

How do you define the male AB serum, human serum albumin or leukopak in cell therapy? Are they ancillary, raw, excipient, or starting material?

Swipe to discover the answer!



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Terminology:

Starting materials are the initial biological materials that are used at the beginning of the manufacturing process to create a cell-based medicinal product.
Examples: Cells, tissues, leukopaks, etc.

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Ancillary / raw materials are substances used during the manufacturing process being in contact with the cells or tissues produced that are not intended to be present in the final product.

While the term "ancillary material" is used in the United States (USP and ISO^{1,2}), it is not a globally recognized regulatory term. In Europe, "raw material" is more commonly used (EP³).

Examples: Growth factors, enzymes, human serum albumin, male AB serum, etc.

References:

1. United States Pharmacopeia. <1043> Ancillary Materials for Cell, Gene, and Tissue-Engineered Products 2020.
2. International Standards Organization. ISO 20399:2022 Biotechnology—Ancillary Materials Present During the Productions of Cellular Therapeutic Products and Gene Therapy Products 2022.
3. European Pharmacopoeia 10.0. 5.2.12 Raw Materials of Biological Origin for the Production of Cell-Based and Gene Therapy Medicinal Products 2017.

Excipient is a substance other than the active pharmaceutical ingredient (API) that is included in the formulation.

Examples: Buffers, human serum albumin, etc.

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