REPORT

A Study to Assess The Cutaneous Irritancy of a Single Occlusive Application of A Disinfectant Wipe

CUTEST
THE SKIN SPECIALISTS

CONFIDENTIAL

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A Study to Assess The Cutaneous Irritancy of a Single Occlusive Application of A Disinfectant Wipe

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1. SUMMARY

A disinfectant wipe *(Clinell Wipes)* has been tested to determine its skin irritancy following a single 1 hour occlusive application in a test panel of 25 normal volunteer subjects. The design of the study was that of a 'single occlusive application' to assess cutaneous irritation. In such a design the material was applied under occlusion to the test site for 60 minutes with assessments at 10 minutes after patch removal and again at 24 and 48 hours. The disinfectant wipe was applied under occlusion using Tegaderm™ dressings.

The prime marker of cutaneous irritancy was considered to be erythema, which was graded using a 0-6 ranking scale. In this scale a grade 2 reaction (moderate, uniform erythema) was considered a noteworthy indication of cutaneous irritancy.

There were no grade 1 or grade 2 or higher reactions to *Clinell Wipes (Marketed Product)* recorded at either the 60 minute, 24 hour or 48 hour assessments. This result indicates that *Clinell Wipes (Marketed Product)* were well tolerated under the conditions of this test.

2. STUDY DETAILS

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Study Dates:

Start of study	24th January 2006
End of study	26th January 2006
Final report ready	7th February 2006

Personnel Involved:

Principal Investigator:	**Professor R Marks** BSc, FRCP, FRCPath .
Co-Investigators:	**P J Dykes** PhD
	A D Pearse MSc, MIBiol, CBiol, FIScT.
Skin Assessments:	
Staff Nurse:	**Mrs M Clancy** RGN

3. STUDY MATERIAL

Product	Product Description
A	*Clinell Wipes (Marketed Product)*

The study material was supplied by Gama Healthcare Ltd.

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4. INTRODUCTION

This study was performed as described in Gama Healthcare Ltd protocol 01 and was designed to assess the skin irritancy of a disinfectant wipe after a single 1 hour occlusive application to the skin of 25 normal volunteer subjects. The study design was that of a single occlusive application to assess cutaneous irritation. The test material was applied under occlusion to the test site for 60 minutes with assessments at 10 minutes after patch removal and again at 24 and 48 hours.

4.1 Regulatory Guidelines

No formal claim of GCP compliance was required for this study, however the practices and procedures adopted during the conduct of this study were consistent with the principles of ICH, GCP. All routine activities conducted during the course of the study were performed in accordance with Cutest Systems Ltd Standard Operating Procedures. In addition this study was designed to comply with the Guidelines for Medical Experiments in non-patient human volunteers that were initially published in the United Kingdom by the Association of the British Pharmaceutical Industry (ABPI) in March 1988 and further amended in May 1990.

5. THE STUDY

5.1 Test Panel

A total of 25 male and female subjects were recruited from the volunteer test panel of Cutest. Details of the age and sex of the subjects is given in Table 1. The mean age of the 25 subjects tested was 42 years, age range 20 – 59 years. All subjects were normal volunteers who had previously been given a medical examination before joining the test panel. Each subject's medical history was also updated and recorded immediately prior to participation in this study by the study nurse.

In addition all subjects fulfilled the inclusion and exclusion criteria as detailed in the protocol, these were as follows:

Inclusion Criteria

1. Subjects who are aged 18 years or over.
2. Subjects who are healthy with no significant concurrent illnesses.
3. Subjects who have signed the consent form after the nature of the study has been fully explained.

Exclusion criteria

1. Pregnant or lactating females at the start of the study or females of reproductive age who do not agree to take contraceptive measures to avoid becoming pregnant during the course of the study.
2. Subjects who have used any systemic or topical medication likely to interfere with the study. e.g. Systemic anti-inflammatory drugs.
3. Subjects who have used a new chemical entity (NEC) within the previous 56 days prior to study commencement.
4. Subjects who have taken part in a study involving the test sites during the previous 4 weeks (28 days).
5. Subjects with skin disease or a history of skin disease or allergy likely to interfere with the study.
6. Subjects with a history of, or evidence of alcohol or drug abuse.

5.2 Ethical Considerations

Ethical approval for the study was obtained from the Cardiff Independent Research Ethics Review Committee (CIERC).

All subjects had the nature of the study explained to them and were given written information concerning the study. All subjects gave their written, witnessed informed consent before starting the study. They were informed that they were able to withdraw from the study at any stage without obligation and without being required to state a reason.

5.3 Materials

The study material was supplied by Gama Healthcare Ltd and was as follows:

Product	**Product Description**
A	*Clinell Wipes (Marketed Product)*

5.4 Application of products

The test site for the study was the outer aspect of the upper arm.

The test site was not specially cleaned before application. The test site was inspected for any features such as moles or blemishes and the product applied in such a way as to avoid covering such features.

5.5 Test Procedures

Each subject received the disinfectant wipe to the designated test site on the upper right or left arm. The application of the disinfectant wipe to the test sites was randomised (see Appendix I).

