



INTISARI

Sediaan parenteral merupakan bentuk sediaan obat yang umum digunakan di rumah sakit, terutama bagi pasien rawat inap. Sterilitas sediaan parenteral harus selalu dipertahankan selama proses penyiapan sediaan parenteral hingga sediaan diberikan kepada pasien. Kontaminasi mikroorganisme pada sediaan parenteral meningkatkan risiko infeksi pada pasien. Penelitian ini bertujuan untuk mengevaluasi sterilitas hasil pencampuran sediaan parenteral serta menentukan *Beyond Use Date* (BUD) berdasarkan kondisi pencampuran dan penyimpanan.

Metode penelitian bersifat eksperimental dengan sampel berupa hasil pencampuran 25 mL KCl 7,46% ke dalam infus NaCl 0,9% sebanyak 500 mL. Pencampuran dilakukan di tiga lokasi berbeda: bangsal perawatan ICU, ruang segregated compounding area menggunakan *Laminar Air Flow Cabinet* (L AFC), dan *cleanroom* menggunakan *Biological Safety Cabinet* (BSC). Masing-masing kelompok terdiri dari 10 sampel dan diuji sterilitasnya pada berbagai waktu penyimpanan mulai dari 2, 4, 6, 12, 18, 24, 36, 48, 72, hingga 96 jam. Pengujian dilakukan oleh Instalasi Laboratorium RSUP Dr. Kariadi Semarang mengikuti prosedur Farmakope Indonesia Edisi VI.

Hasil penelitian menunjukkan bahwa seluruh sampel tetap steril tanpa pertumbuhan mikroorganisme, tanpa perbedaan signifikan antar lokasi pencampuran maupun antar waktu penyimpanan sediaan hasil pencampuran. *Beyond Use Date* (BUD) sediaan hasil pencampuran di bangsal ICU dan ruang SCA adalah 96 jam pada suhu kamar, sementara pencampuran menggunakan BSC pada *cleanroom* memiliki *Beyond Use Date* (BUD) hingga 30 hari pada suhu kamar. Hasil penelitian ini menunjukkan lingkungan pencampuran dan teknik aseptik berperan penting dalam mempertahankan sterilitas serta keamanan sediaan hasil pencampuran.

Kata kunci : Parenteral, Rumah Sakit, Uji Sterilitas



ABSTRACT

Parenteral dosage forms constitute a cornerstone of pharmacotherapy within hospital settings, particularly for hospitalized patients. Ensuring the sterility of these preparations from the point of compounding through administration is imperative, as microbial contamination significantly elevates the risk of patient infection. This study aimed to evaluate the sterility of compounded parenteral admixtures and to establish their beyond-use dates (BUD) under varied compounding and storage conditions.

An experimental design was employed in which 25 mL of 7.46 % potassium chloride (KCl) solution was aseptically introduced into 500 mL of 0.9 % sodium chloride (NaCl) infusion. Aseptic compounding was performed in three distinct environments: the intensive care unit (ICU) ward, a segregated compounding area (SCA) utilizing a laminar airflow cabinet (LAFB), and a cleanroom equipped with a biological safety cabinet (BSC). Each experimental group comprised ten samples, which underwent sterility testing following storage intervals of 2, 4, 6, 12, 18, 24, 36, 48, 72, and 96 hours. All sterility assays were conducted by the Laboratory Unit of Dr. Kariadi Hospital Semarang in accordance with the sixth edition of the Indonesian Pharmacopoeia.

Results showed that all preparations remained sterile across time intervals and compounding conditions, with no microbial growth detected. Notably, preparations compounded in the ICU and SCA retained sterility for up to 96 hours at room temperature, while those prepared in cleanroom conditions using BSC remained sterile for up to 30 days at room temperature. These findings suggest that compounding environment and sterile technique play a pivotal role in ensuring extended sterility and safety of parenteral admixtures.

Keywords : Hospital, Parenteral, Sterility test