

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY 10021

DATE	DESCRIPTION OF VIOLATION
March 1972	The storage area is dirty. Layers of dust, powder rest on surfaces of containers and packaging material. These surfaces are not cleaned prior to transfer into the production area. Handling is such that the dust, dirt, powder on the containers and packaging material are discharged into the atmosphere of the drug processing area. Contamination of various products with foreign matter may occur.
February 1972	A second storage area for material requiring air conditioning temperature is also dirty. Cartons and containers and shelving are covered with layers of dust and dirt. No room exists for orderly placement of material.
	Tablets in cellophane strip packages and bottles of Sine-aid tablets were scattered over the floor.
	One drum of Tonal laxative tablets, lot 051124, was also identified as Coricidin tablets.
May 1972	Quarantine material found available for use in the production area.
May 1972	A bird and flying insects were noted in the areas for quarantine, sampling and storage.
	The Howe scale #8142 used in the weighing area was heavily encrusted with residue from previous weighings. There were various colored materials on the equipment.
September 1972	Improper release of products. Analytical records for approved Dihydroxyquin Lot 1-1971, (which is the same item used in the manufacture of the bid tablets), reported a "Loss on Drying" USP Test, of 4.0%. This should never have been approved. The tolerance specified in the U.S.P. is "not more than 0.5%". In addition, the required USP "Identification Test" was never performed.
September 1972	Improper testing of raw material. Dihydroxyquin, Lot 1-1971 "Residue on Ignition" test was run at 500°C, whereas the USP specified 800°C.