ADDITIONAL REQUIREMENT	EXPLANATION AND SIGNIFICANCE
Classification of Defects	Classification of Defects is a list of deficiencies which can be tolerated to a limited extent. These physical defects are detected upon examination of the product. For contractual purposes it is necessary to delineate the physical characteristics, designate a sampling plan, and determine the amount of defective characteristics that are permitted within the sampled quantity. It should be noted that such test characteristics as strength and purity are not designated within the Classification of Defects because compliance with those requirements is fully mandatory. Without a Classification of Defects and an Acceptable Quality Level, a procurement agency could not contractually limit such defects as excessively chipped tablets, excessive powder in a tablet container, broken tablets, cracked capsules, etc. The Classification of Defects, therefore, defines the general quality of the item in terms of physical characteristics, which subsequently may have a bearing on the dosage administration to the patient.
Solubility Time Limit	With the advent of Parenterals for Injection in which powdered or freeze-dried material is solubilized prior to use, it became necessary to assure that the contents would readily and completely solubilize upon addition of diluents prior to use. This requirement establishes the rate of solubility and presents a basis for examining for the presence of particulate matter. Compliance with such requirements renders the product more rapidly available for use and precludes the injection of particulated or undissolved material for which there are no official standards.