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ACUTE DERMAL IRRITATION STUDY OF POLYHERBAL INTRAUTERINE INFUSION URAKSHA IN RABBITS

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Abstract: The current study was designed to study Acute Dermal Irritation potential of Uraksha Liquid (supplied by M/S Ayurvet Limited, Baddi, India) according to OECD guidelines. For new substances it is the recommended stepwise testing approach for developing scientifically sound data on the corrosivity/irritation of the substance. 3 female rabbits were used for the study. Each animal served as its own control. After application of Uraksha Liquid the degree of irritation/corrosion was read and scored. The results revealed no irritation potential of Uraksha Liquid.

Keywords: Uraksha Liquid, OECD, Acute Dermal Irritation

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INTRODUCTION

As animal skin is quite sensitive for most of the chemicals thus all new formulations must be tried on skin for a specified period of time to check any irritation or erythema. Allergic and irritant contact dermatitis and phytophotodermatitis are included among the topical adverse effects of natural products [(1)]. Uraksha Liquid, herbal intrauterine infusion (supplied by M/S Ayurvet Limited, Baddi, India) is used for the treatment of various reproductive disorders in cows [(2)]. Hence it is very important to study dermal toxicity of Uraksha Liquid in vivo.

MATERIAL AND METHODS

The animals for the current study were approved by IAEC (MVC/IAEC/30/2014). Healthy 12 months old 3 female New Zealand white Rabbits (body weight 2.5 kg) rabbits were used. Animals were kept under acclimatization for eight days before application. A day prior to start of the study, the rabbits were weighed. The animals were identified by appropriate identification mark. The cage was provided with a card showing the details of cage number, test formulation, animal number, sex of the animal and the study number. Housing conditions were conventional. The ambient temperature was 25^{o}C and relative humidity of 70 %. The animals were exposed to 12 hour light/dark cycle and provided with standard diet and water *ad libitum.* [(3)]

Preparation of the animals

Approximately 24 hours before the test, fur was removed by closely clipping the dorsal area of the trunk on either side of spinal cord of the animals. Care was taken to avoid abrading the skin, and an only animal with healthy, intact skin was used. The test substance (URAKSHA) was applied in a single dose (0.5ml) to the skin (approximately 6 cm^2) of an experimental animal and covered with a gauze patch (right side of the trunk). Untreated skin areas (left side) of the test animal serve as the control. Rabbits were exposed to the test drug for period of one hour. The degree of irritation/corrosion was read and scored (table 1) [(4)] at specified intervals and was further described in order to provide a complete evaluation of the effects. In addition to the observation of irritation, all local toxic effects, such as defatting of the skin, and any systemic adverse effects (e.g., effects on clinical signs of toxicity and body weight), were fully recorded. Data was recorded at interval of 24hr, 48hr and 72hr after patch removal.

Table 1: Grading of skin reactions

Erythema and Eschar Formation	
No erythema	0
Very slight erythema (barely perceptible)	1
Well defined erythema	2
Moderate to severe erythema	3
Severe erythema to eschar formation preventing grading of erythema	4
Maximum possible: 4	
Oedema Formation	
No oedema	0
Very slight oedema (barely perceptible)	1
Slight oedema (edges of area well defined by definite raising)	2
Moderate oedema (raised approximately 1 mm)	3
Severe oedema (raised more than 1 mm and extending beyond area of exposure)	4
Maximum possible: 4	

RESULTS AND DISCUSSION

Erythema

Erythema is redness of the skin or mucous membranes, caused by hyperemia of superficial capillaries [5]. No changes in skin of experimental rabbits were observed at any time (Table 2)

Table 2: Grading of Erythema and Eschar Formation at different time intervals in experimental rabbits

Animal ID	Grading and time intervals		
	24 hr.	48hr	72hr
I	0	0	0
II	0	0	0
III	0	0	0

Oedema

Edema means swelling caused by fluid in body's tissue. Though herbs are Novel Anti-inflammatory Agents [6] but for a new dermal formulation its irritation potential should be evaluated. The results revealed that there were no edematous lesions at any time of the observation (Table 3). The data obtained from the study on last day of test compound did not reveal any lesion.

