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Süsen Gülce Erismis, BPharm MSc.

Definitions and History

The term ‘insert’ refers a semi-solid pharmaceutical dosage form carrying active pharmaceutical ingredients (APIs) dispersed in a base that melts at body temperature or dissolves, applied by placing into naturally occurring body cavities aside from the mouth or rectum, such as the vagina (1). If the insert is intended for insertion into the vagina, it is called a vaginal insert, vaginal suppository, or pessary (2). On the other hand, if the dosage form is prepared for administration into the rectum, it is called a suppository (3).

Due to their numerous advantages, both vaginal inserts and suppositories have been widely prepared in pharmacies since the 18th century to achieve both systemic and local effects. The first suppositories were molded into a paper cone. However paper was not the best material to mold a suppository especially considering wettability. Therefore, metal suppository molds made from pewter and tin were introduced in 1860. Since the first mold was a one-piece model, it was very difficult to remove the suppositories from the cavities. For this reason, two-piece mold models have been designed to facilitate the removal of the suppository while maintaining its shape (4). With the developments in material science over the years, various two-piece suppository molds have been produced using different metal combinations and are still in use today.

Problems, Solutions and Comparisons

The metal-based suppository molds are known for their durability due to their composition of brass, steel or anodized aluminum. For easy removal of the suppositories from the mold and to maintain the shape, the mold

should be lubricated with a thin layer of a lubricant such as liquid paraffin before pouring the preparation into the mold. However, excessive use of lubricant should be avoided, otherwise excess lubricant may accumulate at the bottom of the suppository mold and cause homogeneity, dosage and application problems. In addition, the metal suppository molds are too expensive, and they can cause fractures and fissures throughout the suppositories if the mold is too cold while opening. To overcome these problems, different suppository molds have been designed with more affordable materials.

Suppository molds, which are most similar to metal molds in terms of material structure, are made of hard rubber. Similar to metal molds, they can be designed in two parts to be opened by separating from the center or in one-piece unlike metal molds. The one-piece rubber suppository molds contain a cap at the bottom of the mold and the suppositories can be taken out by pushing through the top after removing the cap. Although they provide a more affordable solution than metal molds, there is a risk of fracture of the suppositories when opening the lid.

Flexible rubber is another material that is used make one-piece suppository molds. After the suppository mixture has solidified, it is removed from the mold by pushing it through the back of each cavity, thus eliminating the risk of fracture. These types of molds are also suitable for the suppositories that need to be stored in the fridge (5). All of those re-usable suppository molds require a convenient packaging to protect the compounded product.

Primary Packaging Regulations

Packaging is a crucial step of the compounding process to maintain the stability and quality of the preparation throughout its shelf life. According to the World Health Organization (WHO), the package must protect the pharmaceuticals against microbial contamination, physical damage, and external influences such as oxygen, moisture and light. They also point out that there should be no interaction, affecting the protective function, between the packaging material and pharmaceutical (6). Also, Good Manufacturing Practice (GMP) of ISO 15378:2017 states that production and control of primary packaging materials are important for the safety of a patient receiving the medicinal product because of the direct contact between the packaging materials and the product (7).

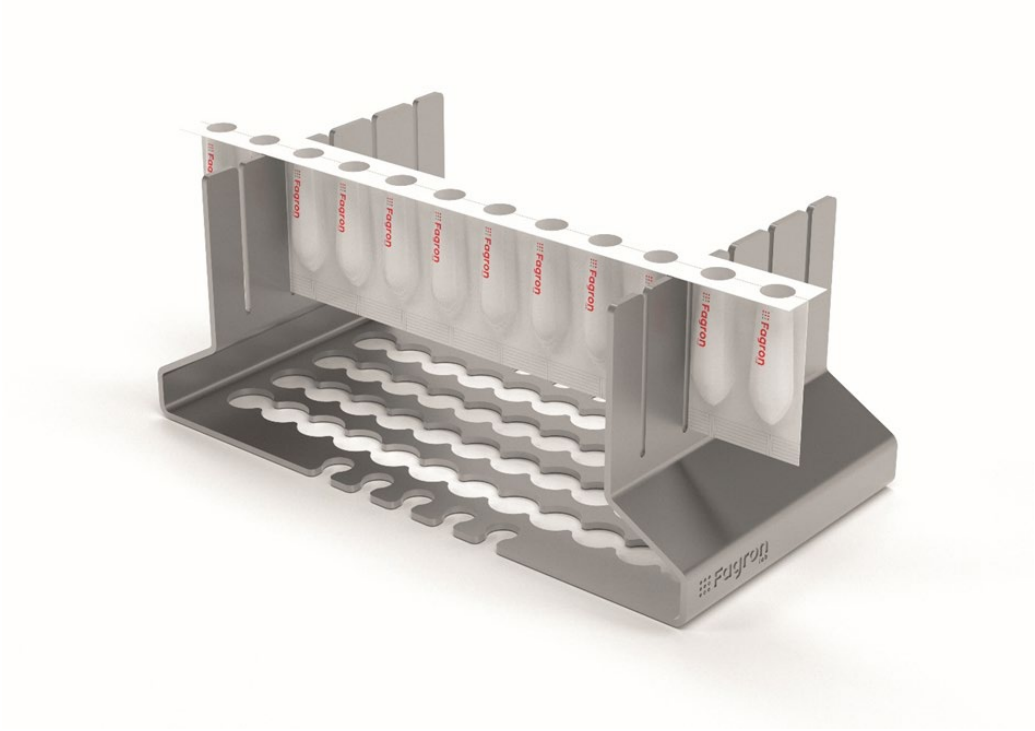
Traditionally, the suppositories are wrapped individually in foil (usually aluminum) as a primary packaging material and then, they are put into a jar as secondary package. However, foil is not an ideal form of packaging for protecting suppositories in accordance with WHO recommendations, as it tears easily. Therefore, there is a need for more convenient solutions for the pharmaceutical packaging of suppositories.

