

Validation of Sterility Method in Gamma-globulin T [†]

David Federico Mereles ^{1,*}, Luciano Adrián Prenol ¹, Ana Lia Reale ¹, Natalia Isabel Quevedo ¹, Marcelo Sebastián Ostorero ¹, Ana Paula Vilches ¹

¹ Laboratorio Hemoderivados UNC; federico.mereles@unc.edu.ar (D.F.M.); luciano.prenol@unc.edu.ar (L.A.P.); ana.reale@unc.edu.ar (A.L.R.); natalia.quevedo@unc.edu.ar (N.I.Q.); marcelo.ostorero@unc.edu.ar (M.S.O.); ana.vilches@unc.edu.ar (A.P.V.)

* Correspondence: federico.mereles@unc.edu.ar (D.F.M.);

[†] 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: It's necessary to validate the sterility method to verify that the product does not have a bactericidal activity that could interfere with the recovery of possible contaminants. As in the Gamma-globulin T formulation, thimerosal (organomercurial compound) is used as a preservative; the validation or aptitude of sterility test must consider its inhibition. The objective of the study is to evaluate the best methodology for inhibiting the antimicrobial power of thimerosal, for which three proposals are tested: dilution with 500 ml of 0.1% Peptone; membrane wash with 100 ml 0.5% sodium thiosulfate (know neutralize mercury compounds) and membrane wash with 500 ml Engley / Day broth (culture broth with a wide range of microorganisms that neutralizes various antimicrobial and disinfectant agents). Membrane filtrations of solutions containing known concentrations of specific microorganisms, the neutralizers under study, and gamma globulin T were performed. Evaluating the quantity and morphological integrity of the recovered colonies, it is concluded that washing with Engley / Day broth is the best thimerosal inhibition alternative. Thanks to the study, the sterility method was validated as a membrane filtration with washes of 500 ml of Engley/Day broth to neutralize the Thimerosal and thus allow the development of possible microbiological contaminants.

Keywords: Gamma-globulin T; Thimerosal; membrane filtration; Engley/Day Broth.

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Funding

This research received no external funding.

Acknowledgments

Special thanks to Hemoderivados Laboratory of the National University of Córdoba for providing the facilities, reagents, and samples to carry out the study.

Conflicts of Interest

The authors declare no conflict of interest.