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(71) Applicant *(for all designated States except US)*: **MILLIPORE CORPORATION** [US/US]; 290 Concord Road, Billerica, MA 01821 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **JIANG, Tongbo** [US/US]; 59 Winterberry Way, Bedford, MA 01730 (US). **FOLLO, Cheryl** [US/US]; 18 Sequoia Street, Billerica, MA 01821 (US). **PHELAN, Maurice, G.** [IE/US]; 62 Rockland Street, Swampscott, MA 01970 (US).

(74) Agents: **CARROLL, Alice, O.** et al.; Hamilton, Brook, Smith & Reynolds, P.C., 530 Virginia Road, P.O. Box 9133, Concord, MA 01742-9133 (US).

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[Continued on next page]

(54) Title: METHOD OF DETECTING FILTER EXTRACTABLES IN BIOPHARMACEUTICAL PRODUCTS BY LIQUID CHROMATOGRAPHY-MASS SPECTROMETRY

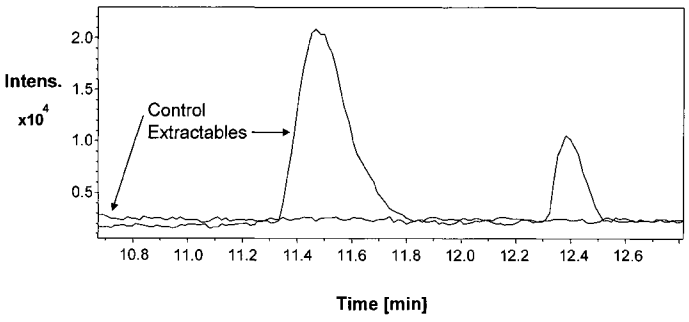


FIG. 3

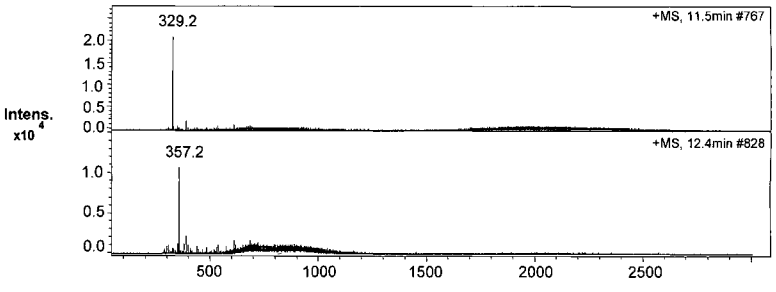


FIG. 4

(57) Abstract: Liquid chromatography-mass spectrometry to verify the presence or absence of the extractables introduced into a biopharmaceutical product during manufacture, filtration or storage at above a certain concentration. The method disclosed herein can be used to detect the presence of extractables in the actual biopharmaceutical product rather than a surrogate solvent system. Detection of the extractables in the actual drug product provides an accurate description of the leachables profile likely to be introduced to the human or animal patient. In one embodiment, the extractable are introduced by filtration of the biopharmaceutical product.

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