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(54) Title: QUANTIFICATION METHOD OF POLYSORBATE IN AQUEOUS FORMULATIONS

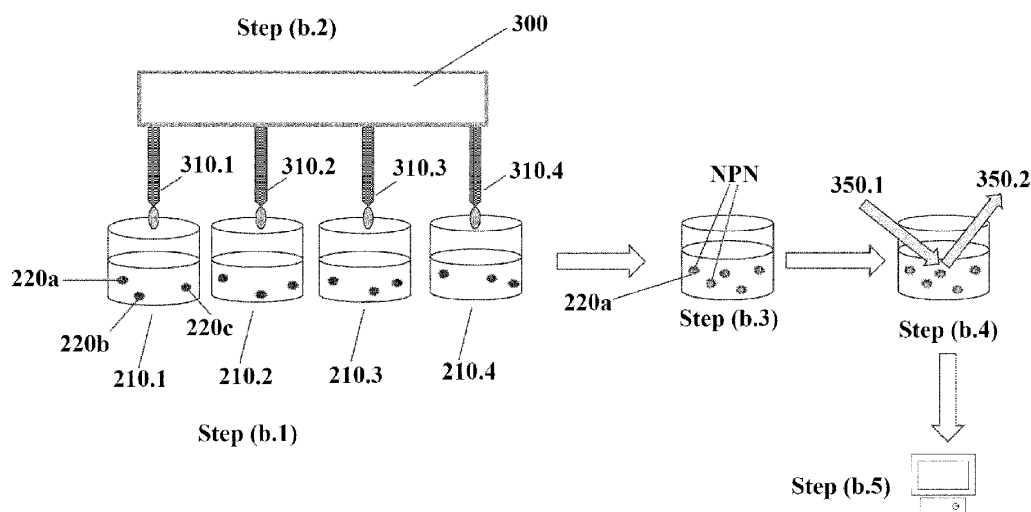


Figure 5

(57) Abstract: The present disclosure is directed to a method (a) for the quantification of polysorbate in aqueous formulations containing polysorbate and one or more (poly)peptides having the following steps: (a.1) providing a sample of the aqueous formulation; (a.2) adding of a solution containing the fluorescent dye N-phenyl-1-naphthylamine to the sample of step (a.1) to obtain a fluorescent dye containing sample to be tested in a fluorescence micelle assay; (a.3) optionally incubating the fluorescent dye containing sample of step (a.2); (a.4) performing a fluorescence micelle assay with the fluorescent dye containing sample obtained in step (a.2) or step (a.3) and (a.5) determining the content of polysorbate present in the sample from the fluorescence micelle assay performed in step (a.4); with the proviso that the method is being performed without the use of a HPLC-system. An additional method (b) of the present invention also allows a high-throughput-screening of a great number of samples. The presence of (poly)peptide(s) does/do not interfere with the

[Continued on next page]

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fluorescence micelle assay measurement in any way.