Summary - Prevention and Control of Fungal Contamination in Tablets

What steps can be taken to prevent and control of fungal contamination in tablets?

This document discusses the prevention and control of fungal contamination in tablets production to include: raw material and API testing, manufacturing processes, environmental monitoring, and final product testing.

Fungal contamination is most commonly introduced into a tablet via the following:

1. Steps of the manufacturing process of the tablet where water is present (*e.g.*, wet granulation, coating solutions).
2. Contaminated raw materials, excipients or active pharmaceutical ingredients (API).

The microbial quality of the raw materials and APIs directly impact the microbial quality of the final tablet product. Fungal populations that may be found in these raw materials can contaminate the final tablet product.

The Total Yeast and Mold Count tests for raw materials and APIs in the tablet formulation are validated and tested according to compendial methods and/or internal requirements. Specific limits for fungal levels in raw materials and APIs are used to ensure that the microbial quality of the final dosage form will not be adversely affected.

During the manufacturing of a tablet, fungal contaminants may be introduced into the tablet via the water introduced into the process.

The holding times of the wet powder should also be validated with microbial/fungal considerations in mind. The validation of a holding time should be based on both time and temperature parameters. The longer the wet powder is stored, the greater the possibility the microbial quality of the tablet will be adversely affected.

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