

Test Protocol Outline

24 Hour Patch - 50 Subject

Objective: to determine the irritation potential of the test product(s) after a single application under occlusive or semi-occlusive patches to the skin of human subjects.

Experimental Design

Subjects: Panels of human subjects, male and female, randomly selected.

- Informed of the nature of the test including possible adverse reactions.
- Written informed consent documents signed by all participants prior to induction.
- Parental consent will be obtained from minors.
- Only subjects that are considered dependable and able to read, understand and follow directions will be requested to participate.
- Prior to initiation of a test, each subject will complete a medical history form. The subjects will not exhibit any physical or dermatological condition which would preclude application of the test material(s).

Test Material Information:

A sufficient quantity of each test material should be submitted by the sponsor.

Please forward **Per 50 subjects:** liquids - approx. 250ml ; powders, semi-solids - approx 250g ; fabrics/fibres - approx 600sq in).

Method

1. The quantity of test materials per test patch will be approx. 0.2mL or 0.2g of each product. The test materials(s) will be placed on a 2cm square Parke-Davis Readi-Bandage occlusive patch or the equivalent. The patches will be applied to either the subject's back between the scapulae and waist adjacent to the spinal column, or to the inner forearm. The nature of the product being tested determined the type of tape to be used. Usually occlusive patches are preferred, however, it is often desirable to use semi-occlusive tape when evaluating products that are known irritants and/or are determined to be volatile.
2. 24 hrs following application of the patch, subjects return to the facility for removal of the patch(es) and evaluation of test sites by trained laboratory personnel.

3. Responses will be scored according to the following scale:

0 = no evidence of any effect

? = query

+/- = minimal, faint, uniform or spotty erythema.

1 = pink uniform erythema covering most of all of the contact site.

2 = pink-red erythema visibly uniform in entire contact site.

3 = bright red erythema with or without petechiae or papules.

4 = deep red erythema with or without vesiculation or weeping.

Accompanied edema (swelling) at any test site is recorded with an "e" and is described as mild, moderate or severe compared with normal surface of surrounding skin.

4. The sites are again scored 24 hours after the removal of the patches. The subjects are asked to report any delayed reactions which might occur after the final reading.

5. At the sponsors request, readings may be taken at additional time periods after application and removal of patches, to follow the course of reversal of reactions.

Reporting:

The final report to the sponsor of the study will include: purpose, test materials, panel selection and demographics, experimental design, results and conclusions. Results of dermal responses will be presented in tabular form.

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References

AMA - Standard Operating Procedures, Clinical Trials 900.00, 24 Hour Patch Test