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Demonstration of Affinity Chromatography Stability Used to Purify a Monoclonal Antibody Employed as Inmunoreagent in Hepatitis B Vaccine Manufacturing

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SUMMARY. **Cuban hepatitis B vaccine active pharmaceutical ingredient was purified by immunoaffinity chromatography using CB.Hep-1 monoclonal antibody (mAb). The main mAb purification process step was an affinity chromatography. However, the affinity chromatography matrix stability has not been demonstrated under specific experimental conditions, which is mandatory for vaccine production. Therefore, in this research, mAb recovery, mAb purity, ligand leakage, and mouse DNA content were studied for more than 100 purification cycles using two independent Protein A-Sepharose (PAS) matrices and mouse ascites as complex biological source of mAb. As results, matrices showed a mAb recovery of 64.7 ± 15.5% and 78.1 ± 11.1%, respectively (p = 0.6974). The high mAb purity (> 90%), and the extremely low content of Staphylococcal Protein A (< 7.0 ppm) and mouse DNA (< 6.0 pg/mg) detected in PAS elution fractions throughout 133 purification cycle supports the matrix stability under specific experimental conditions and does not compromise the application of CB.Hep-1 for vaccine production.**

KEY WORDS: Affinity chromatography, Hepatitis B vaccine, Monoclonal antibody, Protein-A Sepharose.

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