INTISARI

RATRI, R., 2017, PENGEMBANGAN METODE ANALISIS NIFEDIPIN DAN DEGRADANNYA SECARA KCKT DENGAN PENDEKATAN *FACTORIAL DESIGN*, SKRIPSI, FAKULTAS FARMASI, UNIVERSITAS SETIA BUDI, SURAKARTA.

Nifedipin sangat sensitif terhadap cahaya dan terdegradasi menjadi dehidronifedipin. Kromatografi cair kinerja tinggi (KCKT) dapat digunakan untuk menganalisa nifedipin karena dapat memisahkan antara nifedipin dan hasil degradasinya. Penelitian ini bertujuan untuk mengembangkan dan memvalidasi metode analisis secara KCKT agar diperoleh metode paling efisien dan tervalidasi menggunakan metode *factorial design.*

Metode 2^2 *full factorial design* diaplikasikan untuk mengoptimasi kondisi analisis nifedipin dan degradannya secara KCKT menggunakan faktor proporsi fase gerak asetonitril (ACN): metanol (MeOH) dan laju alir fase gerak. Daerah optimum ditentukan dengan *superimposed contour plot* dari parameter waktu retensi (tR), *tailing factor* (tf), jumlah lempeng teoritis (N) dan resolusi (Rs) menggunakan software Design Expert®. Kondisi paling optimum divalidasi pada parameter linearitas, rentang, akurasi, presisi, batas deteksi (LOD) dan, batas kuantifikasi (LOQ)

Peningkatan komposisi ACN dalam fase gerak akan menurunkan tR. Peningkatan laju alir memberikan pengaruh terhadap penurunan tf. Interaksi keduanya memberikan pengaruh terhadap peningkatan nilai N dan Rs. Berdasarkan *superimposed contour plot* diperoleh kondisi analisis optimum dalam menganalisis nifedipin dan degradannya dengan faktor proporsi fase gerak ACN:MeOH 2,38:1 dan laju alir 1,3 ml/menit. Kondisi tersebut tervalidasi pada rentang 1 – 16 μg/mL.

Kata kunci : asetonitril, metanol, nifedipin, KCKT, *factorial design*

ABSTRACT

RATRI, R., 2017, DEVELOPMENT OF AN ANALYTICAL METHOD OF NIFEDIPINE AND ITS DEGRADANT PRODUCTS BY HIGH PERFORMANCE LIQUID CHROMATOGRAPHY USING FACTORIAL DESIGN, UNDERGRADUATE THESIS, FACULTY OF PHARMACY, SETIA BUDI UNIVERSITY, SURAKARTA.

Nifedipin is very sensitive drug when it exposures a daylight and degraded into dehydronifedipine. A high performance liquid chromatography (HPLC) can be used to analyze the nifedipine due to a separation process of nifedipine and its degradants. The aim of this research was to develop and validate an analytical method using HPLC to obtain the most efficient and validated methods using a factorial design approach.

A 2^2 full factorial design approach was applied to optimize of an analytical condition of nifedipine and its degradants by a HPLC using acetonitrile (ACN) to methanol (MeOH) ratio and flow rate of mobile phase as factors. The optimum region was determined by a superimposed contour plot from several parameters i.e. time retention (tR), tailing factor (tf), number of theoretical plat (N), and resolution (Rs) using a Design Expert® software. The most optimum condition was validated on several parameters i.e. liniearity, range, accuration, precision, limit of detection and limit of quantification.

An increase the ACN composition in the mobile phase reduced tR. An increase the flow rate affected on a reduce of tf. The interaction of both factors affected on increase of N and Rs. Depending on superimposed contour plot, the optimum condition of analysis was a ratio between ACN to MeOH of 2.38:1 and flow rate of 1.3 mL/min. The most optimum condition has been validated at range 1 – 16 μg/mL.

keywords : acetonitrile, methanol, nifedipine, HPLC, factorial design