

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY 10157

STANLABS

Codeine Sulfate Tablets
Calcium Lactate Tablets

Major Deficiencies

1. Laboratory Control Deficiency

Absence of written laboratory test methods setting forth test procedures.

Incomplete monograph testing of raw materials.

Absence of in-house standards of finished product to provide uniformity of product. Examples: Company has no standard for hardness of compressed tablets indicating lack of quality of control. Further, firm uses Pfizer tester and Monsanto Tester. No correlation in hardness test values found between the two.

Incomplete testing on finished product.

2. Production Control Deficiency

Failure of Master Formula and Batch Production Record to be exact duplicate. Example: Batch Production Record specifies "Plasdone C" whereas the Master Formula indicates "Plasdone".

Failure to perform inspection of end item in accordance with established sampling plan and classification of defects, thus creating the possibility of non-uniformity of product.

Weighing area for raw material batch components adjacent to open receiving area to street. Flies and other insects accessible to contaminate raw materials.

Batch formulations ready for compression stored in reused fibre drums bearing identification of previous contents creates the possibility of product mix-up and mislabeling.

Reuse of fibre drums without new polyethylene liners creates the possibility of product contamination.

3. Defective overhead construction and openings in walls that permits contamination of products being manufactured.

4. Failure of Regular cleaning to remove drug residues from manufacturing equipment may result in cross-contamination. Drains in production area covered with slime.