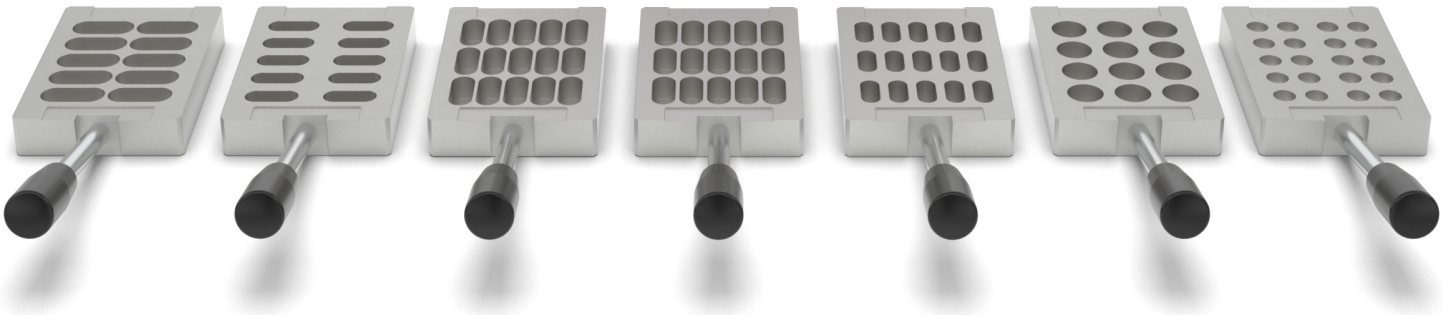

FagronLab™ BLIST-Rx™

Thermo-sealing technology meets with sustainability

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1. Introduction

Blister trays, also known as blister packs, are widely used packaging methods, approximately around 85% in Europe, for oral-solid medications.[1] This popularity is due to the many benefits that blister packs offer in terms of preserving stability and facilitating the administration of pharmaceuticals. These advantages include minimizing exposure to air and humidity, preventing contact between individual doses (Figure 1), aiding in dose tracking, and improving patient adherence to the treatment regimen. Additionally, blister packs meet the tamper-evident requirements recommended by authoritative organizations like the World Health Organization (WHO)[2], the Food and Drug Administration (FDA)[3,4], and the United States Pharmacopeia (USP)[5]. Furthermore, blister trays offer cost-efficient packaging solutions and safety transportation by reducing the risk of breakage, a significant concern associated with traditional glass bottles[1].

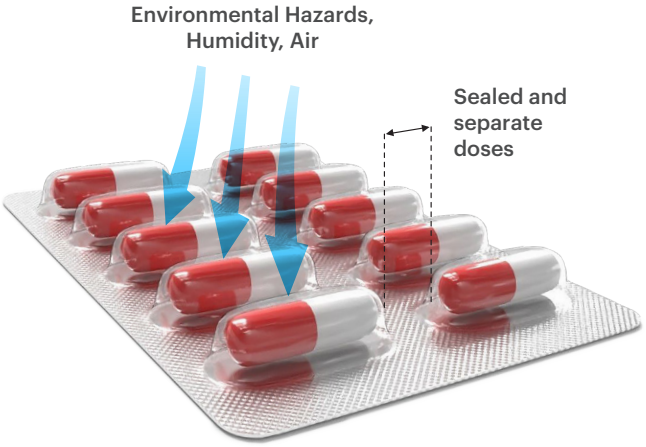


Figure 1. Protection of capsules in a blister tray.

2. FagronLab™ BLIST-Rx™

The **FagronLab™ BLIST-Rx™** is a thermo-sealing device developed for individually packing capsules and tablets in blister trays, protecting the compounding from air, humidity, and contamination until the administration, providing a more convenient dose tracking and application (Figure 2). The device is capable of sealing blister trays composed of various materials, including an aluminum lid with an aluminum or a plastic body.[1]
Our laboratory tests, assessing the application area of the **FagronLab™ BLIST-Rx™**, confirmed that the device can be safely used for packing hard and soft capsules, as well as uncoated, sugar-coated, and film-coated tablets (Figure 3).

Figure 2. FagronLab™ BLIST-Rx™.

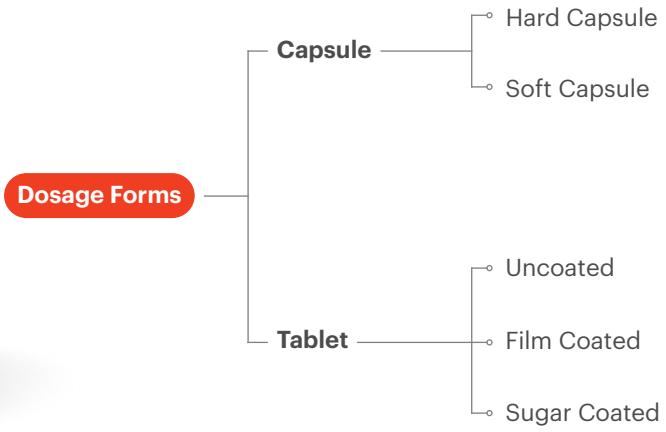


Figure 3. The dosage forms that can be sealed in the blister trays with using FagronLab™ BLIST-Rx™.

