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Validation of the Analytical Method: Determination of Proteins by Gornall Method †

Belen Fracaroli [1,*], Analía Mettan [1], Mariano Pugliese [1], Emiliano Cuarta [1], Tristán Novillo [1], Julieta Dugoni [1], Gabriela de la Iglesia [1], Ana Paula Vilches [1]

[1] Laboratorio de Hemoderivados UNC, área Control de Calidad, Departamento de Ensayos Físicos y físico-químicos; belen.fracaroli@unc.edu.ar (B.F.); analia.mettan@unc.edu.ar (A.M.); emiliano.cuarta@unc.edu.ar (E.C.); mariano.pugliese@unc.edu.ar (M.P.); novillo.tristan@unc.edu.ar (T.N.); julieta.dugoni@unc.edu.ar (J.D.); gabriela.iglesia@unc.edu.ar (G.I.); ana.vilches@unc.edu.ar (A.P.V.)
* Correspondence: belen.fracaroli@unc.edu.ar (B.F.);
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Abstract: The validation of analytical methods is a regulatory requirement as authorities sanitary (INAME). The Gornall Method qualifies within category I include the MA for quantifying components majority of early active in pharmaceutical products (USP 43). Demonstrate that the method used to evaluate the parameter Determination of proteins by the Gornall Method is adequate, effective, and complies with regulatory requirements. It is based on the Biuret reaction. The reagent used contains a mixture of copper, sodium hydroxide, and sodium potassium tartrate that stabilizes the copper in the solution. In an alkaline medium, copper reacts with proteins, forming a complex violet-colored with peptide bonds (Biuret), whose color intensity depends on the concentration of proteins. For evaluations, we worked with three analysts on 3 different days, each analyst preparing 5 different levels of proteins from NIST of Bovine Serum Albumin of Solution to 7% Accuracy : (99.5-102.3%); Repeatability :% CV: (0.1- 4.3%); Intermediate precision: % CV: (0.8-3.7%); Linearity-range: R^2 = 0.9999 and Specificity: No interference in the signal. All parameters comply. The method used to evaluate the parameter Determination of proteins by the Gornall Method is adequate, effective, and complies with regulatory requirements

Keywords: proteins; Gornall; hemoderivatives.

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Conflicts of Interest

The authors declare no conflict of interest.