A Comparison of Barrier Film Non-Stick Coated Stoppers vs. Non-Barrier Film Rubber Stoppers in Pharmaceutical Packaging: A Case Study from Historical Data

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Abstract

In pharmaceutical packaging, the choice of stopper material can significantly impact product quality and safety. Additionally, the type of stopper material alters the efficacy of visual inspection training kits for qualifying visual inspectors. This study compares the performance of coated stoppers with a barrier film non-stick coating (Teflon®; FluroTec®, OmniFlex® barrier film) and non-barrier film rubber stoppers in similar projects to evaluate their effectiveness in training visual inspectors. Two comparable projects were created, one using coated stoppers and the other using uncoated stoppers, with all other components being equivalent. The coated stoppers were evaluated for a validity period of two years, and inspections were conducted to observe the presence of foreign material (FM) in both projects.

The results indicated that particles adhered to the non-barrier film rubber stoppers, preventing the particles from becoming free-floating. After the two-year validity period, the units that utilized coated stoppers had particles that were found to be free-floating, and no additional FM was present in these vials. Utilizing barrier film non-stick coated stoppers in visual inspection training kits and training inspectors how to use different lighting, angles, and tools to detect FM enhances the overall inspection capabilities and consistency of the visual inspectors.

Coated Stopper Uncoated Stopper

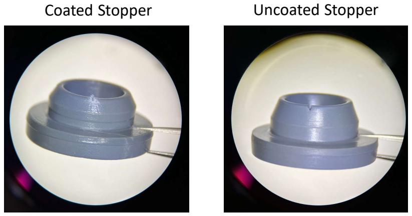


Figure 1: A pin-pull technique was used to confirm that the stoppers were coated or uncoated. A small tear is created in the surface of the stopper, and if the stopper is coated a thin layer of film will be visible in the torn area.

1. Background and Differences Between Stopper Types

Coated and uncoated stoppers are used in pharmaceutical packaging, particularly for sealing vials. Here are a few key differences between them:

Material Composition:
Coated Stoppers have an additional layer or coating, often made from materials such as fluoropolymer. The coating is applied to the surface of the stopper that comes into contact with the drug product.
Uncoated Stoppers are made from elastomeric materials without any additional surface coating. They are typically made from rubber or similar materials.

Chemical Interaction:
Coated Stoppers have a coating that acts as a barrier, reducing the interaction between the stopper material and the drug product. This is particularly important for sensitive formulations that may react with the elastomer.
Uncoated Stoppers have a higher risk of interaction between the drug product and the stopper material, which can lead to contamination or degradation of the drug product.

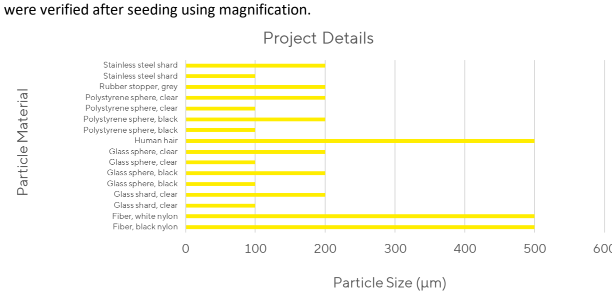
Extractables and Leachables:
Coated Stoppers minimize the risk of extractables and leachables.
Uncoated Stoppers have a greater potential for extractables and leachables, which can affect the safety and efficacy of the drug product.

Cost:
Coated Stoppers are typically more expensive due to the additional manufacturing processes required to apply the coating.
Uncoated Stoppers are generally less expensive as they involve fewer manufacturing steps.

Choosing between coated and uncoated stoppers depends on the specific requirements of the drug product, including its sensitivity, formulation, and regulatory considerations

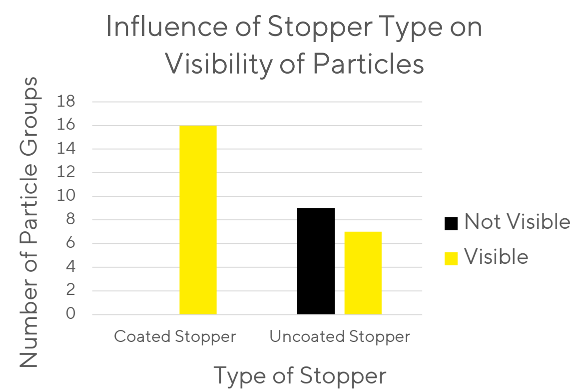
2. Evaluation Parameters

Two similar Particle Validation Standard projects were created. Each project consisted of 80 glass vials filled with Bacteriostatic water. The particle materials included glass shards, glass spheres, polystyrene spheres, nylon fibers, hair fibers, stainless steel shards, and rubber particles. Particle sizes ranged from 100 µm to 500 µm. The varying parameter in the two projects was the stopper types. In one project, barrier film non-stick coated stoppers were used while in the other project non-barrier film rubber stoppers were used. Fabrication, processing, and inspections were performed in accordance with the International Organization for Standardization (ISO) 9001 Quality System guidelines. The presence and number of particles were verified after seeding using magnification.



3. Results

The results showed particles adhered to the non-barrier film rubber stoppers preventing the particles from being free-floating. The project which used the coated stoppers had particles that were found to be free-floating in the units and no additional foreign material was present in these vials. Utilizing barrier film non-stick coated stoppers aids in minimizing foreign material sticking to rubber and potentially being introduced into the product. Additionally, this type of stopper aids in Visual Inspection training kits and training inspectors how to use different lighting, angles, and tools to detect different materials, thus enhancing the overall inspection capabilities and consistency of the visual inspectors.



4. Conclusion

Opting to utilize coated stoppers when creating Particle Validation Standards offers several benefits:

- Minimizes the likelihood of particles sticking to the stopper over time, thus allowing the Visual Inspection kit to be used in more studies
- Lessens the risk of interation of extractables from the rubber stopper
- Reduces the accumulation of leachables in the drug formulation