TURBISCAN

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Pharmaceuticals

STABILITY OF PHARMACEUTICAL PRODUCTS

Abstract

The world of drug delivery is getting every day more efficient with new product forms, which are directly targeting the deficient organs. Colloidal systems such as emulsions (simple or multiple) or nanoparticle suspensions are now widely used as drug carriers or nutritional solutions in this respect. These new product forms allow better targeting and assimilation for the patient, and give rise to new solutions for drug designers. However, the stability of these inherently unstable colloidal systems makes them complex to formulate and study.
The Turbiscan® technology is a unique and complete tool, which enables the study of the colloidal dispersions stability without any dilution or modification of the product. Destabilization processes can be identified and quantified easily up to 50 times earlier than the naked eye. Determining shelf life can be automated *via* the use of the ageing station, Turbiscan ags.

Keywords: emulsion, suspension, nanoparticles, shelf life, stability, Turbiscan®.

Introduction

Many products available in the pharmaceutical industry are liquid dispersions (cream, syrup, suspension, aerosol etc.), even if tablets remain the most common product form. The stability of these formulations is not only critical from the esthetical side, but more importantly from the health point of view, as an unstable product can lead to serious health issues, even to death (*e.g.* particle size increase in a parenteral emulsion can lead to embolism).

The Turbiscan® range provides the formulator with a complete set of tools to investigate the stability of formulations developed. The different instability phenomena (creaming, sedimentation, flocculation, coalescence) can be identified and quantified *via* different parameters, allowing an objective analysis to be made. Shelf life can be determined up to 50 times earlier than visual observation, allowing the development time for new products to be significantly reduced. The stability measurements can also be completely automated using the robotized ageing station, Turbiscan ags.

Experimental procedure

1. Principle of the measurement

The heart of the optical scanning analyser, Turbiscan®, is a detection head, which moves up and down along a flat-bottom cylindrical glass cell (Figure 1)[1-2]. The detection head is composed of a pulsed near infrared light source (λ = 880 nm) and two synchronous detectors. The transmission detector (at 180°) receives the light, which goes through the sample, while the backscattering detector (at 45°) receives the light scattered backward by the sample. The detection head scans the entire height of the sample, acquiring transmission and backscattering data every 40 µm. The Turbiscan LAB can be thermo-regulated from 4 to 60°C and linked to a fully automated ageing station (Turbiscan ags) for long-term stability analyses. Increasing temperature is the ideal parameter to accelerate destabilisation processes, while maintaining realistic testing conditions.

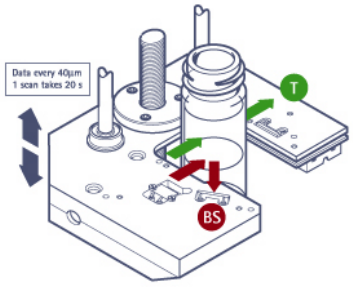

Figure 1. Principle of Turbiscan® measurement

The Turbiscan® makes scans at various pre-programmed times and overlays the profiles on one graph in order to show the destabilisation. Graphs are usually displayed in reference mode, whereby the first profile is subtracted to all other profiles, in order to enhance variations. A stable product has all the profiles overlaid on one curve (Figure 2), as an unstable formulation shows variations of the profiles (Figure 3). Backscattering and/or transmission fluxes are shown in ordinate and the height of the cell in abscissa (Figure 2 and 3). The first profile is displayed in pink, the last one in red.