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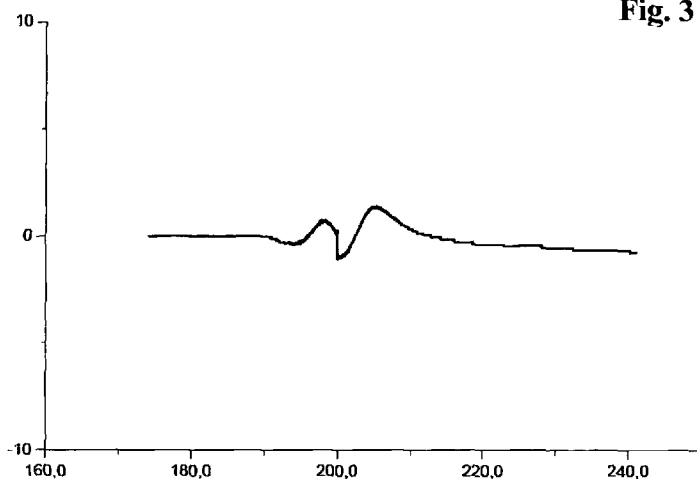
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(54) Title: CHARACTERIZATION OF RE-USEABLE CHROMATOGRAPHY EQUIPMENT

**Fig. 3**

(57) Abstract: Herein is reported a method for determining whether a re-useable chromatography column packing, which is used at least for the second time in a purification step of a purification of a polypeptide, has reduced separation efficacy in said purification step of said purification of said polypeptide. The method comprises the following steps: a) identifying and determining the experimental data of an inert change of at least one physicochemical parameter of a mobile phase passing through said re-useable chromatography column packing, b) determining the parameters of a function of formula I by fitting the experimental data of the inert change of the physicochemical parameter of the at least second use, c) determining the difference between the experimental data of the inert change of the physicochemical parameter of the at least second use and the function of formula I with the parameters determined in step b), d) calculating the difference between the maximum value and the minimum value of the difference determined in step c) and normalizing said difference, e) determining reduced separation efficacy of said re-useable chromatography column packing when the absolute value of the difference calculated in step d) is more than 0.1, wherein the function of formula I is with

$$yI = \frac{1}{2} P1 \cdot (1 + \operatorname{erf}(\frac{x-m}{s \cdot \sqrt{2}})) + A0 \quad (I)$$

the amplitude P1, the starting value A0, the mean value m, the standard deviation s, and wherein *erf* is the error function.