INTISARI

ASSEM, VS., 2017, OPTIMASI FORMULA *FAST DISINTEGRATING TABLET* CETIRIZINE HCL DENGAN *FILLER BINDER* AVICEL PH 102, STARCH 1500 DAN MANITOL DALAM KOMPLEKS INKLUSI β-SIKLODEKSTRIN METODE *SIMPLEX LATTICE DESIGN*. TESIS FAKULTAS FARMASI, UNIVERSITAS SETIA BUDI, SURAKARTA.

Cetirizine HCl merupakan antagonis reseptor histamin-1 yang digunakan sebagai antihistamin dengan aksi panjang. Formulasi cetirizine HCl dalam sediaan *fast disintegrating tablet* cetrizine HCl dalam kompleks inklusi β-siklodekstrin merupakan alternatif yang tepat untuk meningkatkan kenyamanan dengan rasa yang menyenangkan dan cepat hancur di mulut. Penelitian ini bertujuan mengoptimasi dan mengevaluasi pengaruh dari optimasi starch 1500, manitol avicel dan PH 102 terhadap *wetting time*, waktu hancur, kerapuhan, kekerasan, rasa dan pelepasan obat pada *fast disintegrating tablet* cetirizine HCl dalam kompleks inklusi β–siklodekstrin.

Metode *simplex lattice design* diaplikasikan untuk mengoptimasi *fast disintegrating tablet* cetirizine HCl dalam kompleks inklusi β-siklodekstrin. Menggunakan variabel starch 1500, manitol dan avicel PH 102, sebagai variabel bebas. Daerah optimum ditentukan dengan *superimposed contour plot* dari *wetting time*, waktu hancur, kerapuhan, kekerasan, jumlah obat yang terlepas pada menit 1 dan *dissolution efficiency* menggunakan *software Design Expert*.

Hasil menunjukkan variabel starch 1500 berpengaruh terhadap peningkatan *wetting time*, waktu hancur dan pelepasan obat. Peningkatan manitol meningkatkan mutu rasa dan kekerasan, serta menurunakan *wetting time*, waktu hancur dan kerapuhan. Avicel PH 102 dapat membantu proses *wicking* sehingga menurunkan waktu hancur. Interaksi antara manitol dan avicel PH 102, starch 1500 dan avicel PH 102 serta interaksi antara ketiga variabel menurunkan *wetting time* dan pelepasan obat. Diperoleh formula optimum *fast disintegrating tablet* cetirizine dalam kompleks inklusi β–siklodekstrin dengan kombinasi komponen *starch 1500* : 0 mg, manitol : 103,218 mg, avicel PH 102 : 11,782 mg.

Kata kunci : FDT, cetirizine HCl, β-siklodekstrin, Starch 1500, Manitol, Avicel PH 102, *simplex lattice design*.

ABSTRACT

ASSEM, VS., 2017, OPTIMATION OF FORMULATION OF *FAST DISINTEGRATING TABLET* CETIRIZINE HCL USING *FILLER BINDERS* STARCH 1500, MANITOL AND AVICEL PH 102 IN β-CYCLODEXTRIN INCLUSION COMPLEX *SIMPLEX LATTICE DESIGN* METHOD. POST GRADUATE THESIS. FACULTY OF PHARMACY, SETIA BUDI UNIVERSITY.

Cetirizine HCl is an antagonist of a histamine-1 receptor has used as an long-action antihistamine. Formulation of cetirizine HCl in a fast disintegrating tablet (FDT) using an inclusion complex with β-cyclodextrin is an appropriate alternative to enhance the palatability and disintegrate rapidly in the mouth. This research aimed at optimizing and evaluating the influence of starch 1500, mannitol dan avicel PH 102 on *wetting time*, disintegration time, friability, hardness, palatability and drug release of FDT cetirizine HCl using the inclusion complex with β-siklodekstrin.

A simplex lattice design method was applied to optimize the fast disintegrating tablet of cetirizine HCl in inclusion complex with β-cyclodextrin. Avicel PH 102, Starch 1500 and mannitol were used as independent variables. The optimum area was determined using a superimposed contour plot of combination of disintegration time, wetting time, friability, hardness, the amount of drug released at 1 minute and dissolution efficiency using a Design Expert software.

The result showed that starch 1500 affected on the reducing of wetting time, disintegration time and drug release. Enhancement of manitol concentration increased the mouth feel and hardness, and reduced the wetting time, disintegration time and friability. Enhancement of avicel PH 102 aid the wicking process thus reduced the disintegration time. Interactions between manitol and avicel PH 102, starch 1500 and avicel PH 102, and interaction of three variables reduced the wetting time and drug release. The optimized formulae of FDT cetirizine HCl with β-cyclodextrin complexation was obtained at mannitol of 103.22 mg, avicel PH 102 of 11.78 mg, and absence of Starch proportion in filler-binder composition.

Key words: FDT, cetirizine HCl, β-siklodekstrin, Starch 1500, Manitol, Avicel PH 102, simplex lattice design.