

## ABSTRAK

Dalam studi biofarmasetika menunjukkan bahwa adanya perbedaan formulasi dan proses produksi obat dapat mempengaruhi ketersediaan obat dalam tubuh sehingga juga berpengaruh terhadap efektifitas obat tersebut. Pengetahuan terkini mengenai kelarutan, permeabilitas, disolusi, dan farmakokinetik obat harus mempertimbangkan gambaran spesifikasi uji disolusi untuk proses persetujuan obat. Metilprednisolon merupakan kortikosteroid dengan aktivitas utama glukokortikoid. Penelitian ini meliputi uji kekerasan, uji waktu hancur, dan uji disolusi. Kekerasan tablet metilprednisolon generik bermerek lebih tinggi daripada generik berlogo dan inovator. Tetapi waktu hancur tablet metilprednisolon generik bermerek lebih rendah daripada generik berlogo. Hal ini membuktikan bahwa formulasi sediaan dapat mempengaruhi kualitas obat. Penelitian mengenai uji disolusi terbanding pada berbagai jenis metilprednisolon tablet di pasaran menunjukkan bahwa tablet methylprednisolone generik bermerek dan generic berlogo memiliki profil disolusi yang mirip dengan metilprednisolon innovator ( $50 < f_2 < 100$ ). Analisa statistik hasil uji disolusi menggunakan uji T-*independent* menunjukkan tidak adanya perbedaan antara tablet metilprednisolon generik bermerek dan berlogo terhadap tablet metilprednisolon inovator.

**Kata kunci:** Uji disolusi, faktor kemiripan, metilprednisolon, generic, inovator.



## ABSTRACT

The study of biopharmaceutical showed that the differences of formulation and process manufacture can influence drugs bioavailability and effectiveness. Current knowledge about the solubility, permeability, dissolution, and pharmacokinetics of a drug product should be considered in defining dissolution test specifications for the drug approval process. Methylprednisolone is a corticosteroid with mainly glucocorticoid activity. This research include the hardness, disintegration, and dissolution test. The hardness of methylprednisolone generic brand-named is higher than generic and innovator. But the disintegration time of methylprednisolone generic brand-named is lower than generic. Those mean that tablet formulation can affect the quality of drug. The research of comparative dissolution testing of various dosage methylprednisolone in circulation showed that methylprednisolone generic brand-named and generic have similar profil dissolution with methylprednisolone innovator ( $50 < f_2 < 100$ ). The statistic analysis with T-test independent method of dissolution testing showed no differences between methylprednisolone brand-named and generic compared with methylprednisolone innovator.

**Key words:** Dissolution test, similarity factor, methylprednisolone, generic, innovator.

