

10160 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

Kapco Inc.

Sodium Aminosalicylate Tablets

Major Deficiencies

1. Failure to provide adequate space for orderly placement of materials to minimize any risk of mix-ups between components.

Commingling of approved material, material with no approval sticker and in-process material with no indication of approval for use in the storage area for approved materials.

In addition, an affiliate company utilizes approximately 25% of the warehouse for general equipment and raw material storage.

2. Laboratory Control Deficiency

In complete testing of incoming raw materials.

Suppliers' protocols missing to substantiate material approved for use.

3. Production Control Deficiency

Lack of adequate control to ensure that only approved material is issued for manufacturing purposes.

4. Common loading platform for shipping and receiving is not arranged to prevent the commingling of incoming and outgoing material.

5. Unsanitary household practice.

Food is stored and eaten in the packaging room.