New Pursuits: FagronLab™ Suppository Strips

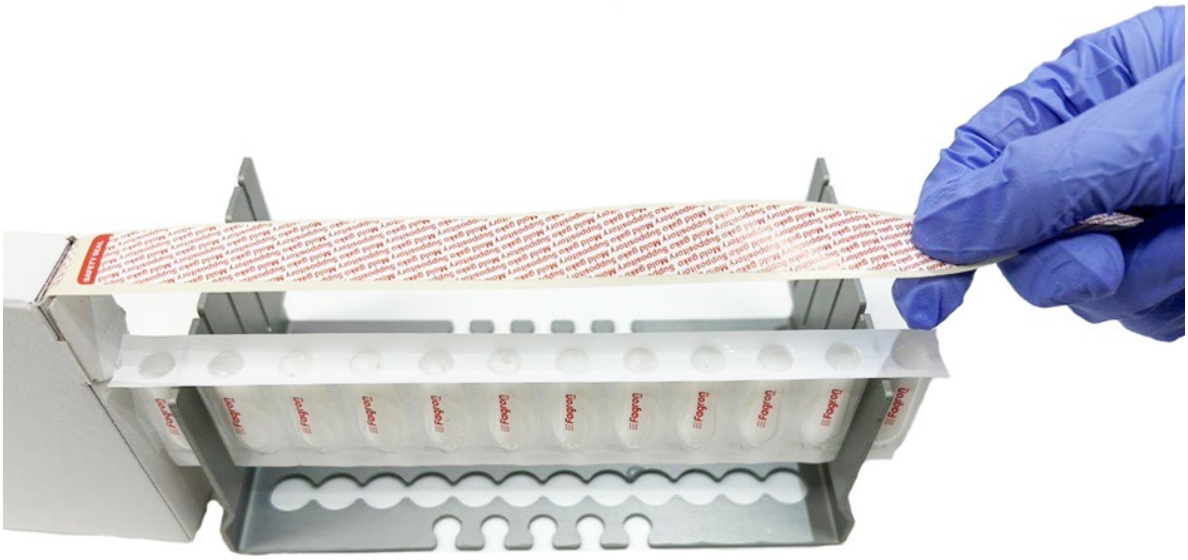
FagronLab™ Suppository Strips are disposable molds that are also used as the final packaging. The suppositories are removed from the mold by the patient peeling the two halves of the mold apart from the bottom. There is no need for the suppositories to be opened and re-packaged after preparation in the pharmacy, thus they are a more hygienic and practical solution, fulfilling the WHO recommendations, to deliver the inserts to the patients.

FagronLab™ Suppository Strips are composed from polyvinyl chloride (PVC) material coated with polyvinylidene chloride (PVDC), reducing the permeability of the film to oxygen, moisture and light, thus offering a stable packaging option for the duration of the compounded beyond use date. They also have high chemical resistance to alkalis, acids and organic solvents and are a safe primary package as specified in the GMP guideline. This feature also eliminates the need of using lubricants during preparation, preventing complication in case of excessive lubricant usage.

The strips are resistant to tearing during transportation, eliminating the risk of contamination caused by packaging material or cross-contamination with the environment. Moreover, they are cost-efficient and valuable tools for the compounding pharmacy, eliminating the need to purchase additional packaging. For more information, reach out to the Fagron Academy team at facts.support@Fagronacademy.us.



Suppository strip tape allows for easy sealing of suppositories and negates the need for heat sealing.



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