

CliniMACS® Formulation Solution

REF 170-076-327

CliniMACS Formulation Solution has been developed for cell based drug product formulation.

For U.S. CAUTION:

Clinical Research Buffer Limited by Federal (or United States) Law to Investigational Use or under an FDA Approval.



Miltenyi Biotec B.V. & Co. KG








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For U.S. distributed by:

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Contents	One bag contains 1000 mL of CliniMACS Formulation Solution.														
QTY															
Composition	<p>100 mL contain:</p> <table> <tr> <td>Sodium chloride</td><td>473 mg</td></tr> <tr> <td>Sodium gluconate</td><td>452 mg</td></tr> <tr> <td>Sodium acetate trihydrate</td><td>331 mg</td></tr> <tr> <td>Trisodium citrate dihydrate</td><td>289 mg</td></tr> <tr> <td>Potassium chloride</td><td>34 mg</td></tr> <tr> <td>Magnesium chloride hexahydrate</td><td>28 mg</td></tr> <tr> <td>Human serum albumin</td><td>2500 mg</td></tr> </table>	Sodium chloride	473 mg	Sodium gluconate	452 mg	Sodium acetate trihydrate	331 mg	Trisodium citrate dihydrate	289 mg	Potassium chloride	34 mg	Magnesium chloride hexahydrate	28 mg	Human serum albumin	2500 mg
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Intended purpose	CliniMACS Formulation Solution is intended as excipient for processing of human cells from heterogeneous cell populations in combination with the CliniMACS Prodigy® System.														
Limitation	Miltenyi Biotec as the manufacturer of the CliniMACS System does not provide any recommendations regarding the use of the manufactured cells for therapeutic purposes and does not make any claim regarding a clinical benefit.														
Disclaimer	CliniMACS Formulation Solution has been developed for cell based drug product formulation. (The CliniMACS Formulation Solution alone is not intended for <i>in vivo</i> application). For regulatory status in the USA, please contact your local representative.														
Quality statement	CliniMACS Formulation Solution is manufactured and tested under a quality management system (ISO 13485) and is in compliance with GMP requirements.														
Precautions	<p> For the manufacturing of cells intended for therapeutic use in humans the national legislation and regulations must be followed. Thus, any clinical application of cell based drug products is exclusively within the responsibility of the user of a CliniMACS System. In particular, genetic modification of cells, handling and any clinical application of genetically modified target cells must be performed in compliance with legislation regarding genetic engineering work, biological safety containment levels, and environmental risk assessment.</p> <p>All materials which have come into contact with blood and blood products must be treated as infectious material. Regulations for the treatment of infectious materials must be observed.</p> <p>The corresponding CliniMACS Prodigy User Manuals must be followed.</p> <p>The processing of cells using the product must be performed by trained operators only.</p> <p>Aseptic working procedures must be applied for the unpacking, assembly, and use of the product.</p>														
Warnings	<p>Do not use if precipitation is observed in the product.</p> <p>Do not use if any leakage of the product is observed during priming, separation, and/or final formulation.</p> <p>Do not connect the product directly to the patient.</p>														
	Do not use after the use-by date indicated on the product label.														
	Do not use if package is damaged. Before opening, inspect the packaging for damages, punctures, or tears. Use the product only if package is undamaged and sealed.														
	Do not re-use, the product is only for one process.														
Storage															
	The CliniMACS Formulation Solution must be stored at +2 °C to +8 °C (+36 °F to +46 °F). Do not freeze.														
	Keep away from sunlight.														
Sterility															
STERILE	Sterile. The CliniMACS Formulation Solution is sterile filtered.														
Performance	<p>The performance of the product depends on the chosen user-specific filling process.</p> <p>The optimal storage of cells must be validated by the user.</p>														
Instructions for use	<p> Refer to the corresponding CliniMACS Prodigy User Manual for the validated combinations of CliniMACS Reagents, application processes, tubing sets, and buffers/media.</p> <p>Storage of cells should be performed at +2 °C to +8 °C (+36 °F to +46 °F). Temperature fluctuations during storage should be avoided.</p> <p>This document and corresponding information can be found under www.miltenyibiotec.com/170-076-327.</p>														