

10154 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

Zenith Labs.

FSN 6505-550-8464 Meprobamate Tablets

Major Deficiencies

1. Production Control Deficiency.

Improper testing schedule for in-process hardness of tablets.

2. Laboratory Control Deficiency.

Improper testing of active ingredient and end item.

3. Improper Control of Raw Material.

Commingling of drums of raw material with empty drums for discard.

Presence of 2 different lot numbers on drum of raw material.

Drum of raw material labeled "Ascorbic Acid" and "Starch".

Non-released material commingled with approved material in the release storage area.