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**Drug Photodegradation In The Solid State: Unexpected Photochemistry Observed In A Lyophilized Product**

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A small molecule oncolytic is being studied clinically for the treatment of various cancer types, and the presentation for phase II studies is a lyophilized cake consisting of drug, mannitol, and phosphate buffer. It was discovered that exposure of the lyophilized cake to either a cool white fluorescent lamp or to a xenon arc lamp (window glass filtered) resulted in discoloration and in the formation of water-insoluble particulates. This is particularly interesting since the crystalline drug substance is photostable. Investigation of this phenomenon led to the discovery that the photo-instability is not related to the presence of excipients but is solely related to the amorphous state of the drug. Further investigation into the causative wavelengths indicated that irradiation in the region of 340-400 nm is causing the photodegradation. This is remarkable since the UV-VIS spectrum of the drug substance in solution shows no absorption above 300 nm. Recent results of this investigation will be discussed.