

# Product formulation portfolio; evaluation pro-forma 5 (pfpe5)

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Product Formulation Portfolio; Evaluation pro-forma 5 (PFPE5) Table 5 How new formula does defer from the old formula including amount for ingredients (include the full list of new formula)

Old Formula:  $C_7H_6O_3$  (Salicylic acid) +  $C_4H_6O_3$  (Acetic anhydride)  $C_9H_8O_4$  (Aspirin) +  $C_2H_4O_2$  (Acetic acid)

Pyridine

New Formula:  $C_7H_6O_3$  (Salicylic acid) +  $C_2O_2H_3Cl$  (acetyl chloride)  $C_9H_8O_4$  (Aspirin) +  $HCl$  (hydrochloric acid)

Old Ingredient

Amount

New ingredient

Amount

Justification of new ingredient amount is it suitable for this formulation (for example some chemicals can only be used certain concentrations in human consumption products, see MHRA, FDA, EMEA or any scientific resources)

Acetic anhydride  $(CH_3CO)_2O$

2ml for every 1gram of salicylic acid= (4ml for 2gms of salicylic acid)

Acetyl Chloride  $(C_2O_2H_3Cl)$

1ml

The amount of the new ingredient used is justified because it is within the allowed concentrations of Acetyl Chloride in human consumption products as recommended by the US Food and Drug Administration (FDA) agency. For example, the specified volume of acetyl chloride is small enough to ensure the purity of the aspirin produced. This is critically important because Acetyl Chloride is a poisonous chemical and the amount used in the preparation of

Aspirin should not exceed the maximum concentration allowed in human consumption products (3). On the other hand, the amount of Acetyl Chloride used is sufficient enough to make salicylic acid the limiting agent (1). For instance, since the reaction is reversible, the presence of excess Acetyl Chloride will force the equilibrium towards the production of the desired end product (Aspirin).

85% Phosphoric acid

1drop

Pyridine

5drops

The 5 drops of pyridine used are sufficient to neutralize the resulting hydrochloric acid without making the solution basic while at the same time acting as a catalyst for the reaction(4). This is because Pyridine is a base catalyst that plays the dual role of being a catalyst and a neutralizing agent at the same time. Additionally, the use of many drops of pyridine justified because pyridine as a base catalysts is less reactive than most acid catalysts such as 85% Phosphoric acid and, therefore, a greater volume of the ingredient may be required for the reaction to be effectively catalysed.

What is the process of making the new formula? It might be as the same as start-up formula or it might be different as you may want to develop process as well as ingredients

Both the two methods involve acetylation salicylic acid to produce aspirin (acetylsalicylic Acid). However, despite the remarkable similarities between the process of making aspirin using the new formula and the mechanism used in the old formula, the main difference between the two distinct

processes is that the leaving group in the new process is a chloride ion as opposed to the acetate ion in the old process. On the other hand, the by-product of the overall process is hydrochloric acid while the old process produces acetic acid as a by product (2).

#### Reference List

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4. Zumdahl, S. S. 2009. Chemical Principles 6th Ed. New York: Houghton Mifflin Publishing Company.