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(54) Title: AFFINITY CHROMATOGRAPHY-COUPLED NATIVE MASS SPECTROMETRY FOR ANTIBODY ANALYSIS

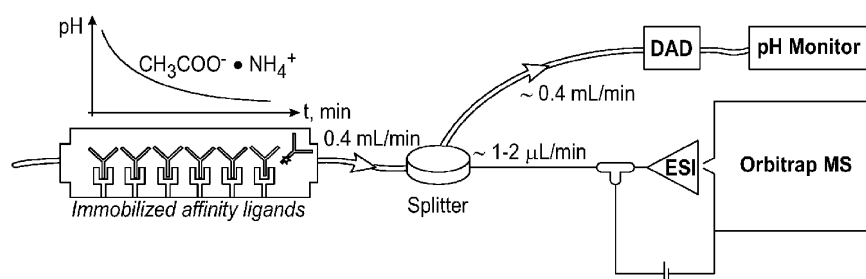


FIG. 2A

(57) Abstract: The present invention provides rapid, sensitive high-throughput methods and systems for characterizing peptides or proteins using affinity-based chromatography-coupled native mass spectrometry to improve manufacturing process of biopharmaceutical products, such as identifying impurities during antibody purification, monitoring post-translational modification variants during production, or characterizing drug-to-antibody ratio of antibody-drug conjugates. The separation profiles of the peptides or proteins are generated and compared to identify or qualify the peptides or proteins, wherein the separation profile is based on differential affinity binding.

[Continued on next page]

Declarations under Rule 4.17:

- *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*
- *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))*

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