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Standard Guide for Sensory Evaluation of Axillary Deodorancy[1]

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1. Scope

1.1 This guide provides procedures which may be used in the design and analysis of studies to quantitatively assess the intensity of human axillary odor for the purpose of substantiating deodorant efficacy of personal care products.

1.2 This guide includes protocols for the selection and training of assessors, selection of subjects, experimental design, and statistical analyses. This practice is limited to assessment of axillary odor by trained assessors. Self-evaluation protocols are valid for selected sensory tasks but may be less sensitive.

1.3 With respect to the source of axillary odor, three groups of secretory glands are present in the axillae which participate to a greater or lesser extent in its production—eccrine, apocrine, and sebaceous. Axillary odor has been primarily ascribed to the apocrine gland secretion (**1**).[2] Body odor intensity has been correlated with the volume of the secretory portion of the apocrine gland (**2**) and the density of the glands.

1.3.1 Apocrine glands are found primarily in the axillary vault in conjunction with axillary hairs (**3**). Pure apocrine sweat is sterile and odorless and axillary odor results from degradation of apocrine sweat by resident skin bacteria (**4**). High bacterial populations are found in moist regions of the body, especially in the axillae, providing the appropriate environment for growth (**5**).

1.3.2 Eccrine glands keep the axillae moist through thermally and emotionally induced secretions (**6**).

1.3.3 The sebaceous glands excrete higher molecular weight lipid materials which absorb and retain the volatile materials resulting from bacterial action (**7**). The aerobic diphtheroids are able to produce the typical acrid axillary odor and the micrococcaceae produce an isovaleric acid-like odor when incubated with apocrine sweat (**8**). Therefore, the most undesirable component of axillary odor is caused by degradation of apocrine sweat by particular bacteria normally found in the axillary vault.

1.4 Personal care products are sold and used primarily for their ability to reduce the perception of body odor not only by the individual using the product but also by individuals within the scope of contact. Deodorant protection may be achieved by these products through various modes of action. Antiperspirants achieve their primary efficacy by means of the action of inorganic salts on the eccrine gland production of sweat. Antimicrobial agents achieve deodorancy by inhibiting the growth and activity of the microflora in the axillary vault thus reducing the microbial decomposition of sweat and the consequent production of body odor. Absorbents function either by "binding" available moisture or malodorous substances. Fragrances are effective by altering the perception of malodor and increasing the degree of "pleasantness." Other modes of control become important from time to time, representing changes in the state-of-the-art in product development.

1.5 The studies discussed herein are interpreted through the use of statistical tests of hypotheses. These hypotheses are usually of the form:

The Deodorant Efficacy of Treatment A
= The Deodorant Efficacy of Treatment B

1.5.1 It should be noted that failure to reject this hypothesis at a specified level of significance does not prove the hypothesis, but merely that the weight of evidence provided by the experiment is not sufficient to reject the hypothesis. This could occur because either: *a*) The hypothesis is close to truth and great experimental power would be required to reject it, or *b*) The experiment by design was low in power and, therefore, incapable of rejecting the hypothesis; even when it is far from true. This can occur due to design structure or low sample size. These facts must be taken into consideration when interpreting study results.

2. Referenced Documents

2.1 *ASTM Standards:*[3]

E 253 Terminology Relating to Sensory Evaluation of Materials and Products

E 1697 Test Method for Unipolar Magnitude Estimation of Sensory Attributes

[1] This guide is under the jurisdiction of ASTM Committee E18 on Sensory Evaluation and is the direct responsibility of Subcommittee E18.07 on Personal Care and Household Evaluation.

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[2] The boldface numbers in parentheses refer to the list of references at the end of this standard.

[3] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

3.1.1 For definitions of terms relating to sensory evaluation, see Terminology E 253.

3.1.2 *5-alpha-androst-16-en-3-one* (delta^{16}(5-alpha) androsten-3-one) $C_{19}H_{28}O$—CAS No. 18339-17-7—component of axillary odor which has a "urinous" character and results from the action of certain skin bacteria on apocrine secretion **(9)**.

3.1.3 *5-alpha-androst-16-en-3-alpha-ol* (delta^{16}(5-alpha) androsten-3-alpha-ol) $C_{19}H_{30}O$—CAS No. 14152-27-3—component of axillary odor which has a "musky" character and results from the action of certain skin bacteria on apocrine secretion **(9)**.

3.1.4 *apocrine gland*—a highly coiled tubular system found primarily in axillary epidermis. These glands continuously produce and store apocrine sweat for later excretion onto the skin surface via hair follicles. The excretion is activated by androgenic sympathetic stimuli such as pain or fear **(1)**.

