

嘉南藥理科技大學專題研究計畫成果報告

計畫名稱

Evaluation of the cream-based corticosteroid formulations

計畫類別：個別型計畫

計畫編號：CNIB92-04

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執行單位：生科所

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The major purpose of this project is to evaluate cream-based formulations for mometasone. Mometasone is a synthetic corticosteroid, exhibits antiinflammatory, antipruritic and vasoconstriction properties. It is often used in the relief of the inflammatory and pruritic manifestations of corticosteroid responsive dermatoses. It has very rarely adverse reaction include paresthia, pruritus and sign of skin atrophy. Local adverse reactions rarely reported, include burning, pruritus, tingling and signs of skin atropy.

Since many literatures suggest mometasone may not be stable under certain conditions; in order to apply the drug locally, it is desirable to develop and evaluate its stability profile. As a result, the present project will focus on screening and evaluating several cream formulations under 40 degree and 75 %RH in order to obtain the optimum cream formulation for the drug.

The results (Table 1 and Table 2) show that, within the 6 month periods of study, the steroid is stable in both tubes and bottles. That is, no appreciable degradation was found in both containers. The results suggest two years of shelf-life can be granted for the steroid in both containers.

Table 1. The stability data of mometasone cream in the bottle
(40 degree, 75% RH stability chamber)

Duration (month)	0 month	2 month	4 month	6 month
Appearance	passed	passed	passed	passed
Assay percentage	101.12%	100.47%	100.52%	100.31%

Table 2. The stability data of mometasone cream in the tube
(40 degree, 75% RH stability chamber)

Duration (month)	0 month	2 month	4 month	6 month
Appearance	passed	passed	passed	passed
Assay percentage	101.12%	100.49%	100.55%	100.35%