In the case of sterile solids which are available in strengths of 50 mg. or less of active ingredient, it is our policy to require compliance with the content uniformity specification for sterile solids, as detailed beginning on page 796 of NF XIIII page proof. (The procedure employed will be specified as either Method I or Method II, depending on whether the Assay procedure can be utilized or whether a special procedure is called for.) If the article is such that no strength or size is available in quantities of 50 mg. or less of the active ingredient, it is then presumed that the major portion of the substance present is the active ingredient, and the weight variation test (combined with the Assay) provides adequate assurance of homogeneity of the sterile solid. In such cases, therefore, the monograph will specify compliance with the weight variation test for sterile solids, which appears on page 902 of NF XIIII page proof.

In the case of sterile solids which have no diluents present (these are identified with monograph titles reading "Sterile _____"), the approach is slightly different. As in the case of the other sterile solids, a rubric definition is provided with specified tolerances. Since the article is the pure drug, only prepared and packaged in sterile form, the Assay virtually without exception is identical to the Assay for the drug substance and the tolerances are comparably based upon a sample obtained from the pooled contents of a number of containers. With respect to vial to vial differences, however, the approach in the case of these sterile solids is somewhat different. The article has no diluents or added substances whatever and, as a consequence, the weight variation test provides a reliable index of vial to vial homogeneity without necessitating any more sophisticated analytical approach than simply weighing the contents. As a consequence, such monographs include the specification for the weight variation test. This in itself, however, is not sufficient to assure with certainty the suitability of the article, since the weight variation test requires compliance with the average net weight rather than with a labeled quantity. For this reason, the weight variation test in NF monographs for sterile solids without diluents provides to specify that the mean net weight so determined is within specific percentage tolerances of the labeled amount. The specific range is specified in the individual monographs rather than in the General Tests section to take into account the fact that depending upon the nature of the product, its size, etc., the tolerances specified might need to vary from one monograph to another. This, of course, is analogous to stating the tolerances in all other monographs in the individual monograph rubric definitions.