STABILITY STUDIES AND ANALYSIS FOR CONSUMER HEALTH PRODUCTS

Ensuring stability excellence globally for consumer health products with Recipharm Analytical Solutions™

Through Recipharm Analytical Solutions™, we support customers with a wide range of stand-alone analytical requirements, including stability studies. Our 160-strong team of analytical chemists develop hundreds of methods and stability study techniques every year to support the development of a range of formulations.

Stability studies for pharmaceuticals

For over-the-counter (OTC) drugs, consumer health products and prescription drugs, understanding product stability is crucial to establish its storage requirements and its expiration date, ultimately ensuring patient safety.

Stability studies are conducted at all phases of the drug development cycle for different purposes:

- **During development:** studies are crucial to formulation development, as a way of supporting the safety and efficacy claims of investigational new drugs
- **At registration:** studies can establish the quality and shelf-life of the drug product in their intended packaging configuration
- **Post-approval:** studies can ensure production quality, and to support changes to site or product

Stability is a critical quality attribute (CQA) for pharmaceuticals. They help companies ensure they have evidence to justify process, formulation,packaging, and storage condition changes. They can also provide justification for extending use/review periods (and extrapolating use/review periods). Testing should be carried out following proper scientific principles and after understanding of the current regulatory requirements and as per the climatic zone.

Testing for consumer care

Similarly, consumer care products naturally degrade over time, and stability testing can reveal the rate of degradation. The variety of consumer care products means there is no standardised approach to stability studies, and there is no enforceable protocol outlined by global regulatory bodies for the testing of consumer care products.

As such, a well-designed internal stability protocol must test those product attributes that are susceptible to change during storage, and that can influence the quality, safety, and performance of the product.Testing should be carried out at specific time intervals of a storage period under controlled conditions.

When carrying out stability studies, it is important to include tests for a number of factors:

- Testing under conditions and temperatures that accelerate or predict the effects of stress on product consistency
- Testing for product's aesthetic properties, such as color, fragrance or texture, under varying conditions
- Investigate variations in the manufacturing process that might affect a product
- Measuring the effect of packaging on formulation, and vice versa

Our range of stability study services

- Real or room temperature studies
- Accelerated studies
- Intermediate studies
- Temperature excursion or freeze/thaw studies
- Static thermal/humidity stress studies
- Photostability studies
- Bulk hold stability studies
- Shipping studies
- Period after opening (PAO) stability studies

Regulatory guidance

We can support you in ensuring compliance with a wide range of global stability guidelines:

- World Health Organisation (WHO) climatic zone guidance
- International Council for Harmonisation (ICH) of Technical Requirements for Registration of Pharmaceuticals for Human Use
- Association of South-East Asian Nations (ASEAN) group drug product guidelines
- Cooperation Council for the Arab States of the Gulf (GCC) guidelines
- Regional/country-specific guidelines

Recipharm Analytical Solutions™

At Recipharm, we offer dedicated stability studies support through our Recipharm Analytical Solutions™ service. The size and flexibility of our labs combined with our expert team means we can support you with rapid project initiation. All together we can carry out more than 250 studies for multiple products in parallel. Using our expertise and resource, we can help you to minimise your time-to-market and streamline costs, while ensuring optimum compliance with all local and global regulatory regimes.

We can conduct stability studies throughout the drug development process, from the preclinical stage to final product approval. Whatever your analytical needs, we can work to guide our customers through the process.

About Recipharm: Recipharm is a leading contract development and manufacturing organisation (CDMO) headquartered in Stockholm, Sweden. We operate development and manufacturing facilities in France, Germany, India, Israel, Italy, Portugal, Spain, Sweden, the UK and the US and are continuing to grow and expand our offering for our customers.

Employing around 9,000 people, we are focused on supporting pharmaceutical companies with our full service offering, taking products from early development through to commercial production. For over 25 years we have been there for our clients throughout the entire product lifecycle, providing pharmaceutical expertise and managing complexity, time and time again. Despite our growing global footprint, we conduct our business as we always have and continue to deliver value for money with each customer's needs firmly at the heart of all that we do. That's the Recipharm way.

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