Mesenchymal Stem Cell-Derived Exosomes from Wharton's Jelly: The Gold Standard for Safe, Compliant Regenerative Medicine

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DOI: 10.5281/zenodo.20974697 (all versions). This version: 10.5281/zenodo.23597078.

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Summary

This white paper argues that Wharton's jelly MSC exosomes made under cGMP and regulated under Section 351(a) of the PHS Act, with CBER oversight, should set the standard for cell-free regenerative products. It covers source biology, safety compared with live cells, 351(a) classification, Drug Master Files, batch virology testing and cold-chain shipping. FDA has not approved any exosome product.

Exosome and mesenchymal stem cell-derived extracellular vesicle products are not approved by the FDA for any indication. This paper describes published scientific literature. It does not describe an available treatment.

Questions this paper covers

• What is Wharton's jelly?

• Why is Wharton's jelly studied as an MSC exosome source?

• What does Section 351(a) cGMP manufacturing require for exosome products?

• What is a Drug Master File?

Sources

1. 42 U.S.C. 262 (Section 351 of the PHS Act)

2. 21 CFR Parts 210, 211 and 600 to 680

3. FDA, Drug Master Files (DMFs)

4. FDA Public Safety Notification on Exosome Products, Dec 6, 2019

5. Witwer KW et al. J Extracell Vesicles. 2019. PMID 31069028; Welsh JA et al. MISEV2023. 2024. PMID 38326288

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