CryoSolve®

Syringe (7 mL) Cat # AK8217-0007 | Kit (25 x 7 mL) Cat # AK8217-2507
Syringe (8 mL) Cat # AK8217-0008 | Kit (25 x 8 mL) Cat # AK8217-2508

Product Description:

Akron's CryoSolve® product is manufactured following all relevant cGMP guidelines for ancillary materials. The formulation contains sterile, filtered DMSO (Dimethyl Sulfoxide, USP/EP) and Dextran-40 (USP/EP/JP). Its packaging design (single-use syringe) supports the quality standards for cord blood processing in a closed system. Our CryoSolve® product maximizes the rate of cord blood processing for storage, leading to a notable impact on time and volume.

Sterile filtration and aseptic filling are performed in-house with Endotoxin, Mycoplasma, and Sterility testing performed per USP on the final product. Our cryopreservation media is packaged in syringes and available in 7 mL and 8 mL aliquot sizes. Akron's cGMP-compliant CryoSolve® product is intended for the cryopreservation of various therapeutic human stem and immune cells, and is used extensively in the cord blood banking industry

Product Features:

Raw Material

- Component ratio of DMSO 55%, Dextran-40 5%, and WFI (water for injection) 40%
- Raw materials meet Pharmacopeia standards: DMSO (USP/EP) and Dextran-40 (USP/EP/JP)
- All raw materials are compliant, controlled, and traceable under Akron's Quality Management System (QMS)

Manufacturing

- Manufactured in compliance with cGMP guidelines
- In-house sterile filtration and aseptic filling
- No animal-derived materials are used in the manufacture of this product
- Meets BLA requirements for ancillary materials used in cell therapy products

Packaging

- Packaged in syringes made from borosilicate glass USP Type I
- Luer-lock syringe tip for ease-of-use and eliminates sharps
- All components and packaging meet requirements of low leachables/extractables
- 7 mL syringe volume: 7.11 - 7.73 mL
- 8 mL syringe volume: 8.11 - 8.64 mL
- Syringe inner diameter: 14.25 ± 0.20 mm
- Syringe outer diameter: 17.05 ± 0.20 mm
- Compatible with syringe pump equipment

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Quality

- Relevant cGMP guidelines used in manufacture, testing, and release
- USP <1043>, Ancillary Materials for Cell, Gene, and Tissue-Engineered Products
- ISO/TS 20399-1-3:2018, Biotechnology - Ancillary Materials Present During the Production of Cellular Therapeutic Products

Release Testing:

- Appearance
- pH
- Osmolality
- Identification
- Mycoplasma
- Cytotoxicity
- Endotoxin
- Sterility
- Purity (Concentration)

Stability:

- 5-years shelf life
- Store at 2-8 °C
- Transport on cold packs

For Use Statement:

For research use or further manufacturing use in *ex vivo* cell therapy applications. This product is not intended for direct *in vivo* use or for direct clinical use as a drug, therapeutic, biologic, or medical device.

Related Products:

Catalog Number	Product Name	Size
AK9985-1000	ImmunoCell™ Growth Medium (ICGM)	1000 mL
AK8228-0100	Human Serum Albumin (HSA) 25% Solution	100 mL
AR1037-0100	Human Serum Albumin (HSA) 25% Closed System Solutions (CSS)™	100 mL

For more information on our available products or for technical assistance, see contact info below.
For contract orders under master supply agreement, please inquire.