

WHAT ARE EXOSOMES?

Exosomes are like tiny messengers that carry important information between cells, helping them communicate and do their jobs effectively. When exosomes are injected from human umbilical cord tissues, our old cells receive important messages to repair and replicate into healthier, younger cells.

Available research indicates that exosomes possess anti-inflammatory properties and can potentially be used to support the regeneration of aging or damaged tissues, by delivering rejuvenating signals to the target cells. MSCs are naturally present in our bodies until a certain age, and by replenishing our bodies with them, we have the capacity to accelerate the healing process of injuries by promoting tissue repair, modulating inflammation, and improving immune responses.

HOW DO THEY WORK?

When administered to a target area, such as an injured or damaged tissue, MSC exosomes are taken up by neighboring cells. Once inside the recipient cells, the bioactive molecules in the exosomes can influence gene expression, protein synthesis, and cellular functions. This process can lead to a series of beneficial effects, such as promoting tissue repair, reducing inflammation, and stimulating the growth of new blood vessels, which may collectively aid in the healing and regeneration of the injured area.

Studies have explored the potential applications of stem cell-derived exosomes in various areas, including peripheral nerve damage, traumatic brain injury, wound healing, bone fusion, tissue repair, inflammation modulation, skin health, cartilage health, ligament/tendon injuries, osteoarthritis, bone health, and women's health. It is important to note that, as of now, there are no FDA-approved exosome products available in the United States.

WHERE DO EXOSOMES COME FROM?

MSC exosomes are intricate nano-packages secreted by specialized cells known as mesenchymal stem cells (MSCs). These extraordinary MSC stem cells are sourced from the resilient Wharton's Jelly found in the human umbilical cord. Wharton's Jelly plays a vital role in safeguarding the umbilical vessels from torsional and compressive stresses during fetal development. One of the key advantages of these cells is their youthfulness and protection against damages caused by aging, environmental toxins, and diseases. All of our exosomes are sourced from a woman's clinic in Baton Rouge, Louisiana. The umbilical cords are donated by patients who have had healthy full-term pregnancies.

WHY EXOGENIX?

Exogenix takes pride in representing one of the only exosome manufacturers registered as a biological product in the United States. This distinction ensures that our exosomes adhere to the highest standards of safety, purity, and potency of the biological product subject to the FDA's rigorous oversight and approval. Because of this, our exosomes can be regarded as among the safest and most potent exosomes available in the market. As a 351(a) biologic product, they can only be sold for research and investigatory use, and must undergo a thorough testing accompanied by virology reports from third parties to establish safety and potency.

CERTIFICATE OF ANALYSIS (COA)

With every batch, we provide a Certificate of Analysis verifying the precise quantity contained within your vial. A CoA is a crucial document that ensures that the product has been tested and meets specific quality standards. It verifies that the product is of the expected quality, free from contaminants, and meets the specifications outlined in the document.

- SAFETY: It provides information about the absence of harmful substances or contaminants, helping to ensure that the product is safe for its intended use or consumption.
- **COMPLIANCE**: A CoA includes information about regulatory compliance, confirming that the product meets legal and regulatory requirements.
- CONSISTENCY: It helps ensure batch-to-batch consistency by confirming that each batch of the product meets the same quality and purity standards.
- TRANSPARENCY: A CoA provides transparency to customers, regulators, and other stakeholders by offering a detailed breakdown of the product's composition, test results, and compliance with industry standards.
- PRODUCT VERIFICATION: It allows customers or regulatory authorities to verify the product's authenticity and quality, reducing the risk of counterfeit or substandard products in the market.

QUALITY STANDARDS:

FDA DRUG MASTER FILE

Submission of a Drug Master File demonstrates the manufacturer's commitment to regulatory compliance and quality assurance. It ensures that the FDA has access to the necessary information to assess the safety and potency of the product, as well as manufacturing practices and processes.

