

SKRIPSI SARJANA FARMASI

**UJI TOKSISITAS AKUT DERMAL SEDIAAN PATCH YANG MENGANDUNG
SEKRETOM MSC (*MESENCHYMAL STEM CELLS*)
PADA TIKUS WISTAR (*Rattus norvegicus*)**



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PADANG**

2026

ABSTRAK

UJI TOKSISITAS AKUT DERMAL SEDIAAN PATCH YANG MENGANDUNG SEKRETOM MSC (*MESENCHYMAL STEM CELLS*) PADA TIKUS WISTAR (*Rattus norvegicus*)

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Sekretom *Mesenchymal Stem Cells* (MSC) merupakan kumpulan molekul bioaktif yang berperan dalam regenerasi jaringan, modulasi inflamasi, dan penyembuhan luka. Sekretom MSC memiliki komponen biokatif seperti sitokin, faktor pertumbuhan dan vesikel ekstraseluler. Penelitian ini bertujuan untuk mengamati tanda klinis toksisitas akut dermal, perubahan berat badan, dan mortalitas pada tikus wistar (*Rattus norvegicus*) selama 14 hari periode pengamatan setelah pemberian sediaan *patch* yang mengandung sekretom MSC. Pengujian toksisitas akut dermal secara *in vivo* ini mengacu pada Peraturan BPOM Nomor 10 Tahun 2022 dan OECD Test Guideline 402 dengan kelompok dosis 200 mg/kgBB, 1000 mg/kgBB, dan 2000 mg/kgBB. Sekretom MSC diperoleh melalui proses kultur *Adipose-Derived Mesenchymal Stem Cells* (ADMSC) menggunakan media pertumbuhan DMEM pada *passage* 5, kemudian diformulasikan dalam sediaan *patch* film menggunakan metode *solvent casting*. Hasil evaluasi menunjukkan seluruh formula *patch* film memiliki penampilan bening, tidak berbau, ketebalan kurang dari 1 mm, daya lipat diatas 300 kali, pH rentang 7,1 – 7,4, persentase elongasi diatas 30%, dan nilai tensile strength diatas 1 N/mm². Hasil pengujian toksisitas akut dermal menunjukkan tidak ditemukan kematian maupun tanda klinis toksisitas sampai dengan dosis tertinggi (2000 mg/kgBB). Nilai *Primary Irritation Index* (PII) yang diperoleh adalah 0, dikategorikan tidak mengiritasi dan terdapat penurunan berat badan yang melebihi 10% dari nilai awal pada seluruh tingkatan dosis uji. Berdasarkan hasil tersebut, dapat disimpulkan bahwa sediaan *patch* film yang mengandung sekretom MSC bisa digunakan untuk pengobatan dermal akut dan dinyatakan aman secara toksikologis.

Kata Kunci: Sekretom, *Mesenchymal Stem Cells*, toksisitas akut dermal, *patch* film

ABSTRACT

ACUTE DERMAL TOXICITY TEST OF PATCH FORMULATION CONTAINING MESENCHYMAL STEM CELL (MSC) SECRETOME IN WISTAR RATS (*Rattus norvegicus*)

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Mesenchymal Stem Cell (MSC) secretome is a collection of bioactive molecules that play roles in tissue regeneration, inflammation modulation, and wound healing. MSC secretome contains bioactive components, including cytokines, growth factors, and extracellular vesicles. This study aimed to observe clinical signs of acute dermal toxicity, changes in body weight, and mortality in Wistar rats (*Rattus norvegicus*) during a 14-day observation period following the administration of a patch formulation containing MSC secretome. The in vivo acute dermal toxicity test was conducted in accordance with BPOM Regulation Number 10 of 2022 and OECD Test Guideline 402, using dose levels of 200 mg/kg body weight, 1000 mg/kg body weight, and 2000 mg/kg body weight. MSC secretome was obtained through the culture of Adipose-Derived Mesenchymal Stem Cells (ADMSCs) using Dulbecco's Modified Eagle Medium (DMEM) as the growth medium at passage 5, and was subsequently formulated into a film patch using the solvent casting method. The evaluation results showed that all film patch formulations had a clear appearance, were odorless, had a thickness of less than 1 mm, a folding endurance of more than 300 folds, a pH ranging from 7.1 to 7.4, an elongation percentage of more than 30%, and a tensile strength of more than 1 N/mm². The acute dermal toxicity test results showed no mortality or clinical signs of toxicity up to the highest tested dose of 2000 mg/kg body weight. The Primary Irritation Index (PII) value was 0, indicating that the formulation was classified as non-irritating. However, a decrease in body weight exceeding 10% of the initial body weight was observed at all tested dose levels. Based on these results, the film patch formulation containing MSC secretome can be considered suitable for acute dermal application and was considered toxicologically safe under the conditions of this study.

Keywords: Secretome, Mesenchymal Stem Cells, acute dermal toxicity, film patch