

What Is an Exosome?

Understanding extracellular vesicles in regenerative medicine

IN BRIEF

Exosomes are extremely small packages, 30 to 150 nanometers across, that cells release naturally to communicate with one another.

They carry proteins, genetic material, lipids and metabolites, and because the body makes them already, researchers are studying them as carriers for therapeutic cargo.

The underlying biology is well established. Clinical application is an active research area, and isolation and potency testing methods are not yet standardized across the field.

Introduction

Exosomes are the smallest subtype of a broader category of cell-secreted particles called extracellular vesicles. Interest in exosomes has grown rapidly across nanomedicine and precision medicine because of their potential diagnostic, prognostic and therapeutic applications.[1]

Basic biology

Exosomes are nano-sized, lipid-bilayer-enclosed particles, typically 30 to 150 nanometers in diameter, secreted by cells after intracellular multivesicular bodies fuse with the plasma membrane.[1] They carry a mix of biological cargo:

- Proteins
- Nucleic acids, including microRNA
- Lipids
- Metabolites

This cargo allows exosomes to act as mediators of cell-to-cell communication, with roles in processes such as immune response regulation and neuronal communication.[1]

Why exosomes are studied as delivery vehicles

Because they are produced by the body itself, exosomes are being studied for potentially superior biocompatibility and stability compared with synthetic drug-delivery carriers. That is one reason researchers are exploring them as vehicles for therapeutic cargo.[1] Current research focuses on methods for isolating and characterizing exosomes, and on the practical obstacles that must be resolved before they can be used reliably as delivery systems.[1]

Regulatory considerations

Exosome products are generally regulated as human cellular and tissue-based products (HCT/Ps) under FDA 21 CFR Part 1271 where applicable. Depending on the degree of manipulation and the claims made, some products may be subject to closer regulatory scrutiny as biologic drugs. Regulatory treatment continues to evolve and should be verified for each specific product and claim before clinical use.

Evidence status	
Evidence status	What this means
Established	The basic biology, structure and cell-to-cell signaling role of exosomes is well documented in the scientific literature.[1]
Emerging	Exosome-based diagnostic and therapeutic applications are an active area of nanomedicine and precision-medicine research, with growing interest in fields ranging from oncology to regenerative medicine.[1]
Limited	Isolation methods, potency assays and dosing units for exosome products are not yet standardized across the field. A 2026 methodological review of PRP noted that reproducibility challenges exist broadly across cell-derived biologic products where manufacturing methods are not standardized, a consideration that extends to exosome products.[2] This should be weighed when interpreting any individual product's claims.

- Key points**
- Exosomes are nano-sized extracellular vesicles, 30 to 150 nanometers, carrying proteins, RNA, lipids and metabolites.
 - They act as natural mediators of cell-to-cell communication.
 - Their endogenous origin makes them of interest as delivery vehicles, but isolation and potency-testing methods are still being standardized.
 - Clinical application is an active and emerging research area rather than a field with large-scale, standardized clinical evidence.

Claim in this document	Source	Evidence strength	Limitations
Exosomes are 30 to 150 nm lipid-bilayer vesicles formed by multivesicular body fusion	Di Bella, Biology (Basel), 2022. PMID 35741325	High, peer-reviewed review	Written for a scientific and clinical audience
Cargo includes proteins, nucleic acids, lipids and metabolites, with a role in cell communication	Di Bella, 2022	High	None noted
Isolation methods and delivery-system obstacles are active research areas	Di Bella, 2022	High as a characterisation of the field	Field moves quickly; recheck currency periodically
Manufacturing standardization challenges apply broadly to cell-derived biologics	Berdini et al., LabMed, 2026. DOI 10.3390/labmed3010008	Moderate	Sourced from PRP literature and applied by analogy, not an exosome-specific finding

References

[1] Di Bella MA. Overview and Update on Extracellular Vesicles: Considerations on Exosomes and Their Application in Modern Medicine. Biology (Basel). 2022 May 24;11(6):804. DOI 10.3390/biology11060804. PMID 35741325. PMCID PMC9220244.

[2] Berdini M, Clementi G, Torcianti M, Del Bianco D, Cantori I, Procaccini R, Gigante A. Standardization of Platelet-Rich Plasma Preparation in Orthopedics: A Review of the Literature and Proposal for a Reproducible Protocol. LabMed. 2026;3(1):8. DOI

10.3390/labmed3010008.

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