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(54) Title: MONITORING POLYSORBATE HYDROLYSIS IN PHARMACEUTICAL FORMULATIONS USING AN ULTRA-SENSITIVE EXTRACTION-FREE FATTY ACID QUANTITATION METHOD

(57) Abstract: The present invention generally pertains to methods of quantifying free fatty acids in a pharmaceutical formulation. In particular, the present invention pertains to a method of quantifying free fatty acids released from polysorbate hydrolysis in a pharmaceutical formulation comprising a pharmaceutical product, polysorbate and free fatty acids, using liquid chromatography-mass spectrometry, without the use of an extraction step.

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