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**REPEATED INSULT PATCH TEST
ON HUMAN SUBJECTS WITH
RIPT/BA/C11303
OF SAMI LABS LTD., BANGALORE**

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SUMMARY

The repeated insult patch test study was designed to determine by repetitive epidermal contact the primary or cumulative irritation and or allergic contact sensitization potential of **RIPT/BA/C11303** supplied by Sami Labs Ltd., Bangalore. The test substance in the amount of 0.05 ml measured by a syringe was applied to absorbent cotton placed over a Finn chamber. The Finn chamber was then placed to the upper back of the human subjects between the scapulae. The site of application was carefully observed and the reaction evaluated.

The product did not produce any reaction in the induction as well as challenge phase in all the 50 patients.

INTRODUCTION

The repeated insult patch test study now reported was designed to determine by repetitive epidermal contact the primary or cumulative irritation and or allergic contact sensitization potential of **RIPT/BA/C11303** on human subjects.

MATERIALS AND METHODS

TEST SUBSTANCE

Sponsor	Sami Labs Ltd., Bangalore
Label on sample	RIPT/BA/C11303
Characteristics of Sample	Consistency - Liquid

TEST SYSTEM

Species	Healthy Human subjects
Sex	Male and Female
Age	16 years and above

EXPERIMENTAL PROCEDURE

INDUCTION PHASE

Test material was applied as received. The patch unit was applied to the upper back between the scapulae. The patch unit was applied to the same site three times a week, for a total of nine applications. Following supervised removal of the first induction patch, participants were instructed to remove the patch at home, twenty-four hours following all subsequent induction patch applications. Scoring of the test site was made just prior to re-application.

CHALLENGE PHASE

After two weeks following the final induction patch application, a challenge patch was applied to a virgin test site adjacent to the original induction patch site, following the same procedure as described for induction. The patch was removed and the site scored twenty-four hours after application and scored again seventy-two hours post-application.

Each site of application was carefully observed and the reaction evaluated as follows:

- 0 No visible skin reaction
- + Barely perceptible or spotty erythema
- 1 Mild erythema covering most of the test site
- 2 Moderate erythema, possible presence of mild edema
- 3 Marked erythema, possible edema
- 4 Severe erythema, possible edema, vesiculation, bullae and/or ulceration

ADVERSE REACTIONS

If at any time during the induction phase of the study, an evaluation score of '2' was observed, then the reapplication of the test material was moved to an adjacent site. Should an evaluation score of '2' be observed on this new site, further applications were discontinued. Evaluation scores of '3' and above entitled for discontinuation of further applications.

RESULTS

Summary of the results as a consolidated report following application of
RIPT/BA/C11303 on human subjects

Study Numbers: 50 patients

Observations

INDUCTION EVALUATIONS									CHALLENGE EVALUATIONS
1	2	3	4	5	6	7	8	9	72 hrs
All 50 patients = 0									All 50 patients = 0

CONCLUSION

It is concluded from the present repeated insult patch test study that the test substance **RIPT/BA/C11303** supplied by Sami Labs Ltd., Bangalore did not produce any reaction in the induction as well as challenge phase in all the 50 patients.

ARCHIVING

The raw data and all relevant details and a copy of the study report will be stored for a period of one year in the archives of the Dept. of Pharmacy Practice, Al-Ameen College of Pharmacy, Bangalore.