

# Innovative Products for Life Sciences

## Certificate of Analysis

Product: CryoSure-DMSO 10 ml. Lot-Number USP22B1. Expiration Date 10/2025.

Primary Packing material: transparent glass vial, borosilicate glass type I, combination seal, total tear off, 20 mm

This batch of CryoSure-DMSO complies with the specifications of the USP and Eur. Ph. for DMSO. Below tests show the compliance of the final product.

	<b>Test for:</b>	<b>Method:</b>	<b>Specification</b>	<b>Result</b>	<b>Pass/Fail</b>
1.	Deliverable volume in container	EP 2.9.17	≥ 10 ml	10.4 ml	Pass
2.	Identification				
2.1	Chemical test (Hydroiodic acid)	USP Monograph DMSO Identification B	with HI violet cristaline solid is obtained, sol. in chloroform with red color	Complies	Pass
2.2	Complex formation with NiCl	EP Monograph DMSO Identification D	green (RT), blue at 50°C	Complies	Pass
2.3	Infrared spectrum	USP Monograph DMSO Identification A, USP <197F>, EP 2.2.24	USP reference standard	Complies	Pass
3.	Purity				
3.1	Related substances by GC	USP <621>	resolution between dimethylsulfone and dibenzyl ≥5	145.9	Pass
	individual impurity	USP <621>	≤ 0.03 %	< 0,03%	Pass
	all impurities	USP Monograph DMSO USP <621>	≤ 0.1 %	< 0,1%	Pass
3.2	UV- Absorbance	USP Monograph DMSO UV-Absorbance			
	between 270 nm-350 nm		no absorption maxima	Complies	Pass
	absorbance at 275 nm		≤ 0.20	0.15	Pass
	absorbance ratio 285 nm/275 nm		≤ 0.65	0.55	Pass
	absorbance ratio 295 nm/275 nm		≤ 0.45	0.39	Pass
3.3	Specific gravity 20°C (25°C)	EP 2.2.5, (USP <841>)	1.100-1.104 (1.095-1.101)	1.102 (1,099)	Pass
3.4	Refractive index 20°C (25°C)	EP 2.2.6, (USP <831>)	1.478-1.480 (1.4755-1.4775)	1.479 (1.4771)	Pass
3.5	Congealing temperature	EP 2.2.18	≥ 18.3°C	18.6°C	Pass
3.6	Water content (KF)	USP Monograph DMSO USP <921>	≤ 0.1 %	< 0.1%	Pass
3.7	Non-volatile residue	USP Monograph DMSO	≤ 0.01 %/100g substance	< 0.01%	Pass
3.8	Acidity titration with 0.01N NaOH	USP Monograph DMSO Acidity	≤ 5ml /50g substance	Complies	Pass
3.9	Content of DMSO	USP Monograph DMSO Assay	≥ 99.9 %	100%	Pass
4.	Color	EP 2.2.1, 2.2.2	clear (≤ ref. Soln B9)	Complies	Pass
5.	Visible Particles	EP 2.9.20	Free of visible particles	Complies	Pass
6.	Closure Test (100% control)	Negative Pressure Test	Containers are tight	Complies	Pass
7.	Sterility Test	EP 2.6.1, USP-NF	Sterile	Complies	Pass
8.	Endotoxin (LAL)	EP 2.6.14, USP-NF	< 0,05 I.E./ml	Complies	Pass
9.	Mycoplasma Test	EP 2.6.7	Free of mycoplasma	Complies	Pass
10.	Vitality Test	Cell culture test	complies	Complies	Pass



Date: 14th of October 2022

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