The wipes were cut into 2 x 2cm squares and applied to the skin using Tegaderm™ dressings (4.4cm x 4.4cm, 1622w, 3M). Applications were for 60 minutes under occlusion.

5.6 Application and assessment schedule

The test material was applied under occlusion for a total of 60 minutes. The Tegaderm dressing/test material were removed and the site assessed using the following schedule:

Day 1. Apply material under occlusion for 60 minutes. Remove, wait 10 min. Assess sites (1 hour assessment).

Day 2. Assess sites (24 hour assessment).

Day 3. Assess sites (48 hour assessment). End of study.

5.7 Assessments

The test site was assessed visually for erythema at 24 and 48 hours. Assessment was made using a 0-6 ranking scale as follows:

5.7.1 Erythema Assessments

0 = No reaction.

0.5 = Slight, patchy erythema.

1 = Slight uniform erythema.

2 = Moderate, uniform erythema.

3 = Strong erythema.

4 = Strong erythema, spreading outside patch.

5 = Strong erythema, spreading outside patch with either swelling or vesiculation.

6 = Severe reaction with erosion.

This scale has been published.

Dykes P J & Marks R (1992). An evaluation of the irritancy potential of povidone iodine solutions: Comparison of subjective and objective assessment techniques. Clinical & Experimental Dermatology 17, 246-249.

5.7.2 Clinical Scoring

If in addition to erythema other clinical signs of cutaneous irritation are observed the following letters will be appended to the numerical score as follows:

OE = Oedema

V = Vesiculation

S = Scaling

C = Cracking or crazing

SC = Scabbing

P = Papules

SO = Reaction spreading outside area of application

G = Glazing

If the volunteer reported burning or stinging at the test site this was recorded as BS = Burning or Stinging.

5.8 Skin Tolerance

The skin tolerance of the test product was determined by the number of grade 2 (moderate, uniform erythema) or greater skin reactions recorded.

6. RESULTS

6.1 Test Panel Attendance

All of the 25 subjects recruited for the study attended every assessment and were deemed to have completed the study.

6.2 Presentation of the Results

The individual scores for the test material at the various assessment times are presented in Table 2. A summary is presented in Table 3.

7. COMMENTS

Clinell Wipes (Marketed Product)

There were no grade 1 or grade 2 or higher reactions to *Clinell Wipes (Marketed Product)* recorded at either the 60 minute, 24 hour or 48 hour assessments.

This result indicates that *Clinell Wipes (Marketed Product)* were well tolerated under the conditions of this test.

8. DECLARATION AND SIGNATURES

The undersigned hereby declare that this study was performed under our direction and in accordance with the procedures and undertakings specified in the study protocol.
This report is a true and accurate record of the results obtained.

Professor R Marks
Principal Investigator

Dr P J Dykes
Co-Investigator

Mr A D Pearse
Co-Investigator

Mrs V P Pearse
Study Co-ordinator

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TABLE 1

Details of Test Panel Subjects

Subject Number	Test Panel Number	Age	Sex
1	2019	56	F
2	0580	47	F
3	2465	24	M
4	0371	59	F
5	2442	59	M
6	2295	26	F
7	2276	40	M
8	1183	55	F
9	2300	42	F
10	2065	47	F
11	2194	35	F
12	2463	43	F
13	2454	20	F
14	1586	31	M
15	1712	49	F
16	0411	51	F
17	2443	35	M
18	1228	41	F
19	0518	54	F
20	2307	31	F
21	2468	45	F
22	1433	41	F
23	1042	37	F
24	1257	53	F
25	1050	43	F
	Mean =	42	
	Upper age	59	
	Lower age	20	

TABLE 2

Clinell Wipes - Erythema Scores

Subject	Day 1 60 mins	Day 2 24 hrs	Day 3 48 hrs
1	0	0	0
2	0	0	0
3	0	0	0
4	0	0	0
5	0	0	0
6	0	0	0
7	0	0.5	0
8	0	0	0
9	0	0	0
10	0	0	0
11	0	0	0
12	0.5	0	0
13	0	0	0
14	0	0	0
15	0	0	0
16	0	0	0
17	0	0	0
18	0	0	0
19	0	0	0
20	0	0	0
21	0.5	0	0
22	0	0	0
23	0	0	0
24	0	0	0
25	0	0	0
No. grade 0	23	24	25
No. grade 0.5	2	1	0
No. grade 1	0	0	0
No. grade 2	0	0	0
No. grade >2	0	0	0
No. of NR	0	0	0

TABLE 3

Summary of Results

Results are expressed as the number of subjects reacting with each erythema grade

Product	Erythema Score	Day 1 (60 mins)	Day 2 (24 hours)	Day 3 (48 Hours)
Clinell Wipes (Marketed Product)				
	Grade 0	23	24	25
	Grade 0.5	2	1	0
	Grade 1	0	0	0
	Grade 2	0	0	0
	NR = Not reapplied	0	0	0

APPENDIX I

Randomisation List

Subject	Upper Arm
1	L
2	L
3	R
4	R
5	L
6	L
7	R
8	R
9	L
10	L
11	R
12	R
13	L
14	L
15	R
16	R
17	L
18	L
19	R
20	R
21	L
22	L
23	R
24	R
25	L