Sterile Cryoprotectant Solution (DMSO)

Instruction for Use (English)

EXPLANATION

CryoFit DMSO is a sterile, endotoxin-free, non-pyrogen and disposable solution. CryoFit DMSO can be taken from a bottle multiple times using the syringe, but the product in the syringe cannot be used more than once.
It is sold as 10 ml (11 gm) in 15 ml flacons. The product is sterilized by aseptic filtration.

COMPOSITION QUANTITY

The purity level of CryoFit DMSO (Dimethyl Sulfoxide) is at least 99.9 %. Water content is maximum 0.5 %.

FEATURES

DMSO is a water-holding component and its simple formula is C_2H_6OS and its CAS number is 67-68-5. Its molecular weight is 78.13 g / mol.
Melting point is 20 ° C.

FLACON

Flacons are sealed with a snap-on/tear cap.
Before CryoFit DMSO use, only the cap (white part) of the bottle is opened, leaving the aluminum part in place.

WARNING

CryoFit DMSO is for single use only, not resterilized, not reused, not suitable for injection.
Do not use CryoFit DMSO if the solution in the flacon is not clear or if the flacon cap has been previously opened or damaged.

TARGET USER PROFILE

Health institutions that perform cryopreservation of bone marrow, peripheral stem cells, umbilical cord blood and biological cells.

CLINICAL BENEFIT

Cells that are desired to be stored for a long time should be stored at -80 °C. However, at this temperature, the cell loses water, the water coming out of the cell crystallizes and freezes, and the cell dies. DMSO is a water-holding solution. When added to the environment, it enters the cell membrane and retains the water inside. Thus, it prevents the water from coming out and icing outside the cell, allowing the cell to live longer.

ISSUES TO BE CONSIDERED

Avoid prolonged contact with skin, eyes and inhalation heated DMSO or DMSO aerosol mist.
Avoid contact with DMSO solution containing toxic substances or material of unknown toxicological properties, because under certain conditions DMSO can penetrate the skin and transport such materials into the body.
DMSO should not be added directly to the cells because heat is generated when it is mixed with water.
DMSO is highly polar organic solvent and is aggressive against many commonly used plastics, and unwanted byproducts may be released.

STORAGE

CryoFit DMSO starts to crystallize below 20°C, so it should be stored between 20°C-30°C.
If it is crystallized, it can be holded again between 20°C and 30°C in the room temperature until it melts and can be used after melting.
It should be protected from strong sunlight and stored in a dark and dry place.

INDICATION

It is used as a preservative agent in the cryopreservation of bone marrow, peripheral stem cells, umbilical cord blood and biological cells.

CONTRENDICATION

It has no known contraindications. However, CryoFit DMSO should not be used for sperm and embryo storage as sufficient clinical studies have not been conducted.

SIDE EFFECTS

Side effects such as nausea, vomiting, flushing, fever, chills, shortness of breath, cardiac symptoms, transient hyper- or hypotension, anaphylaxis, encephalopathy, and convulsions may occur, although not very often. The patient may have an onion-garlic odor.
It is important that the patient is well hydrated before and after transplantation to reduce side effects.

WORKING MECHANISM

DMSO easily passes through the cell membrane and blocks the freezing inside the cell by binding the water molecules. Thus, it prevents the cell from exploding. DMSO is used in the protection of bone marrow, peripheral stem cells, umbilical cord blood and biological cells.

USAGE AREA

DMSO is used in cell culture and pharmaceutical industry for freezing of biological cells.
It is also used for storing blood forming stem cells, human umbilical cord blood, and biological tissues.

FREEZING PROCESS TERMS OF USE

DMSO has a direct toxic effect on the cell. Therefore, it should be given as diluted. The most preferred concentration is 10 %.
DMSO is prepared with autolog plasma, HES or the other liquids to be added in a separate place to reduce its toxicity and the cryoprotectant solution containing this mixture is injected to the cell suspension very slowly (as 10 ml in 4-5 minutes).

MELTING PROCESS TERMS OF USE

Before the bone marrow is transplanted to the patient, thawing should be applied at 37°C and it is recommended that DMSO must be removed from the bone marrow if possible.

GENERAL DIRECTIONS FOR USE

1. Use aseptic technique.
2. Assure the vials are closed with a plastic flip-off cap, aluminum crimp seal and Bromo butyl stopper.
3.To withdraw DMSO from the flacon, first remove the plastic cap, clean the stopper with an alcohol swab, insert the syringe and aspirate the DMSO.
4. Perform cell or tissue freezing according to your hospital's own protocol.
5. It is recommended to use in 10% concentration.
6. It is recommended to cool the bag containing bone marrow to +4°C before use.
7. It is recommended to give 10 ml of DMSO in 4-5 minutes into the bag.
8. The amount of DMSO in the bone marrow to be applied to the patient within 24 hours should not exceed 1g / kg.
9. Half-life of DMSO is 11-14 hours, it is removed from the body through the urine.

MANUFACTURED BY

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PICTOGRAMS

CE	The product meets the justifications of the European Medical Devices Directive.	2 STERILIZE	Do not resterilize.
2195	Notified Body number.		Do not re-use.
	Consult instructions for use.		Do not use if package is damaged.
	Caution.		Fragile, handle with care.
	Manufacturer.	20 °C 30 °C	Temperature limit.
	Date of manufacture.		Keep away from sunlight.
LOT	Batch no.		Keep dry.
REF	Catalog number.		Non-pyrogenic
	Use-by date.	TR	Country of manufacture.
STERILE A	Sterilized using aseptic processing techniques.	MD	Medical device

Revision Date / No: 20.05.2024 / Rev 07