

IMPORTANCE OF PHOTOSTABILITY

TESTING IN OTC PRODUCTS

Photostability testing is crucial for ensuring the safety, efficacy, and quality of products. While there are not specific requirements, the FDA makes it clear it is recommended for all products susceptible to light.

Key components of a Photostability Testing Protocol:

- Stability data must demonstrate that the drug product is not susceptible to light.
- At least one batch of the drug product, in its proposed container closure, should undergo photostability testing.
- Testing may be omitted if scientific justification proves that the product will not be affected by photostability.
- Irradiation of the package drug product must follow the ICH Harmonized Guideline for Photostability testing of new drug substances and products.
- If certain testing parameters are not applicable, scientific judgment must be documented to determine the appropriate subset for photostability assessment.



THE EUROFINS SUPPLEMENT AND OTC SOLUTION

The Eurofins Supplement & OTC Testing lab in Madison, WI is a state-of-the-art facility designed for precision and efficiency. Spanning over 100,000 square feet, it houses advanced chemistry, microbiology, and stability chambers, ensuring seamless integration with the world's most comprehensive laboratory network.

