

Certificate of Analysis

Product:	MUSE Exosomes		
Source:	Wharton Jelly from healthy* full term placentas and cords.		
Intended use:	For <i>ex vivo</i> and clinical use		
Order number:	01/03/2025	Lot No.:	EXMSC20250307
Production:	03/2025	Expiry:	03/2027
Formulation:	0.22 µm-filtered solution containing 20 mM glycine, 100 mM Trehalose, 200 mM Mannitol, 20 mM NaH ₂ PO ₄ (pH 7.4); As liquid.		
Exosome count per vial:	1 trillion ±10 billion per vial		

<u>Release Testing:</u>	<u>Specification</u>	<u>Lot Result</u>
Size (mean):	130±40 nm	125 nm
Purity:	≥97 %	>99.5 %
Identity:	Complies	Complies
Sterility:	Sterile	Complies
Endotoxin level:	<10 EU/mg	<2.3 EU/mL
DNA/RNA concentration ng/mL	>400 ng	1876 ng/mL
Protein concentration µg/mL	>800 µg/mL	1800 µg/mL

Purity and identity was determined by Nanosight LM10 measurements.

Protein was measured using Lowry standardized assay, DNA/RNA concentration was measured using standardized Qbit analysis assay. Sterility test of vial product was performed according to Eur.Pharm. (Inoculation method). Endotoxin was determined using the gel clot assay according to Eur.Pharm.

Handling Instructions:

General usage:	Open cap, clean the rubber stopper with disinfectant napkin or other cleaning disinfection method / material. Puncture rubber stopper with sterile needle and draw the ready to use product (see below) into sterile syringe according to doctor instructions.
Using liquid product:	Liquid product is ready to use according to doctor instructions.
Reconstitution if lyophilized:	Recommended in 1–2 mL of sterile water for injection. After reconstitution, liquid exosomes should be used immediately. Do not freeze after reconstitution!
Dilution for <i>ex vivo</i> procedures:	Recommended in CellGro®/CellGenix™ serum-free media. For dilution with PBS or protein free medium, a carrier protein (0.1–1 % albumin or 1–10 % appropriate serum) must be included. Failure to dilute the product according to these instructions will result in a loss of activity.
Storage and stability:	Long term storage at -20 °C or below is recommended. For transportation or short-term storage, lyophilized product can be stored +2 - +8 °C. After reconstitution, liquid exosomes should be used immediately. Do not freeze after reconstitution! Products in unopened and undamaged packaging are stable till expiration date indicated on package when stored as described.

Quality Statement:



This product is manufactured, tested and carried out in compliance with the relevant GMP-guidelines. No animal- or human- derived materials were used during manufacturing. USP chapter <1043> “ancillary materials for cell, gene, and tissue-engineered product” has been considered in the design of this product.

*All the donors are tested according to Europe Union transplantation law. Materials are tested ELISA and NAT method due to HIV, HBV, HCV, CMV, EBV, TPHA, RPR infections.