

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY 10025

DATE OF VIOLATION	DATE OF VIOLATION	DESCRIPTION OF VIOLATION
Abbott Pharmaceuticals Inc. Barcelona, P.R.	June 1973	July 1973
Excessive use of masking tape on capsule filling machines provides a potential for contamination of product.		
Equipment was not routinely inspected and cleaned before each use. A capsule machine in room 506 showed evidence of dust and powdery residues when claimed to be clean and ready for use and start up.		
Bay Laboratories Inc. Skokie, IL	August 1973	September 1973
The Quality Control Director has never worked in a pharmaceutical manufacturing plant. His only experience has been in retail pharmacy stores. On his own admission he does not have the necessary experience related to drug manufacturing operations.		
Abbott Laboratories Ltd. Queensborough, Kent, England	August 1973	September 1973
The operator batch production records for bulk Trimethadione does not reflect the total yield of material obtained in each batch process. The records for blended commercial lots of Trimethadione did not include the quantity and batch number of all production batches entering into the final blend lots.		
There was no operator record covering the milling/blending step for Trimethadione to show such information as component batches, and input weights, times, equipment and operator.		