3.1.5 *deodorant efficacy*—the effectiveness or treatment, or both, of a product in reducing axillary malodor.

3.1.6 *eccrine gland*—a simple unbranched tube with a terminal coil. These glands are found in the epidermis over the entire body surface. The glands are controlled by the autonomic nervous system and serve as an evaporative cooling mechanism. Although heat is the primary stimulus, localized eccrine sweating can also occur as a result of emotional stress and other physiological stimuli **(3)**.

3.1.7 *IVA, isovaleric acid* (3-methylbutanoic acid) $C_5H_{10}O_2$; $(CH_3)_2CHCH_2COOH$. CAS No. 503-74-2—component of axillary odor which has a "sweaty, acid" character and results from the action of certain skin bacteria on apocrine secretion.

3.1.8 *right-left imbalance*—a condition of some subjects who have one axilla with notably more intense odor than the other axilla as determined from the control odor evaluation.

3.1.9 *sebaceous gland*—a gland closely related to the hair follicle which produces sebum which combines with apocrine secretion at the base of the follicle. Sebaceous glands are under androgen control **(6)**.

3.1.10 *sequential analysis*—a statistical technique which may be used to screen potential assessors for sensory acuity to a specific stimulus. The assessor is repeatedly tested until he or she passes or fails the test at a specified level of significance **(10, 11)**.

3.1.11 *trigeminal response*—a sensation caused by stimulation of the trigeminal nerve. The sensation is that of a physical feeling, such as burning and tingling.

4. Summary of Guide

4.1 The protocols described provide for the designation of panels of individuals suitably selected and trained to perform the functions of assessors and subjects for the purpose of assessing deodorant efficacy. Details of specific procedures are given in Appendix X1-Appendix X3. Deodorant products should be tested in a manner which maximizes test sensitivity while still reflecting normal consumer-use conditions. Examples are provided to assist the investigator in the design and performance of test protocols.

5. Significance and Use

5.1 The procedures recommended in this practice can be used to clinically assess axillary deodorant efficacy of personal care products.

5.2 This practice is applicable to the product categories which include deodorant and toilet soap bars, liquid bath soaps and gels, deodorant sticks, antiperspirants, creams and lotions, body talcs, and aerosol and pump delivery deodorants, antiperspirants, and body colognes.

5.3 Procedures of the type described herein may be used to aid in the communication of efficacy within and between manufacturers and to the consumer through the various public communications media. Guidelines are suggested due to the need to determine the relative or absolute performance of experimental materials or of commercial products.

5.4 These procedures may be used by persons who have familiarized themselves with these procedures and have had previous experience with sensory evaluation.

5.5 This practice provides suggested procedures and is not meant to exclude alternate procedures which may be effectively used to provide the same clinical result.

6. Subject Selection and Restrictions

6.1 *Criteria for Selection*—The population should be defined and subjects selected from this population in a random, and unbiased manner according to the experimental design considerations defined in 8.11. If a test is being performed with the product directed at a subset of the consuming population, the subjects should be selected from a population representative of the subset.

6.1.1 The subjects should have a recognizable body odor level when evaluated under the procedures given in this practice.

6.1.2 In situations where it is desirable to enhance test sensitivity, the following criteria may be adopted:

6.1.2.1 Based on the control odor scores (see 8.3), subjects who have low or extremely high odor should not be selected for the test. Subjects may be considered as having a "high" odor relative to a normal population if they develop an odor score in excess of 7.0 on a 0- to 10-point scale or 3.5 on a 0- to 5-point scale. Likewise, subjects may be considered as having a "low" odor relative to a normal population if they develop an odor score below 3.0 on a 0- to 10-point scale or 1.5 on a 0- to 5-point scale. A selection process which excludes "low" odor subjects or "extremely high" odor subjects, or both, must be specified for each test and depends upon the number of subjects required for the test and the relative odor scores of these subjects.

6.1.2.2 There should be no more than a small right-left odor imbalance between axillae of each subject. On the basis of a category, or interval scale, the consensus of the task group was that the control odor score differential should not be greater than 20 % of the overall scale (that is, 2.0 points on a 10-point scale or 1.0 points on a 5-point scale).

6.1.2.3 Appendix X1 contains additional information on the acceptance/rejection history of experimental subject populations. A selection process which excludes approximately 20 % of the lowest odor intensity individuals of a normal population is generally recognized as appropriate.

6.1.3 Chronic medications such as antibiotics, steroids, etc., which may affect the test, should be restricted during all test phases as deemed appropriate by the sponsor.

6.1.4 In addition to the above restrictions it should be recognized that other factors which contribute to protocol operating efficiency should be emphasized, including interest, cooperation, commitment, and punctuality of the subjects.

