Summary - Microbial Attributes Testing of Non-Sterile Solid Oral Dosage Form

The intention of this document is to provide guidance to determine the need for performing microbial attributes testing of drug product raw materials, non-sterile excipients, active pharmaceutical ingredients (APIs) and finished drug products. Because of the wide diversity of materials and finished solid oral drug products, not all products are equally susceptible to microbial contamination, and therefore, microbial attributes testing may not be the same for all products.

The raw materials, non-sterile excipients and APIs of a solid oral dosage form are Consequently, a risk assessment of each material is recommended to determine if microbial testing is appropriate.

Finished product testing of non-compendial solid oral dosage forms provides limited available water within solid dry products precludes microbial growth. Determine if microbial testing is needed for a solid oral dosage final product.

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