

Test Protocol Outline

Cumulative Irritancy Test 21 Day-up to 10 Prod - 20 Subject

Objective: To determine the relative dermal irritancy potential of a group of test products.

Experimental Design

Subjects - Male & female, random selection.

- Informed of nature of test and possible adverse reactions, informed consent docs. (only including those who are dependable, able to read, understand and follow directions)
- Prior to initiation, medical history form completed by subject, exclude those who have a history of physical or dermatological condition which would preclude application of the test materials.

Test Materials - Please forward : liquids - approx. 250ml ; powders, semi-solids - approx 250g ; fabrics/fibres - approx 600sq in)

Up to 10 materials may be tested, including a known low irritation index control, and a known high irritation index control. - controls should represent a similar product category to test products, and all should be submitted blindly.

Method

1. Quantity per test patch - 0.2mL or 0.2g, placed on a 2cm sq.
2. Test patch used - Parke-Davis Readi-Bandage occlusive patch or equivalent.
3. Patches applied to subjects back between scapulae & waist, adjacent to midline of spinal column.
4. The nature of the test material will determine the type of tape to be used (usually occlusive, or semi-occlusive when evaluating known irritating and/or volatile substances).
5. Test materials applied daily to the same test site.
6. Patches removed and sites scored by trained personnel prior to next patch application.
7. Test is repeated for a total of 15 applications over 21 days or until irritation scored of 3 or 4 are observed. If/when a reaction of 3 or 4 is observed, test is discontinued and the score attained will be entered for the balance of 21 days.

Scale

0 = no evidence of any effect

? = query

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

1= pink uniform erythema covering most or 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

Accompanying edema (swelling) is recorded with an 'e' and is described as mild, moderate or severe as compared with the normal surface of the surrounding skin.

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 in tabular form.

References

Phillips, et al: Toxic and Applied Pharmacology 21: 369-382, 1972.