



## STABILITY DATA CONSIDERATIONS

By thoroughly understanding the stability of a drug product or drug substance, data-driven decisions can be made throughout the development process and ensuring that the process can be expedited at every opportunity. By utilizing ASAP studies, it is possible to rapidly assess the impact of changes to a process, mitigating the risk of making such changes and ultimately demonstrating stability after the change.

Accelerated development timelines may limit the availability of real-time stability data, thus launching with reduced real-time stability for commercial material may require:

- Leveraging stability from early development and clinical batches when formulation remains unchanged and product comparability is demonstrated
- Using forced degradation and stress studies to provide additional supporting and comparability data
- Providing the stability protocol for commercial material
- Gaining FDA concurrence and committing to provide more real-time confirmatory data during review and post-approval
- Enhancing temperature monitoring and control of the product during shipment may be considered until shipping validation studies have been completed

### **Stability/Shelf Life Accelerated Stability Assessment Protocol (ASAP) Studies (small molecules and large molecules)**

Accelerated stability studies utilizing modeling for predictive stability assessments have the potential to play a key role in the expedited development and delivery of accelerated access projects. Experimental data when combined with an appropriate statistical protocol gives an opportunity for the prediction of chemical stability, which in turn allows for an accurate estimation of shelf life. ASAP studies give a greater insight into the stability of a product than traditional stability studies where the focus is on demonstrating stability rather than understanding it.

If the registration stability batches are no longer fully representative following a change to the process, ASAP data can be used without the requirement to produce additional formal stability studies before regulatory submission. This is particularly of interest when development timelines are restricted and the time for additional stability studies to be completed would significantly delay the marketing of the product. ASAP studies

also allow an estimation of the impact of humidity on the degradation of solid dosage forms and can be combined with Moisture Vapor Transmission Rate (MVTR) of the packaging and moisture sorption isotherms of the internal components to identify the most appropriate packaging configuration for the solid oral dosage form.

Moreover, any changes to the configuration i.e. change in tablet count, desiccant, wall thickness, initial moisture content can be accurately predicted without the need to repeat the stability studies. Where there is a need to assign a shelf life or retest period within a restricted timescale in order to expedite regulatory submission and delivery of medicines to patients, it is possible for ASAP studies to be used as the primary source of stability data to predict and assign these shelf lives and retest periods, utilizing limited long term 'traditional' stability data as supportive data to verify the model over a shorter timeframe. This would significantly reduce the time for development, and where necessary the long-term stability data can be provided post-approval to demonstrate the appropriateness of the stability assignment. This strategy has already been utilized for post-approval changes.

## DSI Solutions



REGULATORY  
AFFAIRS



CMC



QUALITY  
ASSURANCE

## Contact Us

DSI, a PLG Company  
P.O. Box 532, Harleysville,  
Pennsylvania, 19438  
P: 855-805-8402  
[solutions@dsinpharmatics.com](mailto:solutions@dsinpharmatics.com)