Definition

Statements given under the heading Definition or immediately after the heading Requirements constitute the official definition of the substance or dosage form that is the subject of the monograph. They constitute instructions or requirements with which the article must comply.

A dosage form that is the subject of a specific monograph must be prepared using an active ingredient that complies with the corresponding substance monograph. For example, the active ingredient used in preparing Artesunate tablets must comply with the monograph for Artesunate. is used in preparing such a dosage form, the excipient must comply with that monograph. For example, if lactose is used in preparing Artesunate tablets, it must comply with the monograph for Lactose.