



**Study of the Deterioration of Aspirin  
in the Presence of Various  
Excipients**

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## Abstract

Aspirin is a non steroidal anti-inflammatory drug which can undergo hydrolysis easily in the presence of moisture. As a result of this hydrolysis it forms salicylic acid and acetic acid. This study was carried out to determine the effects of excipients on aspirin hydrolysis. For this purpose, aspirin-excipient binary samples were prepared, by mixing same amount of aspirin with a fixed amount of excipients. Thereafter the binary mixture was subjected to stability test (60 °C, 45% RH, and 21 days). The amount of salicylic acid present in the mixtures was determined using HPLC before and after the stability test.

The results were statistically analyzed to identify the best excipients (\*p< 0.05). Out of all binders, dried maize starch contributes to form low percentage of salicylic acid. Out of all fillers, lactose monohydrate and anhydrous lactose were the best. In the case of lubricants, SLS (Sodium lauryl sulphate) contribute to form low percentage of salicylic acid. Therefore new formulation was developed for direct compression aspirin 300 mg BP tablets by changing the amount of dried maize starch, lactose monohydrate, anhydrous lactose and MCC (Microcrystalline cellulose, low moisture). Various formulations of tablets were prepared and evaluated with respect to the various quality parameters such as powder properties and tablet properties. Based on results formulation which contains dried maize starch, anhydrous lactose, MCC (low moisture) and SLS are suitable for a proper aspirin tablet.

During this research aspirin synthesis was attempted using several methods. Reaction between the salicylic acid and acetic acid derivatives were tested with different catalysts to obtain a better yield. In the first method reaction between salicylic acid and acetic anhydride in the presence of concentrated H<sub>2</sub>SO<sub>4</sub> gave the best yield (70%). In the second method, reaction between salicylic acid and acetyl chloride in the presence of concentrated H<sub>2</sub>SO<sub>4</sub> gave the best yield (69%).

Microwave synthesis will become a widely used technique in organic synthesis. Therefore during this study microwave induced aspirin synthesis procedure was carried out to obtain a better yield, in the presence of concentrated H<sub>2</sub>SO<sub>4</sub>. According to the results, microwave process yields a comparatively higher amount of product than the conventional heating methods within shorter reaction time. However the purity of the product seems to be affected by the microwave radiation.