

10152 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

Kirkman Labs.

FSN 6505-110-4075 Bismuth Subcarbonate Tablets

Major Deficiencies

1. Production Control Deficiency

Inadequate Master Formula and Batch Production Record. Lack of explicit instructions, precautions as to steps to be followed in preparation of the drug which may lead to non-uniformity of batches.

Operating personnel unaware of in-process test standards. Although in-process testing is conducted, it is not known when to take corrective action.

Use of city water instead of purified water in batch formulations. This may affect the purity of the product.

Lack of traceability of water used in batch formulations.

2. Housekeeping Deficiencies.

Potential for product contamination exists due to:

Absence of covers on hoppers of tabletting presses.

Failure of tabletting operators to wear suitable head covering to prevent the possibility of hair, dandruff from falling into the powder.

Insects may enter granulation in drying oven from the outside through oven exhaust.