

INTISARI

Setiap produk kosmetik dan non kosmetik harus melewati uji keamanan terlebih dahulu sebelum dipasarkan. Hal tersebut dilakukan untuk menjamin keamanan produk. Penggunaan hewan untuk uji keamanan dan efikasi merupakan isu yang banyak diperbincangkan di Eropa, pengujian harus memenuhi beberapa standar ilmiah dan memperhatikan pada prinsip tiga R (*three Rs*) yaitu reduksi (*reduction*), perbaikan (*refinement*), dan penggantian (*replacement*). Penelitian mengenai Uji *In Vivo* dan Validasi Protokol *Slug Irritation Test* pada Sediaan *Cooling Gel* Ekstrak Daun Petai Cina (*Leucaena leucocephala* (Lmk) De Wit) dengan Metode *Classification And Regression Tree* (CART) bertujuan untuk mengetahui validitas protokol *slug irritation test* pada sediaan *cooling gel* ekstrak daun petai cina dengan metode *classification and regression tree* (CART).

Jenis penelitian bersifat eksperimental kuasi dan eksploratif. Uji *in vivo slug irritation test* bersifat eksperimental kuasi dan validasi protokol *slug irritation test* yang menggunakan model prediksi yang dikembangkan menggunakan metode statistika *classification and regression tree* bersifat eksploratif. Untuk prediksi sifat iritatif digunakan metode kelas.

Hasil penelitian menunjukkan bahwa prediksi sifat iritatif bahan dengan *slug irritation test* menggunakan metode *classification and regression tree* dikatakan valid karena telah memenuhi syarat sensitifitas dan spesifisitas > 60%. Nilai sensitifitas yang didapatkan 85% dan spesifisitas yang didapat yaitu 100%. Parameter yang digunakan untuk memprediksi sifat iritatif senyawa uji adalah kadar *Alkaline Phosphatase* (ALP) dan persen mukus yang dihasilkan. Nilai *cut-off* untuk tiap parameter adalah 8,25 dan 12%. Menggunakan *classification and regression tree* dari data validasi protokol dapat disimpulkan bahwa sediaan *cooling gel* ekstrak daun petai cina bersifat non-iritan.

Kata kunci: *Slug Mucosal Irritation*, validasi protokol, *slug*, *cooling gel*, *Leucaena leucocephala* (Lmk) De Wit, *cut-off*, *classification and regression tree*

ABSTRACT

Every product has to undergo the safety assessment at the first place before the marketing process to guarantee the products' safety. The use of animals for safety and efficacy assessment is the issue being discussed in the Europe. The assessment has to fulfill several scientific standards and pays attention to three Rs – reduction, refinement, and replacement. Thus, the purpose of this research is to discover the protocol validity of slug irritation test on Petai Cina (*Leucaena leucocephala* (Lmk) De Wit) extract cooling gel using classification and regression tree (CART) method.

In this study, the *in vivo* test was a quasi-experimental design and the slug irritation test protocol validation which used the prediction model developed by statistic method of classification and regression test, was an explorative design. As for the prediction of irritation character, the class method was used.

The result showed that the irritation character's prediction material by slug irritation test using classification and regression tree method was valid since it had the conditions of sensitivity and specification value of $> 60\%$. The sensitivity value was 85% and the specification value was 100%. The parameter used to predict the irritation character of testing compound was the level of ALP (Alkaline Phospatase) and the percentage mucus produced. The cut-off value of each parameter was 8,25 and 12%. Using the classification and regression tree from the protocol validation data, it can be concluded that the product of Petai Cina (*Leucaena leucocephala* (Lmk) De Wit) extract cooling gel was non-irritant.

Keywords: Slug Mucosal Irritation, protocol validation, slug, cooling gel, *Leucaena leucocephala* (Lmk) De Wit, cut-off, classification and regression tree