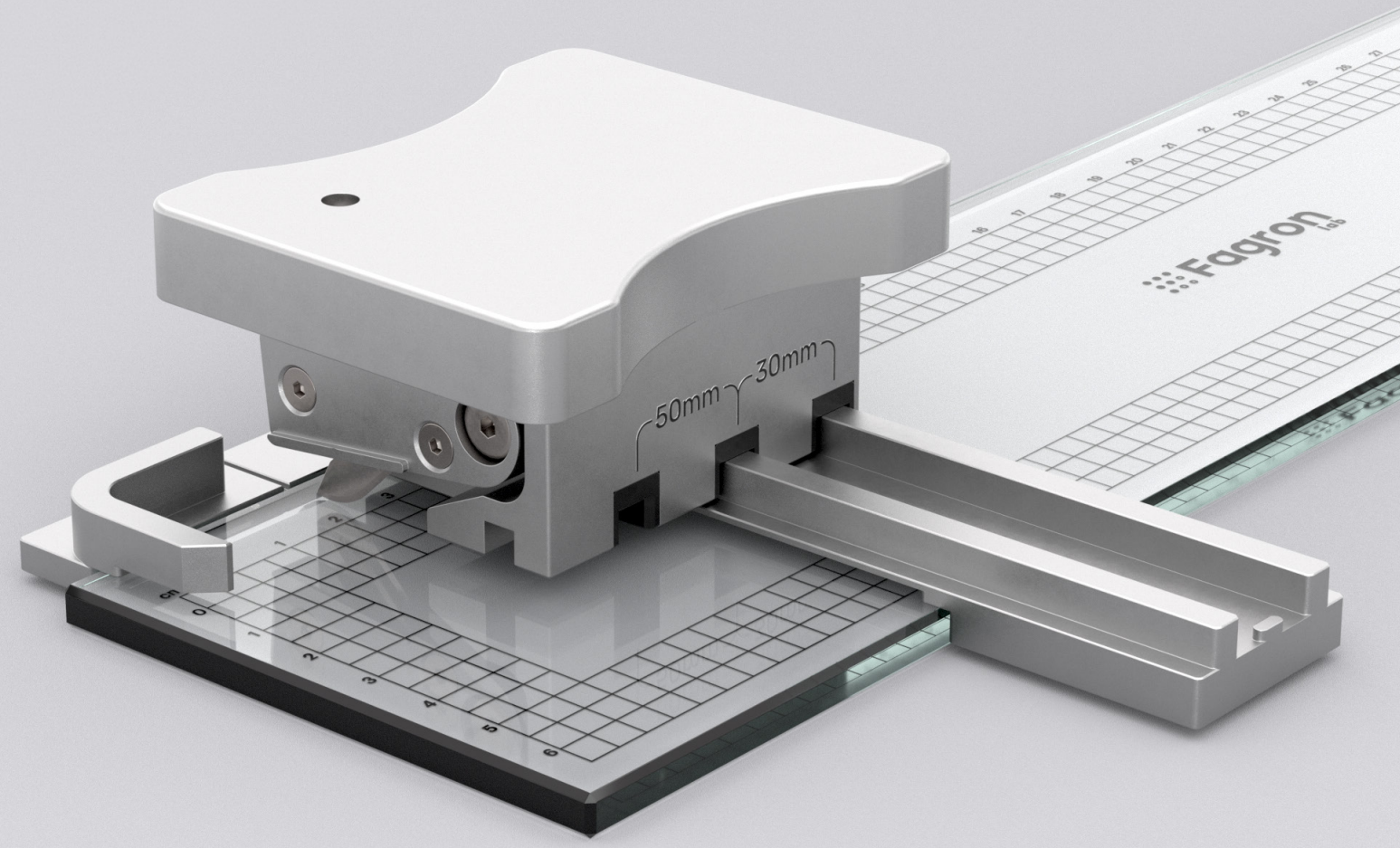

FagronLab™ FILM-Rx

Original User Manual

www.fagronlab.com

Fagron lab

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1. Performance and Main Features

Pharmaceutical films are among the most elegant and advanced drug delivery systems available to compounding pharmacies today. Small, flexible, and highly customizable, they can transform complex therapies into precise, convenient, and patient-centric treatments. This pharmaceutical form can be presented as oral preparations (orodispersible, buccal, or sublingual), and, more recently, as vaginal preparations (mucoadhesive) (Figure 1).[1–3]