Table 3: Edema Formation at different time intervals in experimental rabbits

Animal ID	Grading and time intervals		
	24 hr.	48hr	72hr
I	0	0	0
II	0	0	0
III	0	0	0

Skin observations

Other skin lesions like defatting of skin, adverse skin reactions, local systemic changes etc. were not observed at any time of the observations. From fig. 1 to 8 it was evident that there was no significant difference in control and test groups at different time intervals.

Fig. 1-8: Skin condition at different interval of time

Fig.1 Control (0hrs)

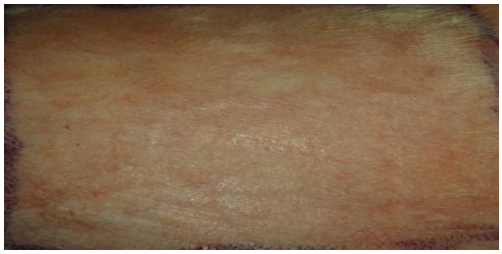

Fig.2 Test (0hrs)

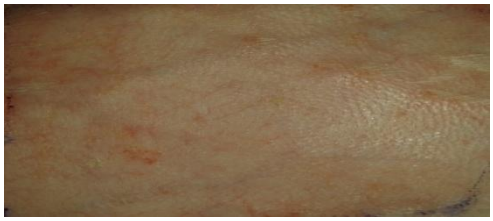

Fig.3 Control (24hrs)

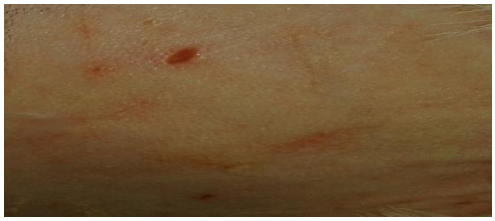

Fig.4 Test (24hrs)

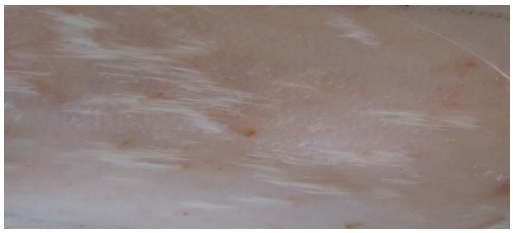

Fig.5 Control (48hrs)

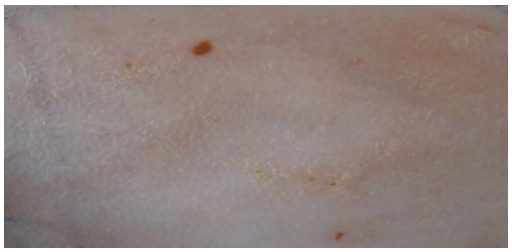

Fig.6 Test (48hrs)

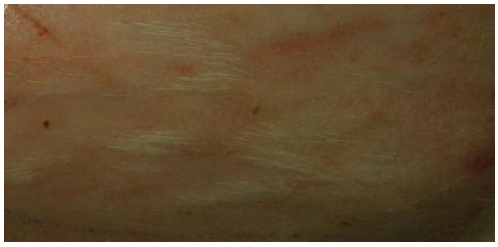

Fig.7 Control (72hrs)

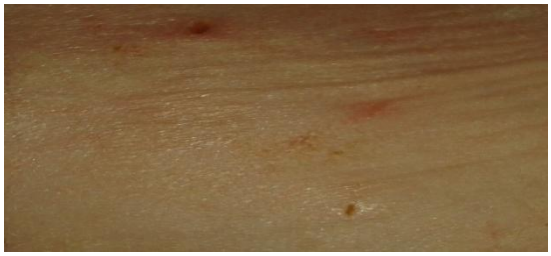

Fig.8 Test (72hrs)

CONCLUSION

Based on the analysis of all the available parameters studied it is concluded that URAKSHA was tolerated in experimental rabbits and there were no skin lesions in animals up to 72hr time interval. The overall observations indicated that URAKSHA did not cause any severe inflammatory changes in given skin irritation test.

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