

Thesis Title           Effect of Temperature and Humidity on  
Physical Properties of Piroxicam Tablets  
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#### Abstract

One of the major causes of failure in drug therapy is the problem of tablet aging with accompanying changes in some properties. The effect of storage for 12 weeks at 40 ° C in moderate and high humidity on piroxicam tablets with various proportions of drug to soluble filler (lactose or mannitol) and prepared by the wet granulation method using povidone as a binder was studied. Storage at 40 ° C / 96 % relative humidity (RH) resulted in a remarkable increase in moisture content of tablets but seems not to correlate with the amount of filler present in tablets. Besides, tablet thickness was also found to increase to a greater extent as the amount of filler was reduced. However, storage at 40 ° C / 52 % RH did have insignificant

effect on weight, moisture content, and dimension of piroxicam tablets. The friability was found to be almost unaffected by aging for tablets stored under either condition.

The hardness was greatly reduced probably due to interrupted bonding by moisture under humid condition while dry condition resulted in a rapid increase probably because of recrystallization upon moisture loss of tablets. Tablets stored under both conditions possessed slower disintegration time which was more pronounced in humid condition and was substantially improved upon addition of either mannitol or lactose filler. Moreover, there seems to be a correlation between the disintegration time and proportions of filler in tablets. The results were additionally confirmed by the D-value which was found to conform to the half-order kinetic model.

Dissolution of tablets stored under both conditions were found to gradually decrease but to a greater extent for 40 C / 52 % RH. The rate-limiting step of dissolution process was suggested not to be the disintegration phase but to be the dissolution of prime particles after deaggregation resulted from the direct moisture-filler interactions. This was supported by the dissolution of piroxicam granules and differential thermal analysis. Aging kinetics in terms of Kitazawa equation were also applied to treat the dissolution of piroxicam tablets.