



## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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<b>(54) Title:</b> TASTE-MASKED ACETAMINOPHEN SUSPENSIONS AND METHODS OF MAKING THE SAME  <b>(57) Abstract</b>  Acetaminophen composition in which the taste of the acetaminophen is effectively masked by suspending the drug in a suspension medium containing suspension agent and additive agents that decrease the solubility of the acetaminophen in aqueous solution. The additive agents preferably include sweetening agents. The concentration of the sweetening agent is preferably at least about 25 weight percent of the acetaminophen composition.		

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**TASTE-MASKED ACETAMINOPHEN SUSPENSIONS  
AND METHODS OF MAKING THE SAME**

**Field of the Invention**

The present invention relates to acetaminophen compositions in which the acetaminophen is presented in taste-masked form. More particularly, the present invention relates to an acetaminophen composition wherein the acetaminophen solubility is limited by the presence of additive agents, such as sweetening agents.

**Background of the Invention**

Acetaminophen is a widely used over-the-counter drug which has beneficial pain relieving and fever relieving properties. Acetaminophen is commonly taken as a tablet by the vast portion of the population. However, the tablet form is hard to administer in treating the elderly and the young. Therefore, liquid formulations of acetaminophen are commonly administered for these patients. However, in liquid form such as in an elixir formulation, the acetaminophen is dissolved into solution. Once dissolved, the strongly unpalatable taste of acetaminophen is found to be objectionable. Therefore, noncompliance among liquid acetaminophen patients is

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commonplace.

Various techniques have been used to mask the taste of acetaminophen in non-liquid forms such as tablet coatings or spray dried particles such as are described in U.S. Patent No. 4,760,094. Cooper, U.S. Pat. No. 4,794,112, suggests the use of sweetening agents and suspending agents for oral administration of an acetaminophen and hydroxyzine composition, however it is not shown how to prevent the acetaminophen from substantially dissolving in solution. Therefore, a need exists for a liquid acetaminophen composition which is suitable for oral administration in which the acetaminophen is effectively presented in a taste-masked form.

#### Summary of the Invention

The invention provides an acetaminophen composition in taste-masked form, suitable for oral administration, containing acetaminophen in an aqueous medium. The acetaminophen composition contains acetaminophen in an amount of up to about 10% by weight, preferably from about 2 to about 8% by weight, in an aqueous medium. The aqueous medium contains suspension agent for dispersing the acetaminophen and additive agent for decreasing the solubility of the acetaminophen in the aqueous medium to below 1.3% wt. The additive agent is preferably comprised of sweetening agents which are preferably present in an amount of at least about 25% by weight of the acetaminophen composition.

Various preferred embodiments of the invention can be prepared. The suspension agent is preferably present in an

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amount of from about 0.03 to about 0.3% by weight and a preservative agent is also preferred to be present in the composition. The sweetening agent preferably comprises at least one agent selected from the group consisting of sucrose, glucose, fructose, lactose, maltose, sorbitol, mannitol, and maltitol, and can consist of mixtures of these.

#### Detailed Description of the Preferred Embodiments

The acetaminophen composition of the present invention is characterized by having a palatable taste and with only a slight gritty feel. The composition is a liquid formulation in which the acetaminophen is suspended, and slightly dissolved, in an aqueous medium containing a suspension agent for dispersing the acetaminophen and an additive agent that decreases the solubility of the acetaminophen in the aqueous solution. The additive agent is preferably a sweetening agent. It has been surprisingly found that when the concentration of additive agent and suspension agent are properly adjusted, the taste of the acetaminophen can be masked effectively.

The acetaminophen which is useful in the present invention is particulate acetaminophen of pharmaceutical grade. It is preferred to use acetaminophen with a small average particle size to decrease the gritty feel of the drug. Generally the particle size of the acetaminophen is such that about 99% wt. is below about 420 microns and about 97% wt. is below about 250 microns. In a preferred embodiment, about 90% wt. is below about 150 microns and about 35% wt. is below about 40 microns, such acetaminophen is commercially available as

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