

New Instrument tests formulations for trace cristallinity

Researchers at Purdue University (West-Lafayette, Indiana) have created a new device which can rapidly and also inexpensively test early stages of pharmaceutical formulations for trace cristallinity. Trace crystalline content can have negative impact on bioavailability and drug stability as it reduces the chance of the drug being dissolved in a time frame required to be bioavailable and effective.

The instrument can be used in very early stages of pharmaceutical formulations. It provides a rapid screening of amorphous solid dispersions by measuring the triboluminescence, an optical phenomenon of light being emitted when the chemical bonds break for example by crushing a pharmaceutical powder. Any light measured is directly proportional to cristallinity in the formulation. Levels as low as 140ppm are detectable.

Many newly developed drugs are larger and more hydrophobic or have reduced aqueous solubility. By reducing the solubility crystalline content raises the negative effects for formulations on bioavailability and effectiveness.

With there being other ways to determine cristallinity, this provisionally patented electro-mechanical technique promises to be a rapid and also simple way to check small amounts of the material at the earliest time point possible. If light is detected, this indicates cristallinity and it can be tested further, while still being in very early stages of formulation.

The triboluminescence instrument is available for licensing. For the next steps of its development the research team is aiming at finding ways to test slurries for drugs that when put in water can spontaneously crsytallize.

Research Paper - Triboluminescence from Pharmaceutical Formulations

Casey J Smith, Scott R Griffin, Gregory S Eakins, Fengyuan Deng, Julia K White, Satyanarayana Thirunahari, Srividya Ramakrishnan, Atanu Sangupta, Si-Wei Zhang, Julie Novak, Zhen Liu, Timothy A Rhodes, and Garth J. Simpson :

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