



SCHEME 8.5 Decision tree for the disposition of particle size variation. (Courtesy of Pharmquest Corporation, Mountain View, CA.)

In such cases, the bioavailability stability can be altered, requiring the choice of specific stable solid dosage forms (Scheme 8.6).

8.2.3.3 Microbiology

Microbiological attributes are required where preparation and storage can significantly compromise microbiological quality. Scheme 8.7 shows a decision tree for the disposition of microbiologically related attributes.

8.2.3.4 Excipients

The excipients chosen, their concentration, and the characteristics that can influence the drug product performance (e.g., stability and bioavailability), or manufacturability