

HELIOS[®] Exosome-Depleted UltraGRO™-PURE GI

For hMSC-derived EV production

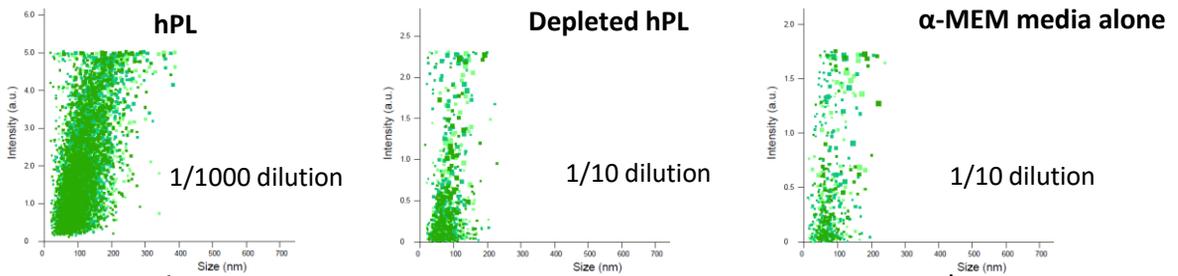
Xeno-Free, Viral Inactivated, Exosome-Depleted for EV Production

AventaCell BioMedical Corp. has developed an exosome depletion process to remove human platelet lysate (hPL)-derived exosomes. Exosome-Depleted UltraGRO™-PURE GI (ED UG-P GI) is able to support human MSC cell viability to secrete abundant extracellular vesicles (EVs) without compromising phenotype over the culture period. Moreover, gamma irradiation processing of the product is used as a pathogen reduction treatment (PRT) for viral inactivation, to comply with regulatory guidance for clinical research and development.

Benefits of Exosome-Depleted UltraGRO™-PURE GI

- Xeno-free with >95% nanoparticle removal from the hPL supplement
- Minimal hPL nanoparticle contamination
- MSCs cultured with the depleted supplement remain highly viable with stable phenotype markers throughout the culture period
- GMP Exosome-Depleted UltraGRO™-PURE GI to produce clinical grade hMSC-derived EVs
- Gamma irradiation processing is accepted by regulatory agencies as a validated PRT

High depletion rate was performed in the manufacturing process



NTA results (n = 5)	Non-depleted hPL	Depleted hPL	Depletion rate
Particle count/mL	$2.73 \times 10^{11} \pm 6.48 \times 10^{10}$	$3.52 \times 10^9 \pm 3.16 \times 10^9$	99.07%

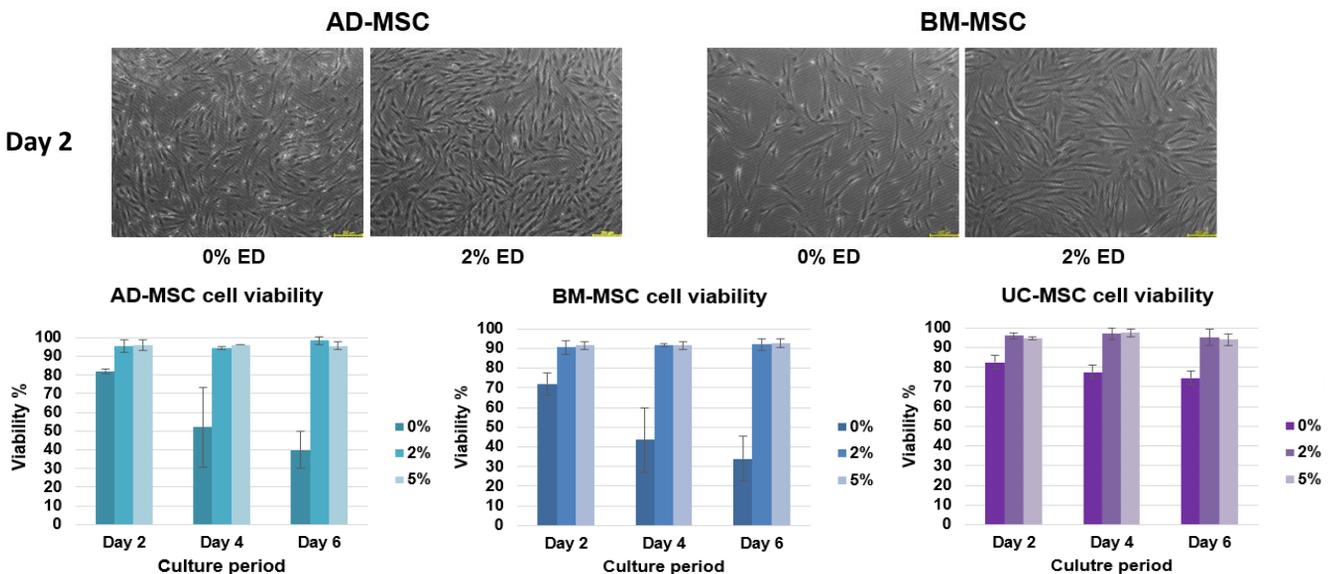


Fig 1. Highly depletion rate was performed, and ED UG-P GI is able to support MSCs for long-term EV production.



