

BLUUM

Manufactured by: Vita Tissue
 Distributed by: Aesthetic Rep Group (ARG)

Certificate of Conformity

Product Name Bluum Exosomes (for Professional Topical Cosmetic Use Only)
Contents Exosomes derived from Human Umbilical Cord (Wharton's Jelly) Mesenchymal Stem Cells 20 Billion or 200 Billion in 5 mL or 6mL suspension with sterile saline

Lot ID 20A0043 **MSC Lot Release Date** 05/13/2023
Cord Lot ID S-051323 **Exosome Manufacturing Release Date** 08/15/2023
Expiration Date 09/09/2028

Storage and Shelf Life from Date Received:
 Samples are shipped frozen on dry ice and should be moved immediately after delivery to a -80° C freezer (for up to 15 months), -20° C freezer (for up to 6 months), or 4° C refrigerator (for up to 3 months). Shelf Life from Date Received is not to exceed Expiration Date.

TESTS	Testing Provider	Test Result	Release Criteria	Approval for release
Initial Pathogen Testing of Umbilical Cord				
HepatitisBSurfaceAg	VRL	Negative	Negative	Approved
HepatitisCVirusAb	VRL	Negative	Negative	Approved
HIV-1/HIV-2PlusO	VRL	Negative	Negative	Approved
SyphilisScreening-Nontreponemal	VRL	Negative	Negative	Approved

Testing performed by Independent CLIA lab (Eurofins DPT CLIA #20A0043)

Exosome Characterization and Quantification by Nanoparticle Tracking Analysis (NTA)

CERTIFICATE OF ANALYSIS				CERTIFICATE OF ANALYSIS			
FILL VOLUME:	6mL	FILL VOLUME:	5 mL				
PRODUCT NAME:	Bluum 20 Billion Exosomes	PRODUCT NAME:	Bluum 200 Billion Exosomes				
LOT NUMBER:	20A0043	LOT NUMBER:	20A0043				
EXPIRATION DATE:	9.9.2028	EXPIRATION DATE:	9.9.2028				
STORAGE CONDITIONS: Product should be stored at -20° Celsius or colder.		STORAGE CONDITIONS: Product should be stored at -20° Celsius or colder.					
ACCEPTANCE CRITERIA:	SPECIFICATIONS:	RESULT:	APPROVAL STATUS:	ACCEPTANCE CRITERIA:	SPECIFICATIONS:	RESULT:	APPROVAL STATUS:
Particle Concentration (particles/mL) by Nanoparticle Tracking Analysis (NTA)	≥ 2.5e10	2.9e10 +/- 1.32e10	APPROVED	Particle Concentration (particles/mL) by Nanoparticle Tracking Analysis (NTA)	≥ 3.5e11	4.71e11 +/- 1.09e10	APPROVED
Sterility Testing of Final Containers and Biological Products (Direct Method) per USP <71>	No Growth	No Growth	APPROVED	Sterility Testing of Final Containers and Biological Products (Direct Method) per USP <71>	No Growth	No Growth	APPROVED
Determination of Endotoxin Using Kinetic Chromogenic LAL- Testing per USP <85>	< 2.5 EU/mL	Dilution Factor: 1 Endotoxin Content: < 0.05 EU/mL	APPROVED	Determination of Endotoxin Using Kinetic Chromogenic LAL- Testing per USP <85>	< 2.5 EU/mL	Dilution Factor: 1 Endotoxin Content: < 0.05 EU/mL	APPROVED
Sterile filtered (0.2 µm). Quality Control (QC) Testing for Sterility, Endotoxin, and Nanoparticle Tracking Analysis were conducted in compliance with current Good Manufacturing Practices (cGMP). ALL TEST RESULTS MEET SPECIFICATIONS OUTLINED ABOVE.				Sterile filtered (0.2 µm). Quality Control (QC) Testing for Sterility, Endotoxin, and Nanoparticle Tracking Analysis were conducted in compliance with current Good Manufacturing Practices (cGMP). ALL TEST RESULTS MEET SPECIFICATIONS OUTLINED ABOVE.			

Safety and Quality Testing of MSCs and Stem Cell Conditioned Media				
Endotoxin	VRL 62003	0.674	< 1.0 EU/mL	Approved
Sterility	VRL 62003	Negative	Negative	Approved
Bioburden	VRL 62003	Negative	Negative	Approved
Mycoplasma	VRL 62003	Negative	Negative	Approved
TreponemapallidumCAPITIA	VRL 62003	Non Reactive	Non Reactive	Approved
HIV/I	VRL 62003	Non Reactive	Non Reactive	Approved
HBV	VRL 62003	Non Reactive	Non Reactive	Approved
HCV	VRL 62003	Non Reactive	Non Reactive	Approved
HTLV/III	VRL 62003	Non Reactive	Non Reactive	Approved

RELEASE SIGNATURE

 Roy Korth, Senior Vice President

DATE August 16th, 2023


 Lorynne Shelton, Compliance Specialist

DATE August 16th, 2023

****Enclosed product is for Professional Topical Cosmetic Use Only. It is not intended for use in clinical diagnosis, patient/donor management or human clinical trials. Product is xeno-free, serum-free, and never tested on animals.****