
8 Drug Product Performance: In Vitro*

Pradeep M. Sathe, John Duan, and Lawrence X. Yu

CONTENTS

Introduction.....	184
Importance of In Vitro Drug Product Characterization.....	184
Types of Solid Oral Dosage Forms	184
Factors Affecting In Vitro Drug Product Dissolution	185
Factors Related to Drug Substance	185
Solubility of the Drug Substance	186
Polymorphism	187
Salt Factor and “pH” of the Diffusion Layer.....	187
Surface Area and Particle Size	188
Formulation Factors	188
Manufacturing Process Factors	189
Dissolution/Drug Release Test Conditions	189
In Vitro Drug Product Performance Evaluation.....	190
Disintegration Test	190
Dissolution Test—IR Solid Oral Dosage Forms	190
Drug Release Test—MR Solid Oral Dosage Forms.....	192
Dissolution/Drug Release Profile Comparisons.....	193
Applications of In Vitro Dissolution.....	198
Product Development.....	198
Quality Assurance	199
Product Stability.....	199
Comparability Assessment.....	199
Waivers of In Vivo Bioequivalence Requirements.....	199
Formulation Proportionality	199
Biopharmaceutics Classification System	200
In Vitro/In Vivo Correlations	201
Limitations of In Vitro Dissolution.....	201
Future Direction.....	202
Summary	202
Websites	203
References.....	203

* Opinions expressed in this chapter are those of the authors and do not necessarily reflect the views or policies of the FDA.