



INFLUENCE OF PACKAGING MATERIALS ON THE STABILITY OF "AFEROL" TABLETS DURING LONG-TERM STORAGE

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Relevance: The medicinal product "Aferol" coated tablets, containing ferrous fumarate as the active pharmaceutical ingredient (API), are widely used for the treatment and prevention of iron deficiency anemia (IDA). The stability of such preparations is critically important, as ferrous fumarate is highly sensitive to environmental factors, including moisture, oxygen, light, and temperature. These factors can induce oxidation of iron (II) to iron (III), hydrolysis, particle agglomeration, and reduced bioavailability, ultimately leading to a loss of therapeutic efficacy.

Packaging materials play a pivotal role in protecting pharmaceutical dosage forms from environmental influences. Different types of packaging provide varying levels of barrier protection against moisture, oxygen, and light. In the context of the pharmaceutical market, investigating the impact of packaging on the stability of "Aferol" is highly relevant to ensuring the quality and safety of the medicinal product, optimize tablet protection and minimize degradation.

Objective: To evaluate the influence of various packaging materials on the stability of "Aferol" tablets during long-term storage, examining the preservation of the API content, physicochemical properties, and organoleptic characteristics as a function of the type of primary packaging.

Materials and Methods: Four types of primary packaging were investigated for their impact on the stability of "Aferol" tablets:

1. Jar – light-protective glass.
2. Vial – polymeric material (high-density polyethylene).
3. Strip – non-cellular flexible packaging sealed between two layers of paper.
4. Blister – composite material (aluminum foil and PVC) with thermoformed cells.

Tests were conducted in climatic zone II (temperature: $25^{\circ}\text{C} \pm 2^{\circ}\text{C}$, relative humidity: $60\% \pm 5\%$) over 24 months. Analyses were performed at 0, 6, 12, 18, and 24 months in accordance with the product's regulatory documentation, evaluating the following parameters: active substance content, dissolution, mechanical strength and organoleptic properties.

Results: Under standard storage conditions, the stability of "Aferol" tablets varied depending on the packaging. The initial active substance content (iron fumarate) was $100 \pm 2\%$.

Glass Jar (light-protective) provided high protection against light and moisture due to its hermetic properties. After 24 months, active substance content decreased by 3–5%, with dissolution remaining within 95–100%. Morphological changes were minimal, with slight darkening of the coating and no agglomeration.

Polymeric Vial exhibited moderate barrier properties, allowing some moisture diffusion. By 24 months, active substance loss reached 8–12%, with dissolution reduced to 85–90%. Minor changes in hardness (10% increase) and slight particle agglomeration were observed.

Paper Strip demonstrated low barrier properties against moisture and oxygen. By 12 months, iron fumarate content decreased by 15–20%, and by 24 months, by 25–30%. Dissolution dropped to



70–80%, with visible changes including darkening, softening, and a strong oxidation odor. There was revealed significant agglomeration and crystallization.

Blister (aluminum foil/PVC) offered the highest protection due to the aluminum layer, effectively blocking light, moisture, and oxygen. Active substance loss did not exceed 2–4% over 24 months, with dissolution maintained at 99–100%. Changes were absent or minimal.

Conclusions: The study demonstrated that packaging materials significantly affect the stability of “Aferol” tablets during long-term storage. Blister packaging (aluminum foil and PVC) and light-protective glass jars provided the best protection due to their superior barrier properties against moisture, oxygen, and light. Polymeric vials were suitable for medium-term storage but were less effective. Paper strips were the least effective and are not recommended for long-term storage due to rapid degradation. Blister packaging or light-protective glass is recommended to ensure the therapeutic efficacy of “Aferol” tablets.