

ACCELERATED PREDICTIVE STABILITY (APS) SERVICES

APS is an accelerated ageing process providing faster predictions for drug substance and drug product shelf-life

3 STAGE PROCESS

*Studies can be completed
in as little as **4 weeks***

- 1 AGEING**
Test material exposed to a range of stress conditions (T/rh)
- 2 ANALYSIS**
Aged test material analysed using Stability Indicating Method (e.g. for degradants or potency)
- 3 MODEL BUILDING**
Stability Predictive Model built using data from ageing and analysis as inputs to modelling software

Cuspor can perform any of the stages on your behalf
Contact us to discuss your requirements



Model

Degradant Formation - Potency Loss - Colour Change - Dissolution Change

Test Materials

APS has been used successfully on most product types:

- Solids (capsules, tablets, powders, lyophiles & more)
- Drug Substance and Drug Product
- Liquids
- Peptides and oligonucleotides
- Medical Devices



Benefits

- Quicker Formulation Development (using tiered approach)
- Packaging Selection (quicker decisions and cost effectiveness):
 - Choose optimum packaging for different climatic zones
 - Choose tablet count, bottle size and desiccant to meet shelf-life required
 - Choose packaging without the need for package screening studies
- Determine effect of excursion on stability (e.g. during shipment)
- Assist during cost modelling (e.g. package choices for different climatic zones)
- Assess effects of process or material change on stability (manufacturing process, ingredient supplier, formulation change)
- APS data has been accepted by regulatory authorities in many countries

Visit www.cuspor.com for more information

Other Products & Services

- Cuspor Ageing System: generation and accurate measurement of environmental conditions (T/rh)
- Calibration Services (10 – 85 °C & 0-90 %rh)
- Stability Chambers (2,000 to 200,000 Litres)
- Laboratory Supplies (range of vials, crimpers and temperature controlled cabinets)

CONTACT

Phone: +353 1 5397919 / Email: info@cuspor.com / Website: www.cuspor.com