

Accelerated Stability Assessment Programme

SERVICES FOR THE PHARMACEUTICAL INDUSTRY

AmTrin
ASAP
LABORATORIES

ASAP

ASAP is an accelerated ageing process allowing faster and more accurate prediction of product shelf-life

www.asaplabs.eu



Benefits

Faster

Quicker and more accurate shelf life prediction (2-4 weeks)

Optimise Packaging selection

Eliminate screening, select packaging while allowing for climatic zone during packaging selection

Applications

- Pharmaceuticals
- Biopharmaceuticals
- Herbal Medicines
- Solids
- Solutions
- Suspensions
- Gels
- Creams
- Ointments



Regulatory Submissions

- Faster into clinical trials for NCEs
- Support QbD filings
- Supplement or replace ICH-based studies for regulatory authorities.
- Improved understanding of packaging, formulation and process choices

Also

- Support for changes that will not affect stability
- Justify acceptance of excursions during storage and shipments
 - Accurately assess stability and shelf-life variations between product lots
 - Compare originator and generic products



SAVE TIME AND MONEY BY BUILDING AN ACCURATE PREDICTION MODEL FOR YOUR PRODUCT

15 OF THE **20**
largest global pharmaceutical companies are using ASAP technique

Process

AmTrin can perform any or all of the three stages involved in an ASAP study on your behalf:

1 Ageing Process

Test material exposed to a range of environmental conditions. AmTrin employs the Amebis system to accurately measure the temperature and relative humidity test conditions. Full traceability of temperature and relative humidity measurements. Operating range 5-80°C / 0-90%rh.



2 Analysis of aged test material

Analysis of aged test material using stability indicating method. AmTrin has a range of quantitative equipment available including HPLC, GC, LC-MS, X-ray powder diffractometer, NIR and more...



3 Build stability prediction model

AmTrin employs ASAPprime® Software to build the prediction model. All model building is performed by scientists with training and experience in the ASAP technique. ASAPprime® Software is the only commercially available software package to quickly and accurately determine drug substances and product shelf-life based on ASAP.



Other Resources

AmTrin has other ASAP relevant equipment and expertise available including:

- A range of characterisation techniques
- Pharmaceutical processing equipment including spray dryers, tablet compression and granulation equipment
- Water Sorption Isotherm Analysis
- Storage of test material at ICH and accelerated conditions
- WVTR Measurements
- Water Content Analysis
- Test material preparation and storage
- Method development, degradation and dissolution studies can be performed
- ASAP expertise providing training, consultancy, study design and management

Research

AmTrin continues to research new applications for the ASAP technique. See our website for current research areas.

Contact us

to discuss your requirements. Visit our website for further information

www.asaplabs.eu

AmTrin ASAP Laboratories is a partnership between Amebis Limited and Trinity College Dublin with dedicated ASAP testing laboratories