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Formulation and Evaluation of Fast Disintegrating Tablet of Cetirizine Hydrochloride

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1. Introduction

Research in developing formulations of drug for allergic and respiratory disorders which are capable of rapid disintegration and quickly dissolves when placed on the tounge is necessary. Fast Disintegrating Tablet (FDT) is a tablet that disintegrates in the oral cavity without the need of water or chewing, where USP requires FDT might be curshed for 1 minute (Anonymous, 2005), and European Pharmacopeia requires 3 minutes (Council of Europe, 2004). Interestingly, the demand for FDT has enormously increased during the last decade, particularly for geriatric and pediatric patients who experience difficulty in swallowing conventional tablets and capsules (dysphagia). Common among all age groups, dysphagia is observed in about 35% of the general population, as well as up to 60% of the elderly institutionalized population and 18-22% of all patients in long-term care facilities (Gupta and Dubey, 2012). Superdisintegrant plays an important role in the success of this FDT formulation.

2. Objectives

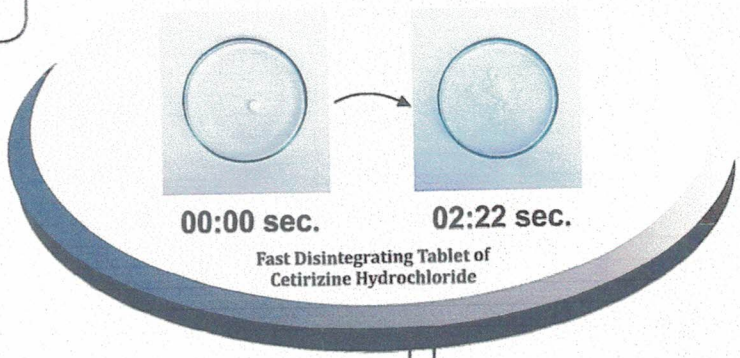
The objective of the present study was formulated Cetirizine HCl in FDT dosage forms with variation of superdisintegrant crospovidone and croscarmellose sodium.

3. Methods

FDT of Cetirizine HCl was manufactured by direct compression. The FDT Formula can be seen in Table 1.

Tabel 1. Formula FDT cetirizine HCl

Material	Weight (mg/tablet)
Cetirizine HCl	5
Avicel PH 102	70
Crospovidone / Croscarmellose sodium }	Optimization 0-6 mg
Mannitol	16
PEG 4000	3
Total	100



Determination of the variation in the percentage of superdisintegrant level in each formula used Design Expert software 10.1.3 and simplex lattice design → FDT formulation was based on variations of formulas provided by the software (as many as 10 formulas) → FDT physical parameters test (hardness test, friability, wetting time, disintegration time) → The results were processed with simplex lattice design and optimum formula software prediction was obtained

Formula was made according to software prediction → FDT physical parameters test of software prediction formula → One sample t-test analyzed between the results of the physical parameters response of the FDT software prediction formula with the actual (optimum formula) → Optimum FDT formula with good physical properties was obtained

4. Result and Discussion

Based on the research results, the combinations of crospovidone and croscarmellose sodium was able to reduce the response of physical properties such as hardness (Figure 1), disintegration time (Figure 2), and wetting time (Figure 3), and enhance the friablity (Figure 4).

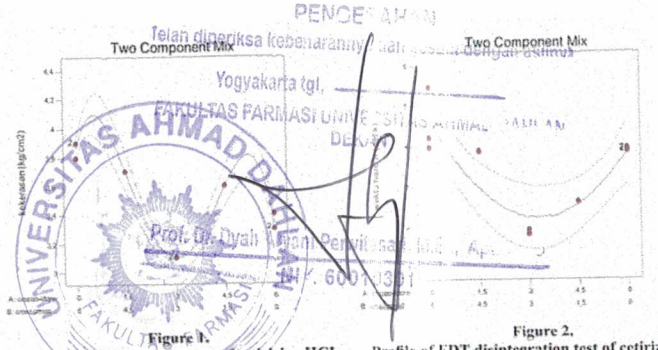


Figure 1.
Profile of FDT hardness test of cetirizine HCl

Figure 2.
Profile of FDT disintegration test of cetirizine HCl

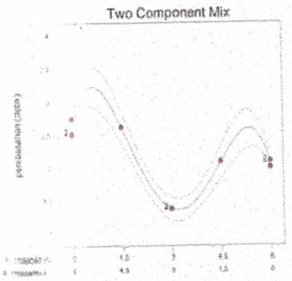


Figure 3.
Profile of FDT wetting time test of cetirizine HCl

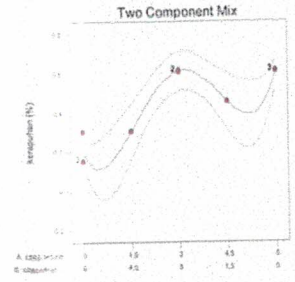
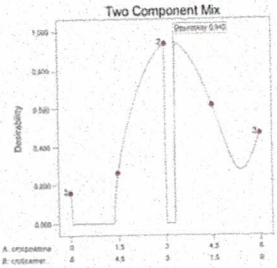


Figure 4.
Profile of FDT friability time test of cetirizine HCl



The optimum formula consist of 3.30 mg of crospovidone and 2.70 mg of croscarmellose sodium in 100 mg tablet

Figure 5.
Graph of prediction optimum formula for FDT cetirizine HCl

Table 2. Verification of Optimum Formula

Physical Properties	Program Prediction	Experimental Results	Sig (2tailed)	Remark
Hardness (kg/cm2)	3.123	3.117	0.258	+
Friability (%)	0.614	0.611	0.194	+
Disintegration time (second)	2.244	2.223	0.289	+
Wetting time (second)	1.363	1.323	0.091	+

Remark : (+) = different not significant

(-) = different significant

5. Conclusion

Based on these results, combinations of crospovidone and croscarmellose sodium was able to produce FDT of Cetirizine HCl

6. Acknowledgement

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