

Mesenchymal Stem Cell-Derived Exosomes from Wharton's Jelly Umbilical Cord: Regulatory Classification Under FDA CBER Section 351(a)

Andrew Jonathan Hillman

ORCID 0009-0001-5396-321X

DOI: 10.5281/zenodo.21169929 (all versions). This version: 10.5281/zenodo.21169930.

<https://andrew-hillman.com/publications/whartons-jelly-msc-exosomes-351a-classification/>

Published 2026-07-03. License: CC BY 4.0.

This PDF reproduces the summary page for this paper at <https://andrew-hillman.com/publications/whartons-jelly-msc-exosomes-351a-classification/>. The full paper is at <https://doi.org/10.5281/zenodo.21169929>.

Summary

This manuscript argues that exosomes from Wharton's jelly umbilical cord MSCs require BLA licensure under Section 351(a) of the PHS Act, because they are manufactured biologics rather than minimally manipulated tissue. It then describes the manufacturing and characterization standards that classification implies, including cGMP, unbroken cold-chain control and quality frameworks such as ISO 13485 and ICH Q10.

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

- Are Wharton's jelly exosomes regulated as drugs or as HCT/Ps?
- What manufacturing standards apply to a 351(a) exosome product?
- Which quality frameworks apply to exosome characterization?
- Are any exosome products FDA approved?
- What does 21 CFR Part 1271 require of tissue products?

Sources

1. 42 U.S.C. 262 (Section 351 of the PHS Act)
2. 21 CFR 1271.10(a)
3. 21 CFR Parts 210, 211 and 600 to 680
4. ICH Q10 Pharmaceutical Quality System

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

Educational content. It is not legal or medical advice.