Advantages and Properties

- Suitable for sealing wide-range blister trays.
- Automatic temperature stabilizer prevents overheating.
- Suitable with all capsule sizes.
- Convenient tablet sizes: Ø 8 mm and 13 mm.
- Precise time settings between 100 - 25,500 milliseconds (ms.) in 1 ms increments.
- Temperature settings between 100 - 170 °C.
- Up to 15 capsules and 20 tablets sealing.
- Low power consumption (250 W).
- User-friendly and quick operation.
- For substances with decomposition temperature > 120 °C.

2.1. Environmental Perspective

The **FagronLab™ BLIST-Rx™** allows the sealing not only of aluminum but also of polyvinyl chloride (PVC) blister trays, which are found to be generally more environmentally friendly according to analysis evaluated by the Life Cycle Assessment (LCA) methodology.[6]

By enabling the usage of PVC blisters, the **FagronLab™ BLIST-Rx™** reduces energy consumption throughout the lifecycle of the blister tray material by up to 63%, global warming potential by up to 70%, and water depletion by more than 80%.[1]

LCA Methodology

LCA Methodology is a framework or a systematic tool for measuring and evaluating the environmental impact of the products or the process throughout its life. It consists of manufacture of raw materials such as aluminum and PVC, the packaging material, manufacturing process, transportation, and packaging.

3. FagronLab™ BLIST-Rx™ Tray

The **FagronLab™ BLIST-Rx™** tray is a partially pre-welded blister pack designed to be used with the **FagronLab™ BLIST-Rx™**. It is composed of a thermoformed rigid PVC body and a hard-tempered aluminum lid. The thermoformed rigid PVC has a low water-vapor transmission rate, meaning a material that protects the compounding from contamination, moisture, and air. Additionally, individual packing breaks contact between each dosage unit, preventing the spread of reactive radicals generated by oxidation to other dose units (Figures 4 and 5). Thus, it maintains the stability of the compounding during shelf-life. The high chemical resistance and flexural strength[2] make the **FagronLab™ BLIST-Rx™** tray an excellent choice for packaging.

Advantages

- More environmentally friendly and cost-efficient as it contains 84% less aluminum.
- Dose tracking and improved treatment compliance.
- Reduced cross-contamination during storage.
- Low water-vapor permeability.
- Dose separation, providing stability maintenance.
- Easy to carry because of its lightweight (0.3 g).
- Tamper evidence.
- Optional personalization by printing.
- Compliance with current Good Manufacturer Practices (cGMP)[7], European Pharmacopoeia (Ph. Eur.)[8,9], USP[10], Japanese Pharmacopoeia (JP)[11], and FDA[12] quality standards.

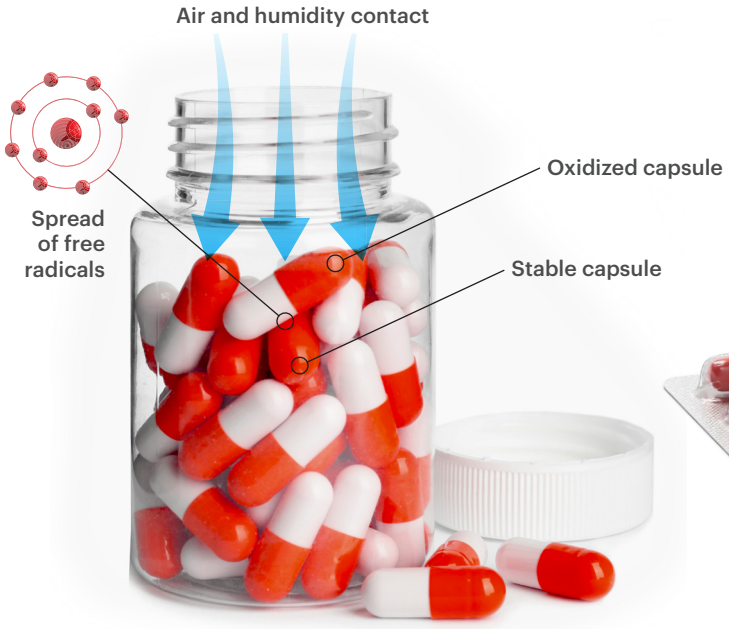


Figure 3. Spread of free radicals.

