

IPEC-Americas Publishes Position Paper on “Accelerated Stability”

Members of IPEC-Americas GMP Committee recently finalized a position paper on “Conducting Accelerated Stability on Excipients”. The paper addresses issues for IPEC-Americas members who are receiving requests from certain countries for Accelerated Stability (AS) data on excipient products that already have long term stability study data. These requests have come from regulatory agencies receiving product registrations in those countries or from excipient user companies exporting finished drugs into those countries. There have also been requests for ICH long term, intermediate and accelerated stability data, and questions regarding differences between storage statements on Safety Data Sheets (SDSs) and product stability documents.

The IPEC-Americas paper establishes its position regarding the necessity of such studies or data on excipients that are already being sold commercially and have documented long term stability studies. The paper does not address excipients that are new chemical entities that do not have a history of storage and transporting.

[Click here to read the entire document.](#)

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