

Test Protocol Outline

Antiperspirant Efficacy - Antiperspirant Screen - 5 Subject

Determination of antiperspirant efficacy for products intended to be applied to the underarm. The protocol can also be extended to include exercising during the sweat stimulation period.

Experimental Design

Sex: Female Age: 18 through 65 years

Standards for Inclusion in a Study

- a. Individuals who will complete a preliminary medical history.
- b. Individuals who will read, understand and signed an informed consent document .
- c. Individuals in good health and free of any dermatological or systemic disorder.
- d. Individuals who will abstain from the use of all deodorant/antiperspirant materials, fragrant and medicated products (on body or clothing) for the entire conditioning and test period.
- e. Individuals who will abstain from shaving the axillae until 24 hrs prior to and again during the entire test period.
- f. Individuals who will abstain from smoking and intake of alcoholic/nonalcoholic beverages, chewing gum, breath mints, mouth washes for at least 1 hour prior to each visit to AMA.
- h. Individuals who are willing to abstain from eating highly spicy food such onions and garlic 24 hours prior to odor evaluation.
- i. Individuals who will abstain from swimming and minimize other physical activities such as tennis, jogging etc. during the entire test period.
- j. Individuals who will produce at least 150 mg of sweat /20 minutes/ untreated axilla during sweat collection.
- k. Individuals who will develop at least slight to moderate malodor and whose left versus right axillary odor levels are not vastly different at the baseline/screening odor evaluation.

Method

1. Baseline sweat collection will be conducted on the first day of the test. Subjects producing 150 mg or more of sweat/20 minutes /axilla will be inducted in the study.
2. Supervised washes will be conducted prior to each test product application.
3. Sweat Stimulation: Sweating will be induced by having the subjects sit in a constant temperature and humidity test chamber maintained at 100oF +/-2oF and 35% +/- 5% RH.
4. Sweat Collections: During the first 40 minutes of the sweat stimulation period, the subjects will hold unweighed pads of Webril (non-woven cotton padding fabric) in their axillae. This preliminary warm up period will be followed by two successive 20 minute collection periods, during which the subjects will hold Webril pads in the axillae. These pads will be weighed in zip-lock storage baggies before and after use. During the sweat stimulation and collection periods, the subjects will be required to sit in an erect position with both feet flat on the floor and with their arms resting against their sides in a symmetrical manner. Insertion and removal of the weighed pads will be made by laboratory technicians. The processing will be carried out at approximately 15 second intervals as the technician moves from subject to subject in the test chamber.
5. Geometric mean amounts of sweat collection at baseline and after applications for treated and untreated axilla will be measured. The treated/untreated ratios of amount of sweat at each collection and also post application ratios adjusted to baseline will be tabulated.
6. Individual and summary of mean malodor scores at baseline and 12 and 24 hours after 2nd application for treated and untreated axilla will also be tabulated.

References

F.D.A. Guidelines for the Effectiveness Testing of OTC Antiperspirant Drug Products June 2003
Cantor Research Laboratories Operating Procedure Manual