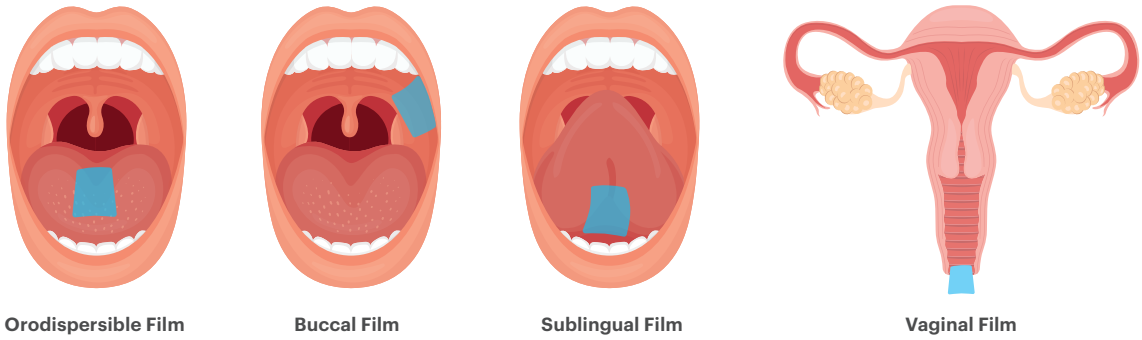
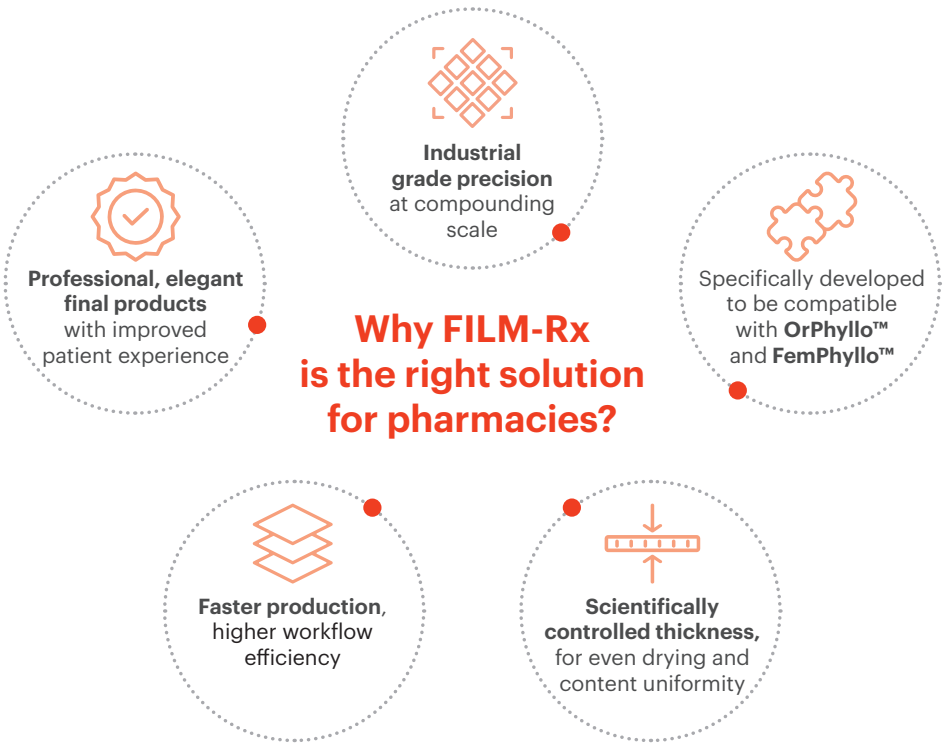


Figure 1. Types of pharmaceutical films.

Although pharmaceutical films differ in their therapeutic application, their manufacturing process remains the same. Film compounding requires a controlled sequence: preparing a homogeneous formulation, casting it to uniform thickness, drying it under controlled conditions, and cutting it into reproducible units. Historically, this made film production more common in industrial environments than in routine pharmacy practice.[1,2,4]

Led by innovation, Fagron bridges this gap by bringing this technology closer to compounding pharmacies through a practical, standardized workflow that combines validated film bases with specialized tools to streamline their production. The result is a more accessible and reproducible way to prepare pharmaceutical films in the pharmacy setting.

This User Manual provides clear, step-by-step guidance to ensure proper use of the FILM-Rx tools, consistent film preparation, and reliable results in every batch.



