Observation 1

Non-pharmaceutical grade components are used in the formulation of human non-sterile drug products.

Specifically, non-pharmaceutical grade (b) (4) water was used to produce the following human non-sterile drug products rather than purified USP grade water. Examples include the following:

1. Rx # (b) (6) on 8/21/17 for C-Diphenhydramine 25mg/5ml liquid.
2. Rx # (b) (6) on 7/28/17 for C-Diphenhydramine 25mg/5ml liquid.
3. Rx # (b) (6) on 7/31/17 for C-Scopolamine 0.25mg/0.1ml topical lipoderm.
4. Rx # (b) (6) on 8/17/17 for C-Omeprazole 4mg/ml suspension.