



An Independent Stability Testing Hub.

The Best Partners have a different mind-set; we provide an engaged, personalised, accessible and thoughtful service that supports you for the lifetime of your stability management requirements.

Accurate assessment of product stability and shelf life are key to the successful development of a potential drug substance or finished product. Ever increasing demand for data integrity coupled with the milestones of product registration necessitate the need to have a reliable, approachable and focused supplier. At Tepnel we understand your needs as a customer to have a pro-active, flexible and reliable support service that allows you to focus on value added activities within the manufacturing supply chain.

40 years plus of supporting stability testing on tablets, capsules, parenteral and lyophilised products.

- ▶ Out-tasking management and sole stability provider for large top 10 Blue Chip Pharmaceutical Companies supporting global registration stability programmes.
- ▶ Development and validation of stability indicating assays including the mapping of impurity pathways for peptide compounds using mass spec techniques.
- ▶ Support routine device testing for inhaled and medical devices on a global footprint.
- ▶ Stability protocol management of multi APIs and Drug Product Programmes generating significant economic value as high as 50% cost savings for some programmes.

Key Features:

- ▶ Continuous monitoring of stability chambers.
- ▶ 24 hour emergency and preventative maintenance.
- ▶ Total Quality Management with EU and FDA cGMP regulatory compliance.
- ▶ Stability testing packages including complete analytical and microbiological testing including Controlled Drugs.
- ▶ Disaster Recovery and Business Continuity planning.
- ▶ Generation of stability study protocols.
- ▶ Comparator Programme Management.
- ▶ Retain sample management.
- ▶ Management of reference materials.
- ▶ Schedule 2, 3 ,4 part 1 controlled drugs licence.

As a leading member of our local Life Science Community, advocating Scotland's shared attitudes and responsibilities, Tepnel has a clear identity and set of values; **People. Progressive. Principled.**

We believe that our characteristics align with those of our customers on both a personal as well as global basis ensuring that, **Together we are Better.**

Call us today on +44(0)1506 424270 or email pharma@hologic.com to explore how Tepnel can provide out-tasking services as a part of your pharmaceutical product development.

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