TURBISCAN

Shelf life prediction by Turbiscan
Method & Case study

INTRODUCTION

Shelf-life is an essential parameter to guarantee product performance, quality, and safety over its lifetime. Predicting shelf-life based on early data acquisition or by accelerating the destabilization process is one of the main challenges of new product development. Shelf-life prediction is a complex topic that associates accelerated stability testing (temperature, mechanical stress) and data extrapolation based on mathematical models. This note covers and explains how shelf-life can be predicted using the Turbiscan® technology based on the ISO/TR13097.

Feature 1 **Feature 2** **Feature 3**

What is Shelf life & Stability?

The technical Report ISO/TR 13097, Guidelines for the characterization of dispersion stability, addresses most questions around stability testing & prediction and gives recommendations about tests. According to **ISO/TR 13097**, shelf life is defined as "the recommended time period during which a product can be stored, throughout which the defined quality of a specified property of the product remains acceptable under expected (or specified) conditions of distribution, storage display and use." In other words, a dispersion is considered stable if its properties remain within an acceptable range at storage conditions.

Most commonly, shelf-life is determined by bottle tests and visual observation. These tests are practical and simple but can take a long time and depend on the operator, causing long "GO/No GO" decisions on product and process development.

Accelerated Stability Tests

A variety of test methods exist, here are the recommendations of ISO/TR13097 for the ideal test method.

Instrumental direct methods

Instrumental methods are **objective** and **traceable** and are preferred. Additionally, they detect destabilization **far earlier than conventional** visual observation and "these methods can be used for measuring shelf life" thanks to their high sensitivity and reproducibility.

Furthermore, the ISO/TR13097 recommends working on **native state: non-diluted & non-perturbated** and so "to select a method that does not require sample preparation, so that the sample is analyzed in its original state".

Accelerated methods

Different methods can be categorized as follows:

- Thermal acceleration: storing and testing the stability at higher temperature (usually between 25°C and 50°C) or by using thermal cycles.
- Mechanical acceleration: use of centrifugation or vibration to test the product.
- Physico-chemical perturbation: adding substances (solvent, acid..) to vary sample composition and test the resistance to this change.

Accelerated studies should be done with caution considering "its limits and its correlation to normal shelf-life conditions and/or typical usage".

The thermal acceleration is the most used method with the benefit of studying stability in storage and shipping conditions.
Mechanical stress is artificial and non-realistic stress. It can induce additional phenomena that are not observed under normal conditions (especially on non-Newtonian samples) and despite the efficiency to quickly separate the dispersion, the stability estimation may be unrealistic [1][2].

Turbiscan® technology

Turbiscan® technology, based on **Static Multiple Light Scattering (SMLS)** is the leading technology for **direct dispersions stability testing**.

The Turbiscan® technology meets ISO/TR13097 recommendation by using an optical scanning that quantifies and studies dispersions in native state enabling thermal acceleration when needed.
SMLS technology consists in sending light pulses (at 880nm) into a sample to measure the amount of scattered light (transmission and backscattering). The reading head moves vertically along the sample cell and acquires the signal every 20µm. Measurements are made over time and variations in the backscattering and transmission levels, due to sample instability, are recorded. The signal is directly linked to the evolution of particle concentration (φ) and size (d) by the Mie theory.