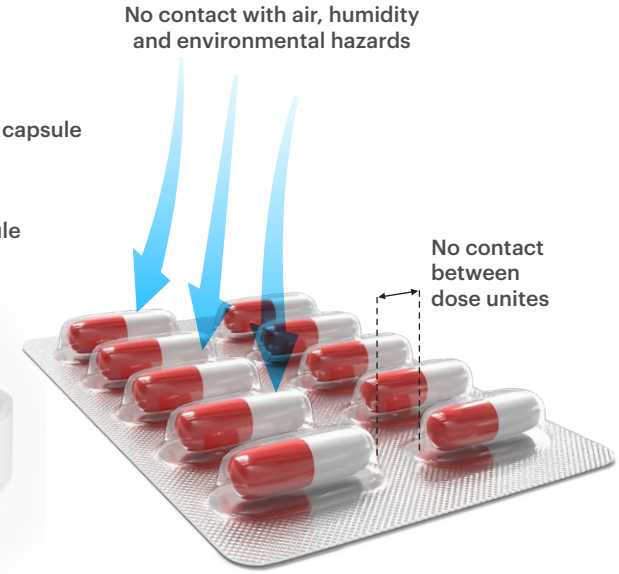


Figure 4. Unit doses separation.

3.1. Tamper Evidence

Besides being environmentally friendly, the **FagronLab™ BLIST-Rx™** tray fulfills the WHO[2]-suggested and FDA[4]-regulated requirements for evidence of tampering, including altering, pilfering, and falsifying the pharmaceutical product, to prevent tragic accidents such as having overdose drugs and malicious tampering by sealing in such a manner that the contents cannot be used without destroying the lid.

3.2. Patient Compliance

The changes in the dose regimen or concentration lead to potential confusion for patients, resulting in variations in the dosage intake. Comparative analyses between blister trays and bottles have demonstrated the advantages of blister packaging in enhancing compliance with various treatments.[13-16] The **FagronLab™ BLIST-Rx™ tray** optimizes patient compliance with personalized treatments by simplifying visual dose tracking.

Figure 5. FagronLab™ BLIST-Rx™ trays.

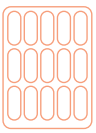
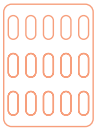
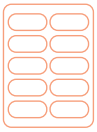
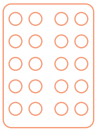
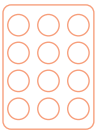
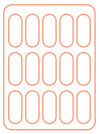
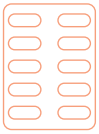
4. FagronLab™ BLIST-Rx™ Holder

The **FagronLab™ BLIST-Rx™ holder** is a tool made from stainless steel that holds a blister tray with the dosage forms to be sealed inside it. Thanks to its durable structure, it is resistant to high temperatures and can be washed in the dishwasher.

Advantages

- Durable structure to scratches.
- Resistant to high temperatures.
- High thermal conductivity, providing quick heat up and cool down.
- Suitable to be cleaned in the dishwasher.
- Available in 7 types designed to accommodate tablets and capsules.

There are seven types of FagronLab™ BLIST-Rx™ holders suitable with tablets (Ø 8-13 mm) and capsules (000-4).

Model		Capacity	Suitable tray	
FagronLab™ BLIST-Rx™ holder 15 00-0 A		15 Capsules	FagronLab™ BLIST-Rx™ tray 15 00-0 A Size: 00-0	
FagronLab™ BLIST-Rx™ holder 15 3-4 B		15 Capsules	FagronLab™ BLIST-Rx™ tray 15 3-4 B Size: 3-4	
FagronLab™ BLIST-Rx™ holder 10 000-00 C		10 Capsules	FagronLab™ BLIST-Rx™ tray 10 000-00 C Size: 000-00	
FagronLab™ BLIST-Rx™ holder 20 Ø8 D		20 Tablets	FagronLab™ BLIST-Rx™ tray 20 Ø8 D Size: Ø8 mm	
FagronLab™ BLIST-Rx™ holder 12 Ø13 E		12 Tablets	FagronLab™ BLIST-Rx™ tray 12 Ø13 E Size: Ø13 mm	
FagronLab™ BLIST-Rx™ holder 15 0-1-2 F		15 Capsules	FagronLab™ BLIST-Rx™ tray 15 0-1-2 F Size: 0-1-2	
FagronLab™ BLIST-Rx™ holder 10 0-1-2-3-4 G		10 Capsules	FagronLab™ BLIST-Rx™ tray 10 0-1-2-3-4 G Size: 0-1-2-3-4	

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Fagron BV
Fascinatio Boulevard 350
3065 WB Rotterdam
The Netherlands

P +49 89 1222 387 200
F +49 89 1222 387 201
www.fagronlab.com

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