Barr Labs.

Meprobamate Tablets, USP.

Major Deficiencies

1. Laboratory Control Deficiency.

Absence of testing of raw materials.

Company does not perform specific identity test to assure material is what it purports to be. (Company relies on suppliers' protocol).

Incomplete monograph testing(suppliers' protocol) of components for DPSC.

Failure to incorporate changes in USP XVIII in test procedures as part of the firm's test procedures of the end item. Example: Dissolution and assay procedures were not performed in accordance with changes reported in the "Fifth Interim Revision to USP XVIII".

Failure to document compliance of in-process testing with written specification requirements.

2. Production Control Deficiency

Failure to record lot numbers of all raw materials used in the production of "crude" Meprobamate on the batch production record.

Failure to identify equipment used in a manufacturing step.

Tabletting operations of as many as 6 different products conducted in a single room at one time without benefit of structural separations between machines creates the potential of cross contamination.

Improper use of hot air ovens during drying operations. All doors of the 12 ovens open at the same time presents the possibility of cross contamination of material in the different ovens.

Failure to provide an appropriate procedure to minimize the hazard of contamination of material in trays to be dried or which have been dried from air borne contaminants.