

Pentastarch Solution

Performance. Value.

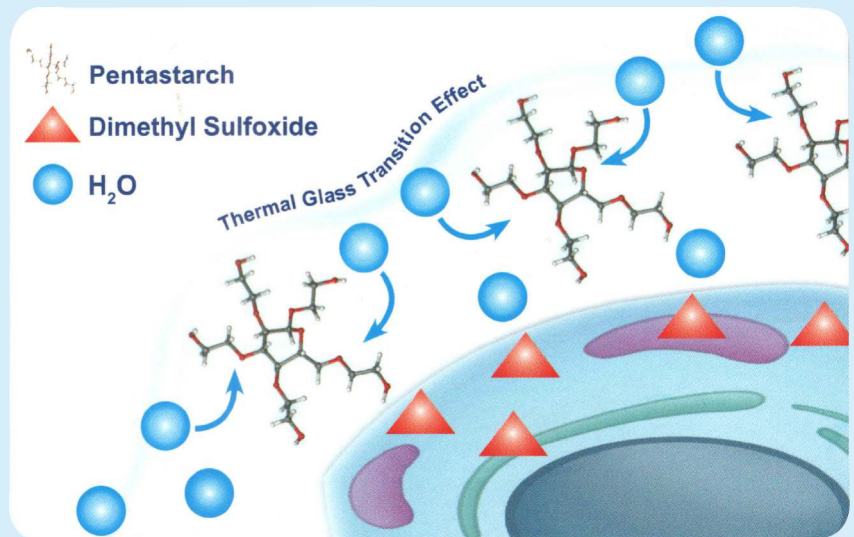
Formulated for better cryopreservation, Pentastarch simplifies the cryopreservation process and delivers an extracellular protective agent that safeguards cells during the freeze/thaw process.

Patient Benefits

- More Viable Cells^{1,2}
 - Higher rate of nucleated cells
 - Highest Trypan Blue viability
- Less Toxic for the Patient³
- Reduced Patient Discomfort⁴
- Fewer Hospital Days⁵
- Less Immunosuppressive Therapy⁶

Lab Benefits

- Reduced Tech Time⁷
- Does Not Require Timed Freezing⁸
- Does Not Require Expensive Controlled-Rate Freezers / N-Tunnels⁹



Now Protect cells on the inside AND outside in the freeze/thaw process

Increasing Pentastarch to a concentration that optimizes the thermal glass transition improves the cryopreservation of cells (Korber et al. 1980, Takahashi et al. 1988). Pentastarch may also act by influencing the freezing properties of the solution, absorbing water in the extracellular milieu and altering the freezing properties. This may allow the Pentastarch Solution to work effectively without complicated controlled-rate freezing (Makino et al., 1991), subsequently reducing technician sample prep time (compared to controlled-rate samples) (Clapissou et al, 2004).

Pentastarch Solution, a hydroxyethyl starch formulated for lab work, helps cryoprotect stem cells from umbilical cord blood, bone marrow, or peripheral blood, as well as tissues and cellular tissue-based products. Using Pentastarch simplifies your cryopreservation process and improves cell viability, with less toxicity and discomfort for your patient.

The Solution is a base component of liquid media for human ex vivo tissues and cell preservation. It is an extracellular cryoprotectant that combines with dimethylsulfoxide (DMSO an intracellular cryoprotectant) to provide an optimum mixture that safeguards cells during the freeze/thaw cycle. The combined solution preserves cord blood at - 80°C for 15 years and bone marrow for 7 years¹⁰.

ISO Certified cGMP Compliant

Pentastarch Solution was developed with the unique needs of the cell preservations centers in mind:

- Sterile filtered, non-pyrogenic and non-toxic
- FBS/animal-derived serum free
- Defined solution components allow users to know exact freeze mix contents
- Manufactured in a cGMP/ISO facility with more than 25 years experience
- Quality Release Testing and Certificate of Analysis available for each lot
- Reduced technician sample prep time (compared to controlled-rate samples)^{7,8}
- Patients transplanted with cells processed using a pentastarch solution engraft faster and are discharged sooner than patients receiving autologous bone marrow transplants^{1,11}

Description

Pentastarch Solution is a clear, sterile liquid product intended for use as a component in cryopreservation media for human ex vivo cells.

Pentastarch acts as an extracellular protecting agent. When mixed with intracellular cryopreservatives, Pentastarch aids in the preservation of cells during the freeze/thaw process. The solution is composed of the following:

Pentastarch Solution	20%	200 mg/mL
Dextrose	0.18%	1.8 mg/mL
Electrolyte Solution*		q.s. to volume

*Electrolyte Solution (per 100mL volume) is composed of 526mg NaCl, 502mg Sodium Gluconate, 368mg Sodium Acetate-3H₂O, 37mg KCl, 30mg MgCl₂-6H₂O

