

**KETOKSIKAN AKUT PRODUK SOLUDIA[®]
MENGUNAKAN METODE *Organization for Economic
Cooperation and Development* (OECD) 425 PADA TIKUS
WISTAR BETINA DAN GAMBARAN HISTOPATOLOGIS
HATI DAN GINJAL**

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INTISARI

Produk SOLUDIA[®] merupakan obat herbal yang memiliki khasiat secara empiris mampu menurunkan kadar glukosa darah dan memperbaiki fungsi sel beta pankreas. Produk ini terdiri dari kombinasi ekstrak daun yakon (*Smalanthus sonchifolius*), daun sambiloto (*Andrographis paniculata* [Burm.f.] Nees) dan herba meniran (*Phyllanthus niruri* L.). Meskipun telah dipasarkan dan dikonsumsi sebagai obat herbal antidiabetes, namun belum ada penelitian mengenai batas keamanan Produk SOLUDIA[®]. Penelitian ini bertujuan untuk mengetahui gambaran ketoksikan akut pemberian produk SOLUDIA[®] pada tikus Wistar betina dengan menggunakan metode OECD 425 yang dilengkapi dengan hasil gambaran histopatologis hati dan ginjal tikus. Metode penelitian ini menggunakan tikus Wistar betina dengan berat badan 140-200 mg yang diberikan dosis tunggal 2000 mg/kgBB sesuai prosedur *limit test*; diikuti pengamatan gejala ketoksikan pada 4 jam pertama secara intensif, dilanjutkan pengamatan secara berkala setiap 24 jam selama 14 hari; dilakukan penimbangan berat badan tikus secara berkala; penetapan nilai LD₅₀; dan pengamatan gambaran histopatologis hati dan ginjal dengan pewarnaan Hematoxylin Eosin. Hasil penelitian, didapatkan bahwa nilai LD₅₀ lebih besar dari 2000 mg/kgBB ditandai dengan tidak adanya gejala ketoksikan dan kematian selama pengamatan sehingga termasuk dalam klasifikasi toksik ringan meskipun hasil gambaran histopatologis menunjukkan adanya perubahan berupa nefrosis pada ginjal dan akumulasi glikogen pada hati.

Kata kunci: SOLUDIA[®], toksisitas akut, tikus Wistar

ACUTE TOXICITY OF SOLUDIA® PRODUCTS USING THE 425 Organization for Economic Cooperation and Development (OECD) METHOD IN FEMALE WISTAR RATS AND HISTOPATHOLOGICAL FEATURES OF THE LIVER AND KIDNEYS

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ABSTRACT

SOLUDIA® products are herbal medicines that have empirically useful properties that can reduce blood glucose levels and improve pancreatic beta cell function. This product consists of a combination of yakon leaf extract (*Smalanthus sonchifolius*), bitter leaf (*Andrographis paniculata* [Burm.f.] Nees) and meniran herb (*Phyllanthus niruri* L.). Although it has been marketed and consumed as an anti-diabetic herbal medicine, there has been no research regarding the safety limits of SOLUDIA® Products. This study aims to determine the acute toxicity picture of SOLUDIA® product administration in female Wistar rats using the OECD 425 method which is completed with histopathological results of rat liver and kidneys. This research method uses female Wistar rats with a body weight of 140-200 mg given a single dose of 2000 mg/kgBB according to the limit test procedure; followed intensively by observing the symptoms of toxicity in the first 4 hours, followed by periodic observations every 24 hours for 14 days; weighing mice periodically; determination of LD₅₀ value; and observation of liver and kidney histopathological features by hematoxylin eosin staining. The results of the study, it was found that LD₅₀ values greater than 2000 mg/kgBW were marked by the absence of symptoms of toxicity and death during observation so that they were included in mild toxic classification although the histopathological features showed changes in the form of kidney nephrosis and accumulation of glycogen in the liver.

Keywords: SOLUDIA®, acute toxicity, Wistar rats