In recent years, advances in biopharmaceuticals production technology made regulatory agencies more rigorous, especially in purification steps and in control analysis. Reference materials (RM) are necessary to make these procedures reliable for product control. RMs are homogenous preparations of well-defined proprieties, for a method use or value attribute, with result consistency for product quality. Recombinant human Erythropoietin (rh-EPO), a 34 kDa glycoprotein, is the most used biopharmaceuticals in the world. Nowadays, the only MR for rh-EPO is from European Pharmacopoeia. In this work a national MR for rh-EPO were developed. A three different baths of rh-EPO were tested. Two batches were stabilized with human serum albumin (HSA) and the other one was stabilized with an amino acid mixture. All batches were analyzed by SDS-PAGE, reversed phase HPLC, western blot and peptide mapping. SDS-PAGE, RP-HPLC and western blot showed consistency in molecular weight, retention time, peak area and band intensity. The peptide mapping result for the batch without HSA also showed consistency for retention time and peak area. These demonstrated that batches with HSA could be used as RMs for SDS-PAGE, RP-HPLC and Western blot for final rh-EPO final product. Batch without HSA could also be used for peptide mapping identification.

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