6.2 *Subject Restrictions*—In order to achieve appropriate experimental control, the following restrictions should be imposed upon all subjects during the conditioning and test phases.

6.2.1 *Conditioning Phase*—This period is often referred to as the "washout" period and is that portion of the protocol preceding the actual test phase. The duration of the conditioning phase should be a minimum of 7 days. The conditioning phase for antiperspirants shall be 17 days as defined by the FDA monograph on antiperspirants (**11**).

6.2.1.1 Subjects should use no antiperspirants, deodorants, antibiotic creams, antibacterial ointments, or any other cosmetic products on the axillae. No antibacterial products, including deodorant and medicated shampoos should be used. Care should be taken not to expose the axillae to any medicated product or product containing alcohol.

6.2.1.2 Subjects should use only the control cleansing agent(s) provided by the sponsor as instructed for personal hygiene.

6.2.1.3 Swimming should be stopped at least 7 days prior to the test phase and during the entire test phase.

6.2.1.4 Subjects who normally shave their axillae should shave using the control cleansing agent no less than 24 h prior to the control evaluation and abstain from shaving for the duration of the test.

6.2.1.5 Spicy foods, including garlic and onions should be restricted 24 h before the control evaluation and during the test phase.

6.2.1.6 It is acceptable to use smokers as subjects, but they are required to refrain from smoking for 2 h before all evaluations.

6.2.2 *Test Phase*—In addition to the conditions detailed for the subjects during the conditioning phase, the following restrictions are required of the subjects during the test phase:

6.2.2.1 Subjects should use no perfumed substances on the body such as perfume, after shave, lotions, bath oils, and hairspray.

6.2.2.2 Pre-laundered wearing apparel (see 8.6) may be worn by each subject at the option of the test sponsor. Shirts should be collected and laundered in accordance with a uniform laboratory procedure.

6.2.2.3 If specified by the test sponsor, laundry additives such as bleach, fabric softeners, etc., may be used on subjects' outer clothing.

6.2.2.4 Subjects should minimize physical exertion such as tennis and jogging.

6.2.2.5 Subjects should refrain from the use of breath mints, toothpaste, mouth rinses and sprays, chewing gum, and from drinking coffee or tea at least 1 h prior to each evaluation. Smoking should be restricted 2 h prior to each evaluation and alcoholic beverages 8 h before an evaluation.

6.2.2.6 Subjects should not wash the axillae during the test week at home. Axillae should only be washed at the test site in accordance with a supervised wash procedure. Care should be taken not to get the axillae wet during bathing or showering at home.

7. Assessor Selection and Training

7.1 *General*—The selection process should include the principles embodied in Ref (**12**). The assessor's task is to detect differences and rate the intensity of perceived axillary odor.

7.2 Assessors employed for assessing body odor intensity should be screened for the following attributes:

7.2.1 Interest and availability;

7.2.2 Qualitative and quantitative olfactory discrimination ability;

7.2.3 Ability to carry out basic sensory tasks, and competency with the scale used, and

7.2.4 Specific anosmias. While it is desirable to identify any olfactory deficit which a assessor may have, there is experience which indicates that specific anosmias may not detract from accurate odor judgments. (See X2.6.3)

7.3 Recommended procedures are presented in Appendix X2 for the screening and selection of *in vivo* deodorancy assessors.

7.4 *Assessor Training*—In addition to the following points, the recommended procedures are given in Appendix X3 for the training of *in vivo* deodorancy assessors.

7.4.1 Assessors should be exposed to the complete range of quantitative and qualitative malodor stimuli which they will later be asked to rate. This establishes the context in which ratings are to be assigned.

7.4.2 *Assessor Training for Category Scales*:

7.4.2.1 After being introduced to the rating scale procedure, either 0 to 5 or 0 to 10 category scales, assessors should assign ratings to the stimuli in an open discussion to obtain a consensus rating for each stimulus.

7.4.2.2 Assessors should be drilled until the ratings they independently assign match those obtained by consensus as closely as possible. Assessors whose ratings disagree with the consensus rating much more often than those of most other assessors should be eliminated. The criteria for rejection of individual assessors must be developed in each laboratory. For example, the responses for each assessor can be graphed to determine if they fall within a specified range across time.

7.5 *Assessor Performance Monitoring*—Trained assessors should be tested periodically to confirm their ability to discriminate (rankings, paired comparisons, ratings can be used as appropriate). In order to evaluate rating performance, it is also important to evaluate within- and between-assessor consistency. On a more routine basis, treatments used for the purpose of scale anchors or reference standards can be included in the regular testing regimen as "unknowns" to determine if assessors are capable of rating these products consistently. The procedure for monitoring assessor performance should be