Title: Solid Oral Dosage Forms-Potential Critical Process Parameters					
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Solid Oral Dosage Forms-Potential Critical Process Parameters

Introduction

This guidance provides an overview of potential critical process parameters for the manufacturing of solid oral dosage forms.

Solid oral drug products come in a variety of dosage forms frequently with common steps and equipment. The potential critical process parameters are often the same from process to process. This guidance provides an overview of process steps and typical equipment involved in manufacturing of solid oral dosage products and notes what might be critical process parameters associated with these process steps and equipment.

Solid Oral Dosage

Critical process parameters (CPPs) and critical quality attributes (CQAs) that need to be monitored during process validation for a bulk solid oral dosage formulation depend on its presentation (e.g. compressed tablet, coated tablet, capsule) and its drug release characteristics (immediate release-IR or modified release-MR). The following table of process parameters and attributes can be used as a guide for use in process validation. Each application should be evaluated on a case-by-case basis to determine which parameters and attributes are critical.

