



Development of pharmaceutical products

INTRODUCTION

The stability of pharmaceutical products is one of the key parameters for good quality product in order to make sure that it is safe for the patient (product dose, risk of embolism, etc.). Moreover, the large range of product forms available (dispersion, cream, aerosol, etc.) and storage conditions make the stability tests long and tedious. Finally, the important number of components in these products leads to a complex interpretation of the data obtained via classical analytical techniques.

Application

Pharmaceuticals

Objective

Details various applications of Turbiscan for pharmaceutical products

Device

TURBISCAN® LAB

APPLICATION 1: DEVELOPMENT OF NANODRUG

1. Common method

Drug delivery is using more and more nano-carriers in order to improve the targeted release and therefore avoid side effects as much as possible. When developing a new formulation it is important to have as much information as possible on the product in order to be able to anticipate possible stability issues. However, bottle tests do not give much information on the instability taking place and it is therefore necessary to use other analytical techniques. Particle size analysers usually require important dilution and this can be a problem in the understanding of the physico-chemical interactions taking place.

2. Turbiscan® method

The Turbiscan enables to identify and monitor destabilisation phenomena (migration or particle size variation) in complex systems as it measures macroscopic parameters directly related to the concentration and the particle size of the system. The coupling of transmission and backscattering detectors enables to work on all kind of systems, shall they contain very small particles (nano range), shall they be diluted or concentrated. Therefore, it helps explaining the destabilisation mechanism by determining which instability is taking place in the system and to evaluate its intensity in an objective and traceable way.

Using the Turbiscan, product developments are not only shortened but also documented and contain many information helping the formulator to understand his products.

APPLICATION 2: LONG TERM STABILITY ANALYSIS

1. Common method:

The stability analyses of pharmaceutical products are done by visual observation of samples stored at low (+4°C), ambient and high (+35 to +50°C) temperatures during up to several years, depending on the temperature. The subjectivity of these tests, which highly depend on the operator, and their lack of traceability lead to tedious and sometimes poor quality results. Moreover, as it is necessary to wait all this time before releasing a new formulation to the production, the development times are long.

Stability tests are therefore subjective and constitute a long time process that is more and more incompatible with the requirements of the development.

