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Vials (100 mL) Cat # AK8899-0100

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### Product Description:

Akron's CryoSolutions™ 100% product is manufactured following all relevant cGMP guidelines for ancillary materials. The formulation contains sterile, filtered DMSO (Dimethyl Sulfoxide, USP/EP), highest purity grade >99.99%. Our CryoSolutions™ 100%, DMSO solution allows for flexibility when using multiple dilutions or working with a variety of cells and tissues. Sterility and Bacterial Endotoxin testing are performed per USP/EP on the final product. Our cryopreservation media is packaged in glass vials and available in a 100 mL aliquot. Akron's cGMP-compliant CryoSolutions™ 100% is intended for cryopreservation of biological cells in cell culture, stem cells, mammalian cells and biological tissues.

### Product Features:

#### Raw Material

- Negligible BSE/TSE risk from all components
- Low Endotoxin ( $\leq 1$  EU/ $\mu$ g)
- High Purity ( $\geq 97\%$ )

#### Manufacturing

- Manufactured in compliance with cGMP guidelines
- No animal-derived materials are used in the manufacture of this product
- Packaged in vials made from borosilicate glass USP Type I
- Septum stoppers and flip-off seals – certified, sterilized - designed for aseptic operations

#### Quality

- Relevant cGMP Guidelines Used in Manufacture, Testing, and Release
- USP <1043>, Ancillary Materials for Cell, Gene, and Tissue-Engineered Products
- ISO 13485:2016, Medical devices - Quality Management Systems - Requirements for Regulatory Purposes
- ISO/TS 20399-1-3:2018, Biotechnology - Ancillary Materials Present During the Production of Cellular Therapeutic Products
- High Purity, Low Endotoxin - Endotoxin and Sterility testing per USP/EP



## CryoSolutions™ 100%

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### Release Testing:

- Appearance
- Acidity
- Water %
- UV Absorbance (270-350 nm)
- Identification (IR)
- Identification (Chemical)
- Refractive Index (at 25 °C)
- Specific Gravity (at 25 °C)
- Freezing Point
- Limit of Non-Volatile Residue
- Purity (anhydrous basis)
- Related Substances
- Bacterial Endotoxins
- Sterility

### Stability:

- Store at room temperature
- Transport ambient

### 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
AK9932-0100	CryoNovo™ P24	100mL
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.