Macedonian Pharmaceutical Bulletin, 72 (Suppl 1) 55 - 56 (2026)
Online ISSN: 1857-8969
DOI: 10.33320/maced.pharm.bull.2026.72.03.025
Short communication

Effect of temperature on the manufacturing process and quality of suppositories

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Background

Suppositories are pharmaceutical dosage forms designed for insertion into body cavities, most commonly the rectum, where they release active substances for local or systemic therapeutic effects. They are among the most widely used rectal dosage forms and are employed in the treatment of various conditions, including gynecological and proctological disorders. (Allen, 1997; Herasymova et al., 2020).

The active pharmaceutical ingredient (API) may be either dispersed or dissolved in a suitable base.The are two main types of suppository bases: lipophilic bases (e.g., cocoa butter), which melt at body temperature, and hydrophilic bases (e.g., polyethylene glycol) which is dissolve in rectal fluids to release the drug. The choice of suppository base depends on the physicochemical properties of the drug as well as the compatibility between drug and base (Herasymova et al., 2020; Margarit and Caballero, 2003).

Temperature represents one of the most critical factors in the production and storage of suppositories, with a direct impact on their physicochemical properties, stability, and therapeutic efficacy (Deekshitha et al., 2024).

Therefore, in the production of suppositories, it is essential to determine the optimal temperature in order to achieve appropriate viscosity and homogeneity of the mass. In addition, important technological factors include the mixing speed and mixing time. Increased temperature may lead to degradation and reduced efficacy of the product. On the other hand, lower temperatures may result in incomplete melting and non-uniform distribution of the active pharmaceutical ingredient (API). During storage, exposure to high temperatures may cause deformation, softening, and melting of suppositories, while low temperatures may lead to increased brittleness (Dmitrievskiy et al., 2015; Herasymova et al., 2020).

Methodological approach for evaluating the impact of temperature on suppository stability

This short communication is based on a review of available scientific literature related to pharmaceutical technology, with emphasis on the influence of temperature on the manufacturing process and quality of suppositories (Allen, 1997; Dmitrievskiy et al., 2015; Herasymova et al., 2020; Margarit and Caballero, 2003).

Temperature influence on suppository quality and stability

According to the reviewed literature, temperature represents a crucial factor in determining the quality

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and stability of suppositories (Allen, 1997; Herasymova et al., 2020).

Lipophilic bases melt at body temperature (approximately 30-35°C), ensuring drug release after administration. In contrast, hydrophilic bases do not melt at body temperature, but are processed at higher temperature (approximately 45-60 °C) (Allen, 1997; Margarit and Caballero, 2003).

At higher temperatures, viscosity decreases, which facilitates processing, however, excessive temperature may lead degradation of the API, and destabilization of the base. Additionally, polymorphic changes in lipophilic bases may further affect the stability, and quality of the final product. Conversely, insufficient temperature can result in incomplete melting of the base and poor homogeneity of the mass (Dmitrievskiy et al., 2015; Margarit and Caballero, 2003).

From a rheological perspective, suppository bases exhibit temperature-dependent behavior. As temperature decreases, the system undergoes a transition from a liquid or semi-liquid state to a structured solid system.

Conversely, increasing temperature induces a transition from a structured solid state to a semi-solid or liquid system, resulting in reduced viscosity and improved flow properties that facilitate processing and mixing.

Since these temperature-dependent changes directly affect the rheological characteristics of the formulation, temperature control during manufacturing is essential to ensure appropriate viscosity, homogeneous distribution of the active pharmaceutical ingredient (API), and consistent quality of the final product (Dmitrievskiy et al., 2015; Margarit and Caballero, 2003).

Considering the critical role of temperature in suppository manufacturing, the aim of the present study was to evaluate the influence of processing temperature on the rheological properties and quality characteristics of suppository formulations. The scientific contribution of this study lies in improving the understanding of temperature-dependent changes in formulation behavior and their impact on product quality, which may contribute to the optimization of manufacturing conditions and the production of more stable and reproducible suppository preparations.

Conclusion

Temperature sensitivity is a critical aspect of stability for suppositories, which are pharmaceutical dosage forms used for drug delivery to the systemic circulation.

Temperature directly affects the bioavailability and therapeutic efficacy of the drug, and influences the physicochemical properties of the suppository base, including melting behavior, viscosity, and structural characteristics. These changes directly affect the release, dissolution, and absorption of the active pharmaceutical ingredient (API).

References

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