

Accepted Manuscript

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PII: S0378-5173(18)30452-6
DOI: <https://doi.org/10.1016/j.ijpharm.2018.06.053>
Reference: IJP 17600

To appear in: *International Journal of Pharmaceutics*

Received Date: 18 April 2018
Revised Date: 20 June 2018
Accepted Date: 23 June 2018

Please cite this article as: H. Wang, P. Tan, D. Barona, G. Li, S. Hoe, D. Lechuga-Ballesteros, D.S. Nobes, R. Vehring, Characterization of the Suspension Stability of Pharmaceuticals Using a Shadowgraphic Imaging Method, *International Journal of Pharmaceutics* (2018), doi: <https://doi.org/10.1016/j.ijpharm.2018.06.053>

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

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Abstract

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
15 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
20 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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