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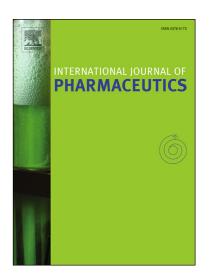
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Characterization of the Suspension Stability of Pharmaceuticals Using a Shadowgraphic Imaging Method

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Abstract

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A new shadowgraphic imaging method and an associated instrument for analyzing the physical stability of pharmaceutical suspensions are introduced in this paper. The new suspension tester consists mainly of a high-resolution camera that takes sequential shadowgraphic images of emulsions or suspensions and a 2D collimated LED for simultaneous whole-sample illumination in bright field. A built-in ultrasonic bath provides controlled initial agitation to the samples of interest. Sequential images acquired by the experimental setup were used to derive normalized transmission profiles from which an instability index was developed for quantitative stability comparison between samples. Instrument performance was verified by measuring the stability of a series of oil-in-water emulsions prepared with surfactant mixtures of different ratios. The new instrument correctly determined the required hydrophilic-lipophilic balance for sunflower oil to be 7.0. The stability of a pressurized suspension of spray dried lipid (DSPC) particles was monitored for 5 days after propellant filling. Although stable for

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