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Particle in medium	α -MEM media alone	2% ED UG-P GI	5% ED UG-P GI	<i>Minimal interference</i>
Particle count/mL	$1.93 \times 10^8 \pm 1.27 \times 10^7$	$3.51 \times 10^8 \pm 1.31 \times 10^7$	$4.32 \times 10^8 \pm 5.54 \times 10^7$	

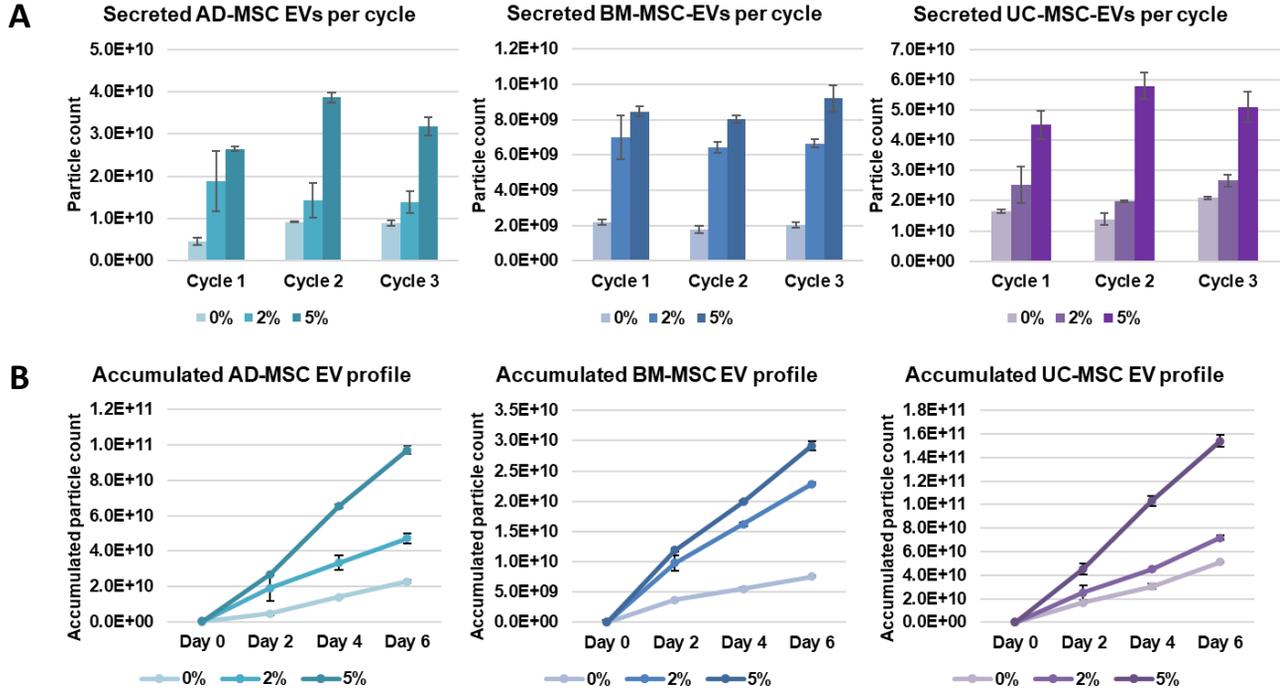


Fig.2: After MSCs reached 50-70% confluency in a T75 flask, the culture media was changed to ED UG-P GI supplemented culture media, and the media refresh was performed every 2 days as one culture cycle. (A) MSC-derived EVs secretion and their (B) accumulation profile were measured by NTA. (C) The MSC specific phenotype was not altered throughout the culture period up to 14 days.

C MSC phenotype characterization

Culture period	CD73	CD90	CD105	CD34
Day 10	97.4%	99.4%	99.7%	1.2%
Day 14	97.9%	99.8%	97.6%	1.8%

Billions of MSC-derived EVs can be easily acquired for further applications!



Specifications	Acceptance
Appearance	Slight yellow
Mycoplasma	Negative
Endotoxin	< 10 EU/mL
Sterility	No growth
pH	6.5 – 8.5
Osmolarity	270 – 330 mOsm/kg
Particle depletion rate	> 95%
Cell assay	Support MSC culture
Gamma irradiation dose	25 – 40 kGy

Ordering Information

Product Number	Product	Bottle Size (mL)
HPCHEFRLI05	Exosome-Depleted UltraGRO [™] -PURE GI	50
HPCHEFRLI10		100
HPCHEFRLI50		500
HPCHEFGLI05	Exosome-Depleted UltraGRO [™] -PURE GI (GMP grade)	50
HPCHEFGLI10		100
HPCHEFGLI50		500



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