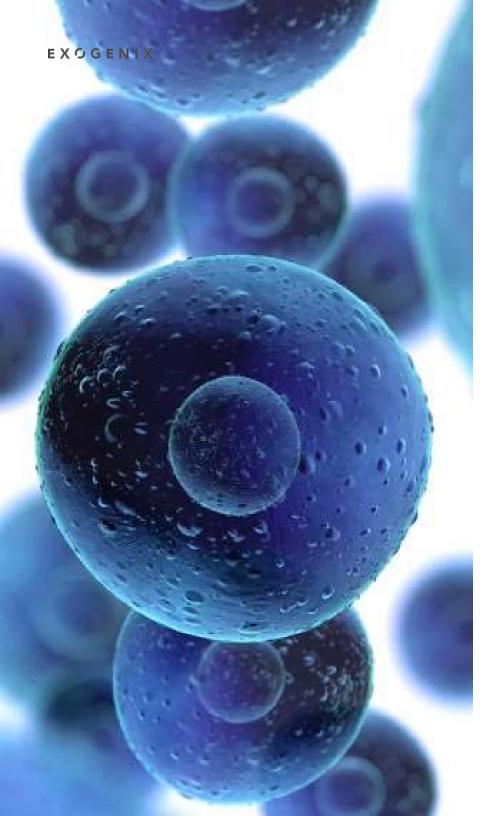
THIRD PARTY TESTING

A third-party virology report for exosomes is crucial for verifying their safety and quality. All batches provided by the manufacturer we contract with are tested by third-party testing company to mitigate the risk of viral contamination. The report adds transparency and assurance to the development and use of our exosomes.

CURRENT GOOD MANUFACTURING PRACTICE (CGMP)

All the product is made in ISO-5 cleanrooms at CGMP-compliant facilities.





OUR MSC EXOSOMES VS LYOPHILIZED EXOSOMES:

Some exosome brands utilize a preservation technique known as "Iyophilization." Lyophilization is a drying process that involves the removal of water from a water-containing sample through sublimation. This sublimation occurs after freezing the sample and subjecting it to a vacuum. However, it's crucial to note that the cell's delicate bilipid layer is highly sensitive, and lyophilization disrupts this layer. While lyophilization provides stability at room temperature, the reconstituted product lacks the necessary chemical structure to maintain this stability.

Additionally, the introduction of chemicals during this process means that the resulting product is not entirely pure. Aside from the operational inefficiencies and disruptions it may cause in your clinic's workflow, there is currently no scientific evidence supporting the notion that lyophilized exosomes possess the same payload and effectiveness as non-lyophilized exosomes. No scientific tests in the lyophilized exosome market have demonstrated the preservation of the initial mRNA and miRNA payload or their efficacy upon reconstitution. For these reasons, our exosome research lab has omitted this manufacturing technique.



EXOSOMES VS STEM CELLS?

Exosomes, being smaller in size, hold great promise as vehicles for delivering therapeutic cargoes systemically throughout the body, a challenge often faced by larger stem cells. These nanosized vesicles can efficiently cross the blood-brain barrier, precisely targeting specific cells and tissues.

In contrast to stem cells, exosomes lack the inherent capability to transform into various cell types. Instead, their influence is exerted through the delivery of their cargo to target cells, where they adjust cellular functions and stimulate the processes of tissue regeneration.

Unlike stem cells, exosomes do not carry live DNA. Remarkably, a significant portion of the therapeutic benefits attributed to stem cells actually stem from the actions of the exosomes they release. This feature sets exosomes apart as a superior choice, offering a safe and highly effective approach to tissue repair and rejuvenation.

EXOSOMES VS PRP (PLATELET-RICH PLASMA)?

A standard PRP injection typically provides a maximum of 12 growth factors to the treatment area. In contrast, exosome injections may deliver a significantly higher number, with approximately 700 growth factors. Exosome therapy is essentially potentially about 60 times more powerful and effective than PRP treatment.

EXOSOMES + PRP?

In general, inflammatory agents can compromise effectiveness, and PRP is considered one such agent due to its inflammatory properties. This creates a challenge where treatments may counteract each other, leading to potential hindrances. It can be likened to using a mix of outdated and new, high-performing components together. When PRP is injected or transfused, it triggers inflammation in surrounding tissues, causing a misdirection of exosomes to unintended areas, impacting their ability to function optimally. Essentially, this issue arises from the inflammation caused by PRP, which leads to exosomes being diverted to the wrong locations, resulting in suboptimal outcomes.



CONTRAINDICATIONS

Exosomes are naturally occurring components in the body, which reduces the potential for adverse drug interactions. Our research lab conducted a thorough testing, using a concentration significantly higher than typical levels, administered three times a week for a month. The results indicated a lack of toxicity, suggesting that exosomes may be used safely, even in elevated amounts. It's important to note that when it comes to exosome therapy, there is no defined upper limit; once approved to be used as drugs by the FDA, the dosage will depend on the specific medical condition being addressed.

