INTRODUCTION: Erythropoietin is a glycoprotein produced by the kidney that acts as a hormonal factor in the formation of erythrocytes. With the advent of genetic engineering, there was obtained a recombinant human erythropoietin (EPOhr) in cultured mammalian cells, a fact which allowed its wide clinical use in the treatment of anemia. Like other glycosylated proteins, the EPOhr comprises a mixture of isoforms related to the degree of glycosylation and the presence of sialic acid, influencing the electrophoretic mobility and isoelectric point (pI) of the molecule. OBJECTIVES: To standardize the distribution of EPOhr isoforms by isoelectric focusing polyacrylamide gel (IEF-PAGE) seeking the quality control of biopharmaceutical in Bio-Manguinhos/Fiocruz. MATERIAL AND METHODS: For this study, we used the Reference Material candidate (cMR), and Biological Reference Preparation (BRP) of the European Pharmacopoeia (E.P.) of EPOhr. The experimental delineation of this study was according to category III of RE 899 from ANVISA, where repeatability is the parameter analyzed. PhastGel dry was used with a combination of ampholytes which generates an acid pH gradient, using 4µg of desalted EPOhr. RESULTS AND DISCUSSION: It has been evidenced the presence of eight major isoforms, and the estimated pI indicated mean values: 6.43 and 4.12. The percentage of each isoform of the samples was calculated from the volume of band and compared to the limit set by E.P. with concordance of results between the replicas. CONCLUSION: The standardization of the methodology showed a good separation of isoforms in agreement with literature data and specifications of the current E.P.

Keywords: Quality control; Recombinant Human Erythropoietin; isoelectric focusing.
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