rotation 比旋度	+197° ~ +201°	ChP / USP-NF / EP / JP
pH (100 mg/mL solution) pH	4.5 – 6.5	ChP / USP-NF / EP / JP
Related substances 有关物质	Glucose, maltotriose and other polysaccharides tightly controlled 葡萄糖、麦芽三糖及其他多糖严格控制	ChP / USP-NF / EP / JP
Bacterial endotoxin 细菌内毒素	< 2.5 IU/g (可依需求提供超低内毒素规格)	注射级控制
Microbial limits 微生物限度	TAMC ≤ 100 cfu/g; TYMC ≤ 10 cfu/g; absence of <i>E. coli</i> and <i>Salmonella</i> 需氧菌 ≤ 100 cfu/g; 霉菌酵母菌 ≤ 10 cfu/g; 不得检出大肠埃希菌与沙门菌	注射级控制

3 Why trehalose rather than sucrose 为什么用海藻糖而非蔗糖

Property 性质	Trehalose Dihydrate 海藻糖二水合物	Sucrose 蔗糖
Molecular volume in mAb solution 单抗溶液中分子体积	Approximately 2.5 × that of sucrose → stronger preferential hydration; equivalent stabilisation at lower concentration 约为蔗糖的 2.5 倍 → 优先水化效应更强，可在更低浓度下等效稳定	Reference 基准
Glass transition temperature 玻璃化转变温度	Approximately 120 °C	Approximately 70 °C
Reducing sugar 还原性	Non-reducing — no Maillard reaction 非还原性，不发生美拉德反应	Hydrolyses to reducing sugars 可水解为还原糖
Acid / thermal stability 耐酸与热稳定性	Stable at pH 2 and 100 °C for 24 h pH 2、100 °C 条件下 24 小时稳定	Hydrolyses under acid conditions 酸性条件下水解

4 Marketed biologics formulated with trehalose 已上市含海藻糖的生物制品

Product 产品	Active substance · company 活性成分 · 企业	Presentation 剂型
Ocrevus	Ocrelizumab · Roche	IV concentrate + SC 静脉浓缩液 + 皮下

Product 产品	Active substance · company 活性成分 · 企业	Presentation 剂型
Cosentyx	Secukinumab · Novartis	SC pen / PFS + IV 皮下笔 / 预充针 + 静脉
Herceptin	Trastuzumab · Roche	Lyophilised powder + SC 冻干粉针 + 皮下
Avastin	Bevacizumab · Roche	IV concentrate · 6% trehalose 静脉浓缩液 · 含 6% 海藻糖

Product names and companies are referenced for illustration of trehalose use in marketed biologics. Trademarks belong to their respective owners; no affiliation or endorsement is implied.
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5 Handling, packaging and storage 操作、包装与贮存

Standard pack 标准包装	[to be confirmed] (建议：25 kg 纸板桶，内衬双层聚乙烯袋)
Storage 贮存	Keep in the original sealed container, protected from light, in a dry place at ambient temperature. 原包装密封、避光、干燥、常温贮存。
Retest period 复验期	[to be confirmed]
Regulatory support 法规支持	Registered in NMPA; China DMF filed; GMO-free, Halal and Kosher declarations on request NMPA 注册；已递交中国 DMF；无转基因、Halal、Kosher 声明可依需求提供

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