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(71) Applicant: **BOEHRINGER INGELHEIM INTERNATIONAL GMBH** [DE/DE]; Binger Str. 173, 55216 Ingelheim am Rhein (DE).

(72) Inventors: **ZEUN, Aline**; Boehringer Ingelheim International GmbH, Global Patents, Binger Strasse 173, 55216 Ingelheim am Rhein (DE). **HALBACH, Felix**; Boehringer Ingelheim International GmbH, Global Patents, Binger Strasse 173, 55216 Ingelheim am Rhein (DE).

(74) Agent: **HÖFER, Friederike**; Dreikönigsgasse 10, 89073 Ulm (DE).

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(54) Title: METHOD FOR DETERMINING THE DEGREE OF OXIDATIVE DEGRADATION OF POLYSORBATE 20 IN AQUEOUS FORMULATIONS

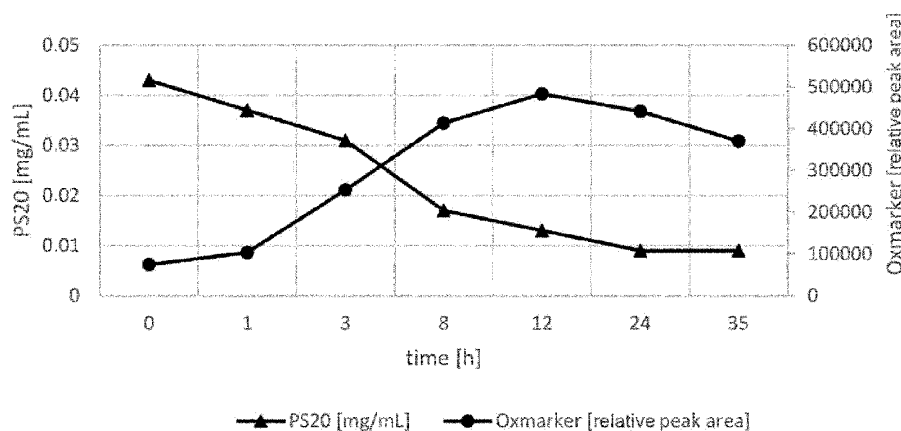


Figure 2A

(57) Abstract: A method is provided for determining the degree of oxidative degradation of polysorbate (20) in an aqueous formulation or a number of aqueous formulations, in particular biopharmaceutical formulations, each containing polysorbate (20), using a liquid chromatography-mass spectrometry based method, by which the relative peak area of the compound polyethylene glycol-6-laurate, a marker substance for the oxidative degradation of polysorbate (20), is determined by comparing a reference sample with a sample to be investigated. The relative peak area for the sample under investigation is proportional to the degree of oxidative degradation of polysorbate (20) in the sample. The method can also be carried out without using a reference sample by comparing the peak areas of polyethylene glycol-6-laurate of two or more aqueous formulations with each other. Further, a process of producing a recombinant protein is provided comprising i.a. the steps of formulating the recombinant protein into a pharmaceutically acceptable aqueous formulation

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suitable for administration using polysorbate (20), obtaining at least one sample containing the recombinant protein and polysorbate (20) therefrom and detecting the degree of oxidative degradation of polysorbate (20).