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CHAPTER 8

DEVELOPMENT OF AN APPROPRIATE AND ROBUST DISSOLUTION METHOD FOR SOLID DOSAGE FORMS

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In vitro dissolution testing is routinely used by pharmaceutical industries for product development, quality and stability assessment of final dosage form and development of in vitro-in vivo correlation (IVIVC). It is also a regulatory requirement for approval of a new product and post approval changes for existing product. Considering its vast application, development of an appropriate and robust in vitro dissolution method has got immense importance to a formulation scientist. The task is equally challenging for drugs with wide range of physical properties like solubility, permeability and stability. The present article involves general concepts and guidelines to develop an appropriate and robust in-vitro dissolution method for solid oral dosage forms like tablets and capsules.

8.1 Introduction

Dissolution is a process which involves solubilization of a solid substance in a given solvent. It is a mass transfer phenomenon from a solid surface to liquid phase. Dissolution testing is an *in vitro* laboratory test method to have an idea how efficiently an active drug substance is released from the dosage form. At early stage of product development, *in vitro* dissolution test guides the F&D scientists to develop a suitable dosage form through optimization of drug release