ABSTRACT

THE USE OF INFRARED AND RAMAN SPECTROSCOPY FOR PREFORMULATION PHARMACEUTICAL DEVELOPMNET

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Within pharmaceutical preformulation development, we are interested in information which is helpful for drug product formulation. The properties expected from drug product are stability and suitability for manufacturing. All of these properties must be in accordance with therapeutic and regulatory requirements. For this purpose, there are many analytical methods used in the pharmaceutical industry that serve for investigation of stability, quality and possible interactions of active pharmaceutical ingredient with excipients. Accuracy, efficacy, and especially promptness and difficultness of analysis are the criteria for selection of a particular analytical method.

Solid state methods are essential, just for their smart use and applicability to acquiring further characteristics of the sample, e.g. polymorphisms, size and particles distribution, which represent crucial knowledge, for formulation of final drug product and its properties.

A survey at thedevelopment department in laboratories of solid state, Zentiva, k.s., was performed using the infrared and Raman spectroscopy focused on study of possible interactions and incompatibilities between an active substance and excipients used for formulation of particular drug product.

Qualitative parameters of two drug products were studied. The one product contained an antiagregation clopidogrel and the second one contained an antagonist on AT_1 receptor telmisartan. Analysis was performed based on using FT-IR spectrometry (ATR and transmission techniques) and Raman spectrometry after the samples had been exposed to the standard and more extreme conditions, particularly high pressure.

Based on this analysis, there were not observed any changes in qualitative parameters for both of active pharmaceutical ingredients.