

STABILITY FILE UPDATE: STAB22-009 18 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 18 months stability data show preservation efficiency is maintained for 18 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>18</u> Months | Pass | Pass | Pass | Pass | N/A | Pass | Pass | Pass | Pass |

Approved by:

| Department | Signature | Date |
|-------------------|---|-------------|
| Quality Control |  | 11 JAN 2024 |
| Quality Assurance |  | 12 JAN 2024 |