

STABILITY FILE UPDATE: STAB22-009 16 Month Timepoint

Product	CryoStor® CS10		
Part Number	210502	Manufacture Date	29APR2022



CryoStor® CS10 in 100mL Bottles P/N 210502 is the exact formulation as the product in other container closure configurations, all of which have an established shelf life expiration date of 24 months from the date of manufacture when stored at 2-8°C.

This product is currently on initial real-time stability in order to establish an expiration date for the product. The 16 months stability data show preservation efficiency is maintained for 16 months from the date of manufacture when stored at 2-8 °C.

Test Results

Verification	Appearance	Viable Cell Recovery Assay	Endotoxin	pH	Sterility	Osmolality	Specific Gravity	Identification	DMSO Content
Acceptance Criteria	Per STAB <u>22-009</u>								
<u>16</u> Months	Pass	Pass	Pass	Pass	N/A	Pass	Pass	Pass	Pass

Approved by:

Department	Signature	Date
Quality Control		20OCT2023
Quality Assurance		20OCT2023