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Validation of Indirect Method for the Detection of Isoagglutinins A and B in Blood Products †

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Abstract: The limit required for anti-A and anti-B isoagglutinins in the European Pharmacopeia is the absence of agglutination in a 1/64 dilution as of 3% (w/v) of Immunoglobulin. There are different techniques for the determination, the indirect type is classified within the qualitative analysis techniques (presence or absence of agglutination). The objective of this study is to evaluate whether this technique is suitable for blood products. The test uses antibodies to human globulins and erythrocytes suspended at 5% in saline. For the evaluation of this test, it was determined: 1- Specificity: Standard Rating: NIBSC Positive control IVIG preparation 07/306 and Negative control preparation 07/308. Evaluation of the interference of excipients of blood products Verification of the interference of the formulated product. 2- Detection limit: The minimum value with which the probability of false negatives is less than 5% was calculated. Specificity: It complies with the recovery of the NIBSC standard. The excipients of evaluated products do not produce interference. Tested products do not produce interference. Detection limit: The value obtained is less than the requirements of the European Pharmacopeia. The studied method proved suitable for plasma derivatives as it ensures the presence or absence of agglutination in concentrations even smaller than those required by the European Pharmacopeia, allowing the release of a safe product for patients of different blood types and factors.

Keywords: isoagglutinin; antibodies; agglutination; plasma derivatives.

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Conflicts of Interest

The authors declare no conflict of interest.