



DISTRICT ADDRESS GMP Trends LLC P.O. Box 1111 Firestone, Colorado 80520		DATE OF ISSUE Introductory	
		C.I. ISSUE MMCX	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED To: Responsible Person, Director of Quality Assurance			
FIRM NAME Pharmaceutical and Related Industries		STREET ADDRESS 5600 Regulation Lane	
CITY, STATE AND COUNTRY United States of America and Worldwide		TYPE OF ESTABLISHMENT INSPECTED Pharmaceutical and Medical Device	
DURING A REVIEW OF INSPECTION REPORTS OF U.S. FIRMS (I) (WE) OBSERVED:			
<b>PACKAGING &amp; LABELING CONTROLS</b>			
1. ....Procedures designed to assure that correct packaging materials are used for drug products are not written and followed. <b>Specifically,</b> <ol style="list-style-type: none"> <li>There is no documentation to support that the desiccant feeder and associated automated bottle reject system is challenged during packaging operations to reject a bottle without a desiccant. Observation of packaging Line ..... noted a bottle without a desiccant after the desiccant feeder reject system during packaging of ..... tablets. SOP ..... does not contain instructions to challenge the system to reject bottles with no desiccant.</li> <li>Not all automated verification and reject systems used in packaging operations are challenged in a bracketed manner. The desiccant feeder and bottle checkweigher have associated automated bottle reject systems that are challenged during line setup. However, no periodic or end-of-run challenges are performed to ensure the reject systems are functioning properly throughout the packaging batch.</li> </ol>			
2. ....A process whose results cannot be fully verified by subsequent inspection and test has not been adequately validated according to established procedures. <b>Specifically, your firm packages a variety of devices in one of four blister packaging configurations. The heat sealing process validation for two of these configurations was inadequate because your firm could not provide evidences that seal integrity was verified when packaged at worst-case sealing parameters.</b>			
3. ....Written records are not made of investigations into unexplained discrepancies and the failure of a batch or any of its components to meet specifications. <b>Specifically, the following package seal investigations lacked adequate root cause assessment, impact assessments, and/or corrective and preventative actions:</b> <ol style="list-style-type: none"> <li>Investigations ..... were initiated after out-of-specification (OOS) of actual yield events. The firm attributed all the OSS yields to small batch size. It concluded that no additional investigation was needed and failed to assess preventative action.</li> <li>Investigation ..... was initiated after the firm received a customer complaint that several cases of ..... contained packets with missing lot numbers and expiration date. Instead of adding additional measures to minimize the recurrence, the firm's preventative action was merely to remind the operator to be more diligent to ensure the equipment is performing as required.</li> <li>Complaint ..... was initiated after the firm received a customer complaint that a strip of empty packets of ..... was found during the routine QA inspection by the customer. A formal investigation was not conducted for this complaint and the firm concluded that "there is no evidence that suggests that the "under fills" (strip of emptying packets) observed by the customer were a result of a systemic packaging issue." No preventative action was assessed.</li> <li>Complaint ..... was initiated after the firm received a customer complaint that ..... contained only ..... A formal investigation was not performed for this complaint and the firm concluded that "this is a random isolated event that was not detected by the operator or QA during the filling and packaging, as no other complaints have been received for this product. No preventive action was assessed.</li> </ol>			
SEE REVERSE OF THIS PAGE		EMPLOYEE(S) SIGNATURE <b>GMP Trends LLC</b>	
		EMPLOYEE(S) NAME AND TITLE <b>Editor</b>	
		DATE ISSUED <b>Introductory</b>	