Abstract

Quality Control (QC) is important to ensure the identity, strength, purity, pharmacological safety, efficacy, and effectiveness of biopharmaceutical products. Biopharmaceuticals are complex drugs that are created from living cells or organisms, which frequently employ advanced biotechnological techniques. In the biopharmaceutical industry, tests are performed on the finished product to ensure that it complies with its specifications in terms of both qualitative and quantitative characteristics before further production or commercialization. Several assays are conducted in order to ensure the quality control of finished products, including physical appearance determination, pH determination, osmolality determination, extractable volume determination, and container closure integrity testing. Each of the tests has its own specifications and the results of the tests are documented in the test form which is used to make product release decisions. All of the samples tested met its specification since it showed a clear and colorless liquid, a pH and osmolality value that was within the acceptable range, a volume or quantity that was not less than the stated value, and no leakage on the container closure. Thus, no deviations from specifications have been reported, indicating that the final product is safe, effective, and of high quality.

Keywords: Biopharmaceuticals, finished products, quality control