

## TAM4-4

### A Review of Pharmaceutical Photostability Testing

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The impact of light exposure on drug substance and drug product quality has been known for almost as much time as the modern pharmaceutical industry has been in existence. The overall impact of photostability is evident from an examination of the United States Pharmacopeia (USP) 27 (2004) Reference Table "Containers for Dispensing Capsules and Tablets". Of the 743 pharmaceutical products listed in the table, 248 (33%) require light resistant packaging. Clearly, developing an improved understanding of photostability would improve the ability of pharmaceutical applicants to effectively control and respond to the specific requirements of each product. There is a large and diverse body of literature noting direct degradation of pharmaceutical substances upon exposure to light. In addition, literature examples exist where the drug is involved in the photochemistry through non-obvious mechanisms. By my estimates, ~15% (or 37 products) of the compounds listed as requiring light resistant packaging in the USP do not have appreciable absorption beyond 300 nm and thus beg the question: What is promoting the photo-instability of the product? The 300 nm wavelength represents a key differentiation determined by a combination of considerations of emission profiles for typical light sources and transmission properties of glasses and typical primary packaging materials. In this presentation, photostability testing of pharmaceutical products will be reviewed in context of the International Conference on Harmonization (ICH) guidance, ICH Q1B. Case studies will be presented that involve both direct and indirect means to couple light into drug compounds. It will be demonstrated that photostability testing of pharmaceutical products is necessary, even when the drug molecule itself does not absorb light at wavelengths > 300 nm.