Use of spectrometric techniques in the identification of mechanical impurities in solid pharmaceutical dosage forms

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The manufacturer of the medicinal product must manufacture medicinal products to ensure that they are fit for their intended purpose; they comply with the requirements of the Marketing Authorization or Clinical Trial Protocol and do not place patients at risk due to inadequate safety, quality or efficiency.

In the study, a case of identification of mechanical impurities incorporated on the surface of the tablets was considered, which with the use of spectrometric techniques was proven to originate from microcrystalline cellulose (Avicel PH 102 /Microcrystalline cellulose), which is used as an excipient in the formulation of solid pharmaceutical dosage forms. Impurities are manifested in the stage of the production process - tableting, as faintly visible black dots incorporated on the surface of the tablets.

The aim of the research in this study is the benefits of using an infrared (FTIR) spectrometric technique in the quick and precise identification of mechanical impurities in a product, which originate from incoming raw materials, and which have been proven by previous research to be a technologically unavoidable phenomenon as a consequence from the production process and the chemical composition of the raw material.

Keywords: solid pharmaceutical dosage forms, mechanical impurities, FT-IR, spectroscopic methods, microcrystalline cellulose.

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