

10158 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

STANLABS

Codeine Sulfate Tablets
Calcium Lactate Tablets

Major Deficiencies

5. Failure to louvers attached to exhaust fan in the manufacturing area to close, thus permitting the entrance of flies and other insects.

6. Improper control and handling of raw materials.

Failure to store raw materials under conditions to prevent their decomposition and deterioration and/or becoming contaminated in storage. Material stored in warm, moist basement near boiler room. Floors in disrepair. Poor lighting exists and flammable finished goods stored near boiler presents safety hazard.

Receiving area for raw material is adjacent to open receiving area adjacent to street.

Sampling of raw material is done in dirty, dusty atmosphere creating the possibility of contamination of the open containers with foreign airborne matter.

Failure to provide adequate space for the orderly placement of materials to minimize any risk of mix-ups. Ex. Commingling of rejected and hold material in the Drug Abuse Finished Goods Storage Area with finished and approved products.

7. Absence of calibration program for test equipment.

8. Absence of a stability testing program.