THAT SAID...

There are a few things that can make our exosome products less effective:

- Recreational drugs (including alcohol) and prescribed opioids
- Blood thinning medications or NSAIDs
- For facial treatment, certain skin care products, especially retinoids and acid-based products such as glycolic acid, and salicylic acid
- Other inflammatory agents.

HOW LONG DO RESULTS LAST?

The outcomes for each patient can differ, but studies have observed the effects of exosome therapy persisting for several years after the completion of a treatment plan. The specific results a patient experiences will be influenced by various factors, including the nature of their concerns and their individual medical condition. Depending on the situation, certain health issues may be resolved with only 1-2 therapy sessions, while others may necessitate an ongoing treatment plan to achieve optimal results. Additionally, the timing of results can vary, and some patients may notice improvements almost immediately, while for others, the full effect of their treatment may become evident within 3-6 months post-treatment. Patients are encouraged to consult their healthcare providers before considering exosome treatment as it has not yet been approved by the FDA.



DELIVERY APPLICATIONS:

- Direct Injection
- Intravenous Injection
- Nebulization
 - Intratracheal
 - Intranasal
- Topical Application

SHIPPING:

- Each order will be priority overnighted to preserve the integrity of the exosomes
- Vials are shipped on dry ice from the lab in Louisiana to its desired destination

STORAGE:

- Room Temperature: 24 hour room half life
- Regular Freezer (-20c): 6 weeks stable
- Cryo-Freezer (-80c): 18 months stable
- Vials can be refrozen up to 3 times

*FOR MORE INFO PLEASE CONTACT US AT INFO@EXOGENIX.COM

STEM CELL-DERIVED EXOSOMES AREEXCLUSI VELY SOLD FOR RESEARCH PURPOSES IN VARIOUS AREAS, INCLUDING:

- · Acne & Acne Scars
- Aging
- Bell's Palsy
- Burns/Wounds
- Erectile Dysfunction/Male Enhancement (P-Shot)
- Endometriosis
- Enlarged Pores
- Glaucoma
- Hair Loss
- Hyperpigmentation
- Inflammation
- Infertility
- Melasma
- Poor Skin Elasticity
- Sagging Skin
- Sexual dysfunction
- Skin regeneration
- Sun Damage
- Uneven Skin Texture
- Vaginal Rejuvenation (O-Shot)
- · Wrinkles and Fine Lines

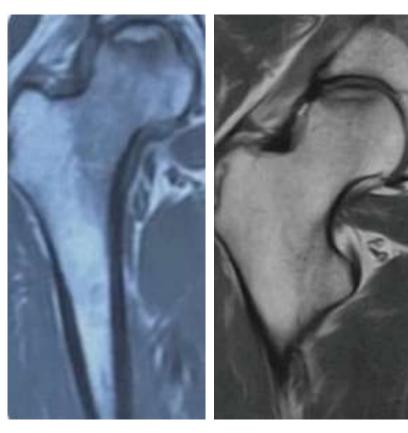
STEM CELL-DERIVED EXOSOMES ARE NOT CURRENTLYAPPROVED B
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*DISCLAIMER: RESULTS MAY VARY PERSON TO PERSON

INCREASED BLOOD FLOW



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STEM CELL-DERIVED EXOSOMES AREEXCLUSI VELY SOLD FOR RESEARCH PURPOSES IN VARIOUS AREAS, INCLUDING:

- Autoimmune Illnesses
- Bone Fractures
- Bone Fusion & Regeneration
- Cartilage Regeneration (i.e. Meniscus tears)
- COVID-19 Long-Haulers
- Dementia
- Injured Ligaments/Tendons (i.e. ACL tears)
- Joint/Systemic Inflammation (i.e. Arthritis)
- Multiple Sclerosis
- Muscle Strains & Tears
- Orthopedics
- Osteoarthritis
- Overuse Injuries (i.e. Shin Splints)
- Peripheral Nerve Damage
- Plantar Fasciitis
- Rotator Cuff Injuries
- Spinal Cord Injuries
- Stroke
- Tendinitis and Tendinopathy
- Tissue Repair
- Traumatic Brain Injury
- & more...

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