

# Fresh Bone Aptitud Assay Verification †

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† Presented at The Sixth International Meeting of Pharmaceutical Sciences (RICiFa), November 10-12, 2021, Córdoba, Argentina

Received: 26.04.2022; Revised: 4.05.2022; Accepted: 6.05.2022; Published: 8.05.2022

**Abstract:** In the processing of fresh bone for therapeutic use, washes with solutions of Sodium Chloride, Acetone, Sodium Peroxide, 96% Ethanol, and sterile osmosis water are used to remove waste products from the bone (lipids, blood, etc.) and suppress possible microbiological contaminants that may affect the biological and structural integrity of the bone piece. Each tissue undergoes a sterility assay to release the product microbiologically; That is why it is necessary to have its validation, to be sure that the final product does not inhibit the growth of possible contaminants that may be present in the tissue sample. To carry out this verification, no more than 100 CFU of the Microorganisms described in the 7th Argentine Pharmacopoeia were inoculated and an in-house strain, along with processed bone chunks. A positive control without tissue was also run. The tests were carried out in triplicate, concluding that the product does not inhibit the growth of the Microorganisms tested because it had comparable turbidity between the tissue tests and the positive control of all the samples analyzed.

**Keywords:** aptitud assay; sterility assay; fresh bone.

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## Funding

This research received no external funding.

## Acknowledgments

The Hemoderivados Laboratory of the National University of Córdoba is thanked for providing the facilities, reagents, and samples to carry out the Study.

## Conflicts of Interest

The authors declare no conflict of interest.