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(54) Title: METHOD FOR DETECTING HOST CELL PROTEINS IN THERAPEUTIC ANTIBODIES BY COMBINING TRYPSIN DIGESTION, CHROMATOGRAPHY GRADIENTS, AND BOXCAR MASS SPECTROMETRY

(57) Abstract: The present disclosure provides an improved method for profiling the nature of undesirable host cell proteins (HCPs) in a therapeutic antibody preparation using an improved assay. The assay includes three (3) exemplary steps comprising: ultra-low trypsin digestion, long gradient liquid chromatography, and mass spectrometry (MS) using, in particular, BoxCar mass spectrometry. The disclosure allows for determining the purity of a therapeutic antibody such that it is suitable for use in patients.

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