

Comparison of Two Methods for the Determination of Total Proteins in Injectable Gammaglobulins UNC[†]

Analia Mettan^{1,*}, Belen Fracaroli¹, Mariano Pugliese¹, Emiliano Cuarta¹, Tristán Novillo¹, Julieta Dugoni¹, Gabriela de la Iglesia¹, Ana Paula Vilches¹

¹ Laboratorio de Hemoderivados UNC, área Control de Calidad, Departamento de Ensayos Físicos y físico-químicos; analia.mettan@unc.edu.ar (A.M.); belen.fracaroli@unc.edu.ar (B.F.); 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: analia.mettan@unc.edu.ar (A.M.);

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Abstract: In the Process Control department, the determination of total proteins in the production of Gamma globulin G-UNC is carried out by the UV Absorption method at 280nm. In the Department of Physical and Physico-chemical tests of the Quality Control area of the Laboratorio de Hemoderivados UNC, the determination is carried out by the Gornall method (Biuret). Evaluating the specificity validation method of Gornall, interference of Sorbitol solution is detected stabilizer present in the formulation Gammaglobulina- UNC. The objective of this work is to compare both methods to verify if there are differences between them is statistically significant due to the interference of sorbitol. UV-Vis Spectrophotometer. Results of total protein by both methods of 73 batches of gamma globulin-UNC years: 2019-2021. It was applied on this couplet paired t-test. Experimental $p = 0.24$ is greater than theoretical $p = 0.05$; alternative hypothesis is rejected. There are no statistically significant differences between the protein results obtained by the mentioned methods. Sorbitol does not affect specificity in UNC injectable Gamma Globulin samples.

Keywords: dexamethasone sodium phosphate injectable; hemoderivatives; excipients degradation.

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Conflicts of Interest

The authors declare no conflict of interest.