

INTISARI

Produk sediaan farmasi, terutama kosmetik sudah sangat tersebar luas di pasaran. Dalam kosmetik, digunakan berbagai macam bahan yang diformulasikan sedemikian rupa agar menghasilkan sediaan yang baik dan aman. Perlu dilakukan uji iritasi terhadap sediaan agar keamanan konsumen terjamin. Penelitian mengenai Uji *In Vivo* dan Validasi Protokol *Slug Irritation Test* Pada Sediaan Bedak Tabur Amilum Manihot (*Manihot utilissima* L.) menggunakan Pewarna Karotenoid dari Umbi Wortel (*Daucus carota* L.) dengan Metode *Classification And Regression Tree* (CART) bertujuan untuk mengetahui validitas *Slug Irritation Test* dalam pengujian sediaan bedak tabur amilum manihot menggunakan pewarna karotenoid dari umbi wortel.

Penelitian ini merupakan penelitian eksperimental kuasi dan eksploratif. Dilakukan uji *in vivo* menggunakan siput telanjang dan validitas metode diuji. Validitas protokol *Slug Irritation Test* dilihat berdasarkan nilai sensitivitas dan selektivitas. Metode dinyatakan valid apabila nilai sensitivitas dan spesifisitas >60%.

Hasil penelitian menunjukkan persen mukus sebagai variabel penting dalam klasifikasi dengan nilai *cut off* sebesar 0,0325. Didapatkan nilai sensitivitas 100% dan spesifisitas 77,5% dan metode dinyatakan valid. Potensi iritasi sediaan bedak tabur diprediksi dibandingkan dengan *cut off* dari persen mukus. Bedak tabur memiliki rata-rata persen mukus sebesar $0,0836 \pm 0,01$, sehingga disimpulkan bahwa bedak tabur memiliki potensi iritasi.

Kata kunci: *Slug Irritation Test*, bedak tabur, pewarna, validasi, *cut off*, *Classification and Regression Tree*

ABSTRACT

Pharmaceutical dosage forms, especially cosmetics, have been spread widely in the market. Wide varieties of materials are used in order to formulate good as well as safe cosmetics products. The irritation test is needed to guarantee the product safety for the consumers. The study about In Vivo Test and Protocol Validation of Slug Irritation Test on Amylum Manihot (*Manihot utilissima* L.) Face Powder Using Carotenoid Dye from Carrot's Tuber (*Daucus carota* L.) by the Method of Classification and Regression Tree (CART) aims to discover the Slug Irritation Test's validity in the examination of Amylum manihot face powder using carotenoid dye from carrot's tuber.

This study is a quasi experimental and an explorative research. The in vivo test using slugs was performed and the protocol validity of Slug Irritation Test was determined by the sensitivity and the selectivity. This method is valid if the value of both are >60%.

The result of the study shows the mucus production (in percent) as the important variable in the classification with the cut off value of 0.0325. The sensitivity value is 100% and the specification value is 77.5%. Therefore, the method is valid. The irritation potential of face powder dosage form is predicted by the cut off from the mucus production. The powder has the average mucus production of 0.0836 ± 0.01 percent. From the result, it can be concluded that the powder has the irritation potential.

Keywords: Slug Irritation Test, powder, dye, validity, cut off, Classification and Regression Tree