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CHAPTER 11

POLYMORPHIC CRYSTALS AND THEIR CHARACTERISATION

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The subject of polymorphism has received attention from a significant number of researchers associated with pharmaceutical crystallisation processes. The phenomenon is difficult to understand and unpredictable, but it is of great importance from scientific as well as regulatory concerns; hence there is a concomitant urgency in addressing the subject. This chapter provides a practical overview of the polymorphism of active pharmaceutical ingredient crystals and briefly reviews the techniques to characterise the polymorphs.

11.1. Introduction

Crystallisation from solution is an important unit operation used in various industries as a technique for separating solid materials in purified forms. It is a technique of choice for solid-liquid separation due to its capability of producing high purity materials. Its importance in the pharmaceutical industries is due to a large number of active pharmaceutical ingredients (APIs) that are utilised in solid form. It is estimated that more than 80% of APIs involve at least one crystallisation step in their manufacturing process (Reutzel-Eden, 2006). The crystallisation operation is often critical because it determines the product properties, such as polymorphic form. Statistically, about 85% of all APIs exhibit polymorphism and 50% have multiple polymorphic forms (Karpinski, 2006). Crystallisations of the APIs that possess multiple polymorphic forms are both critical and challenging. Since different polymorphs exhibit different physico-chemical properties and mechanical behaviour (Hilfiker *et al.*, 2006), pharmaceutical manufacturers have to select a polymorph that has desirable characteristics that