Title:	Semi-Solid Dosage Forms-Critical Process Parameters				
Guidance Number: 043					
Prepared by:		Date:		Supersedes:	
Checked by:		Date:		Date Issued:	
Approved by:		Date:		Review Date:	

Semi-Solid Dosage Forms-Critical Process Parameters

Introduction
This guidance provides an explanation of the semi-solid Drug Product dosage form and recommendations for analysis of the manufacturing process critical process parameters.

Semi-solids come in a variety of dosage forms, yet significant steps and equipment used for the manufacturing processes share commonality. The critical process parameters will often be the same from process to process.

Semi-Solid Dosage and Process Parameters
The most common presentations of semi-solid dosage formulations are therapeutic creams, ointments, gels, lotions, emulsions, salves, pastes and other forms of similar viscous consistency. Topical and ophthalmic are the primary routes of administration for semisolids. Semisolid drug products, depending on their use, can be sterile or nonsterile. Requirements of process validation that are specific to semisolid drug products are stated in another guidance.

Creams/ointments typically contain one or more drug substances dissolved or dispersed in aqueous, oil or a suitable base. Creams posses a fluid consistency and have traditionally been called oil-in-water or water-in-oil emulsions. They also could be dispersions of long-chain fatty acids or alcohols that are water washable or miscible.

Some common manufacturing processes are mixing, heating/cooling, dispersion /homogenization, deaeration, transfer and other techniques for these viscous substances.

Filling and packaging is typically into single-or multiple-unit containers such as rigid bottles or jars, collapsible tubes or flexible pouches.

The critical process parameters and attributes that need to be monitored during process validation for bulk semi-solid dosage formulations depend on dosage presentation and the drug or formulation characteristics. The following table of process parameters and attributes can be used as a starting point for the selection of CPPs for process validation.

Each application should be evaluated on a case-by-case basis to determine which parameters are critical. Also, depending on the specific dosage form and route of administration, some of the attributes listed below may not be applicable or additional attributes could be warranted. For example, the attributes for ophthalmic ointments should include a test for metal particles (e.g., USP <751>). Another example would be if preservatives or antioxidants are used in the product, tests for their content should be included and acceptance would be based upon the level that will maintain product quality throughout shelf life.