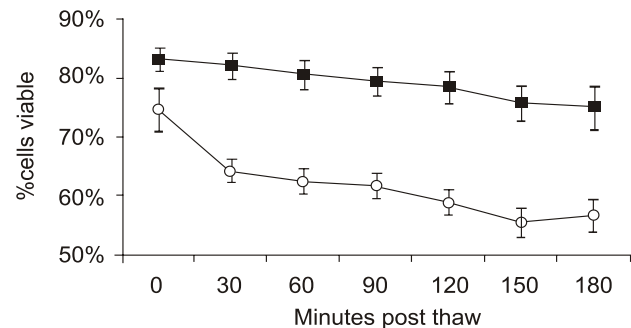
Product Specifications

- 50 mL vial
- 20% Solution (200mg/mL)
- Designed for use in cell processing and freezing applications
- Sterile
- Non-pyrogenic, non-toxic
- Meets USP LVP Particulate Limits
- Store 2-25°C
- Product Code: PST002

The Pentastarch Solutions is a liquid solution supplied in 50 mL glass vials. A shelf carton contains 5 vials. Store at 2-25°C (36-77°F). Avoid excessive heat.

Certified Processes, Proven Solutions

Pentastarch Solution is a certified cGMP product and is manufactured in an ISO 9001 and an ISO 13485 facility



Cell viability after thawing. Cord Blood samples (n=4) cryopreserved in 10% DMSO or 5% DMSO/Pentastarch, analyzed for 7-AAD by flow cytometry. There was a significant difference ($p < 0.05$) between 10% DMSO and 5% DMSO/Pentastarch at time points 30 minutes and onward².

¹ "...a cryoprotective solution consisting of 6% HES and 5% DMSO produced the highest recovery rates for nucleated cells (92.0 +/- 3.5%), CFU-GM (73.98 +/- 4.1%) and BFU-E (82.2 +/- 6.9%), and the highest trypan blue viability (88.4 +/- 3.6%)." (A simplified method for cryopreservation of peripheral blood stem cells at - 80 degrees C without rate-controlled freezing; S. Makino et al, *Bone Marrow Transplant* Oct; 8(4):239-44; 1991)

² "Cryopreservation with HES + DMSO is better than DMSO alone in terms of viability ($p < 0.001$) and Granulocyte Macrophage Colony Forming Unit (GM-CFU) activity ($P < 0.05$)" "In terms of progenitors, BFU-E/kg and CFU-GM/kg were significantly higher with HES+DMSO (respectively $p = 0.02$ and $p = 0.01$). More over, using 5% rather than 10% of DMSO appears less toxic to the cells as shown by viability data obtained." (Cryopreservation with Hydroxyethyl starch (HES) + dimethylsulfoxide (DMSO) gives better results than DMSO alone; Gilles Clapisson et al., *Electronic journal of Oncology*, 1, 97-102; 1999)

³ "Two patients who received components cryopreserved with DMSO alone experienced serious neurological toxicity (seizure, transient ischemic attack) as has been previously observed with the infusion of cryopreserved cells. None of the recipients who received components frozen in DMSO/HES experienced similar serious infusion-related toxicities." (A randomized phase III clinical trial of autologous blood stem cell transplantation comparing cryopreservation using dimethylsulfoxide vs dimethylsulfoxide with hydroxyethylstarch; SD Rowley et al., *Bone Marrow Transplantation* 31;1043-1051; 2003)

⁴ (Ibid)

⁵ Time to initial hospital discharge: DMSO (n=148) 17; DMSO/HES (n=146) 16; $p = 0.54$ " (Ibid)

⁶ "The faster engraftment also resulted in a decrease in the number of days broadspectrum antibiotics were administered." (Ibid)

⁷ "The addition of HES allowed us to put the bags directly into the liquid nitrogen without using an electronic [controlled-rate] freezer. The saving of time is about 1 hour and the cost is reduced." (cryopreservation with Hydroxyethyl starch (HES) + dimethylsulfoxide (DMSO) gives better results than DMSO alone; Gilles Clapisson et al., *Electronic Journal of Oncology*, 1, 97-102, 1999)

⁸ (Ibid)

⁹ McCullough Jet al. Long-term storage of peripheral blood stem cells frozen and stored with a conventional liquid nitrogen technique compared with cells frozen and stored in a mechanical freezer. *Transfusion*. 2010 Apr;50(4):808-19.

¹⁰ "The combined solution preserves cord blood at - 80°C for 15 years and bone marrow for 7 years." (Cryopreservation of Hematopoietic Stem Cells; David Berz et al., *American Journal of Hematology* 82:463-472; 2007)

¹¹ Rosenfeld CS, A strategy for processing of peripheral blood stem cells utilizing the small volume collection chamber and cryopreservation without a race controller using pentastarch. *J. Hematother* 1993 Winter; 2(4): 52508. Review. Pub Med PMID : 7522111.

¹² Hayakawa J. et al.; 5% dimethyl sulfoxide (DMSO) and pentastarch improves cryopreservation of cord blood cells over 10% DMSO *Transfusion*. 2010 Oct;50(10):2158-66



Duraent Lifesciences LLP

32/2, Soundararajan Street, T.Nagar, Chennai - 600 017, India
Tel: +91 44 42323244, Website: www.duraent.com

Manufactured by: Preservation Solutions Inc.
1099 Proctor Dr, Elkhorn, WI 53121