

TOXICOLOGY OF BENZYL ALCOHOL IN PHARMACEUTICAL MANUFACTURING

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Abstract

It is common to use benzyl alcohol in the medicine production process and now it is getting a more and more important component of the injection form of drugs. Because of this tendency paying more attention to the toxicology of benzyl alcohol and its derivatives is becoming an essential duty of toxicology. In this article, most of all important information is accumulated to make the audience aware of the harmful effects of this chemical compound.

Key words: Alcohol, spirit, ethanol, pharmaceuticals, injection, benzyl alcohol, component, toxicity, toxicology.

Introduction

Benzyl alcohols are common chemicals used in the production of pharmaceuticals. They are used as solvents, preservatives, and as intermediates in the synthesis of active pharmaceutical ingredients. While benzyl alcohols are generally considered to be safe, there are concerns about their potential toxicity[1]. This paper will review the toxicology of benzyl alcohols in pharmaceutical manufacturing.

Benzyl alcohol is commonly used as a preservative in pharmaceutical products, especially in injections. It is an effective antimicrobial agent that helps to prevent

the growth of harmful bacteria and fungi that can contaminate the product and cause infections in patients.

The use of benzyl alcohol in injections has several benefits. It helps to prolong the shelf-life of the product, which is important for medications that may not be used immediately after manufacture[2]. It also helps to reduce the risk of adverse reactions to the medication by preventing contamination.

However, it is important to note that benzyl alcohol can also have side effects and may not be suitable for all patients. It can cause allergic reactions, particularly in patients with a history of sensitivity to benzyl alcohol. In addition, it can be irritating to the skin and mucous membranes, and may cause pain or discomfort at the injection site.

Overall, the use of benzyl alcohol in pharmaceutical products, including injections, can be beneficial when used appropriately and with caution. It is important to carefully consider the potential benefits and risks before including it in a product.

Toxicity of Benzyl Alcohols

Benzyl alcohols are classified as mildly toxic by the Occupational Safety and Health Administration (OSHA). They can cause skin irritation and sensitization, as well as respiratory and eye irritation. Benzyl alcohol is also a mild central nervous system depressant. Ingestion of large amounts of benzyl alcohol can cause nausea, vomiting, and headache[3].

The toxicity of benzyl alcohols is dependent on several factors, including the concentration of the chemical, the duration of exposure, and the route of exposure. Inhalation of benzyl alcohol vapors is the most common route of exposure in pharmaceutical manufacturing. Skin contact and ingestion are also possible routes of exposure.

In animal studies, benzyl alcohol has been shown to have low acute toxicity, with no deaths reported in rats exposed to concentrations of up to 2000 mg/kg. However, chronic exposure to benzyl alcohol has been shown to cause liver and kidney damage in rats and mice. Benzyl alcohol has also been shown to have mutagenic and genotoxic effects in vitro.

Regulatory Considerations

The use of benzyl alcohols in pharmaceutical manufacturing is regulated by several organizations, including the United States Food and Drug Administration (FDA) and the European Medicines Agency (EMA). The FDA has established limits on the use of benzyl alcohol in pharmaceuticals, including a limit of 5% for injectable formulations. The EMA has also established limits on the use of benzyl alcohol, including a limit of 1% for injectable formulations.

Conclusion

Benzyl alcohols are commonly used in pharmaceutical manufacturing as solvents, preservatives, and intermediates in the synthesis of active pharmaceutical ingredients. While benzyl alcohols are generally considered to be safe, there are concerns about their potential toxicity. Benzyl alcohol can cause skin irritation and sensitization, as well as respiratory and eye irritation. Chronic exposure to benzyl alcohol has been shown to cause liver and kidney damage in rats and mice. The use of benzyl alcohols in pharmaceutical manufacturing is regulated by several organizations, including the FDA and the EMA. These organizations have established limits on the use of benzyl alcohol in pharmaceuticals to ensure their safety.

Bibliography

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