

1 Abstract

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Title of Thesis: Problematics of active compounds recrystallisation
in pharmaceutical preparations

The topic of the thesis is the recrystallization of active substances in pharmaceutical preparations. The aim of this work is to demonstrate this phenomenon on a real particular pharmaceutical product, in which it has occurred. It includes a detailed description of the manufacturing process including all mandatory conditions, possible critical points, investigations and measures taken. The thesis consists of two parts. The first describes in details the current state of knowledge. It is based on the findings of the available literature on the subject. The basic concepts of crystallization and polymorphism are explained in detail, which form the basis for the subsequent case study. The case study includes a detailed description of a specific medicinal product. Subsequently, its production, good manufacturing practice and gradual investigation of the discovered technological incompatibility are explained step by step. The result of the work points out that the issue of recrystallization and polymorphism is very closely related to pharmaceutical large-scale production and it is necessary to calculate with these phenomena. In the end there are described the follow-up reparative measures, thanks to which these phenomena were prevented, the production itself was subsequently restored and the problem was solved successfully.

Keywords: crystalization, recrystalization, polymorfism, granulometry, pharmaceutical industry, good manufacturing practice, stability, quality control, metamizol