Key components of a USP monograph

A monograph is a written document that reflects the quality attributes of medicines approved by the U.S. Food and Drug Administration (US FDA). **Some of these attributes include:**

Identity—Tests to identify that a particular substance is the medicine that it claims to be.

Strength—Testing methods and acceptable ranges for the potency of a medicine, as reflected in FDA's approvals. For example, this indicates the amount of API in a medicine.

Purity—Information on impurities that may be present in a medicine and the amounts of these that are permitted, along with testing methods to identify and measure them. An impurity is any component in the API or finished dosage form which is not the desired product or other formulation components. Levels that exceed may present patient safety concerns.

Performance—Laboratory tests to predict and demonstrate how a medicine will be released as it enters the human body.

Monographs articulate quality expectations. Compliance with a monograph does not demonstrate biosimilarity or interchangeability, nor is it a license to market a medicine. Approval, biosimilarity, and interchangeability are determined by the US FDA.