2. Applications

The **FagronLab™ FILM-Rx** (Figure 2) is a kit that offers a comprehensive solution for standardizing the entire compounding process of pharmaceutical films, delivering high-quality formulations through seamless operation with consistent results. The FILM-Rx kit integrates four purpose-built tools designed to address all critical quality attributes of film manufacturing with simplicity and reproducibility, each one with a specific role in ensuring batch-to-batch consistency.

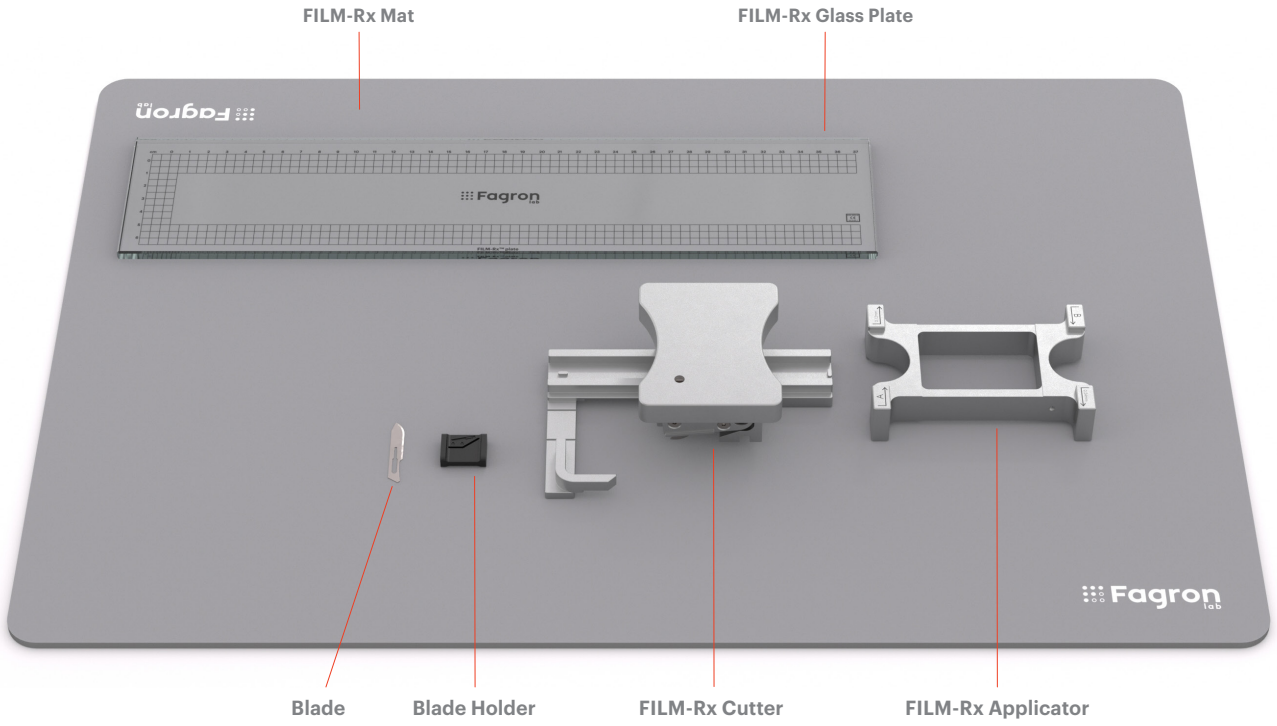


Figure 2. The FagronLab™ FILM-Rx kit.

2.1 FILM-Rx Applicator

The **FILM-Rx Applicator** (Figure 3) enables smooth, reproducible film casting by delivering a consistent wet film layer with four calibrated thickness edges (0.24 – 1.00 mm). Manufactured from an aluminum-magnesium alloy, it combines structural stability with high chemical resistance while reducing vibration and irregular shearing, improving dose accuracy. Its compact, ergonomic design ensures easy handling, while integrated guides support consistent sizing and uniform film dimensions. By minimizing process variability, the applicator contributes to greater batch uniformity and higher final product quality. It is also durable, easy to clean, and cost-effective for routine compounding use.

- Consistent thickness for reliable dosing
- Smooth, controlled casting performance
- Robust and chemical-resistant material
- Compact, ergonomic design for easy handling
- Improves standardization and batch uniformity
- Easy to clean and ideal for routine use

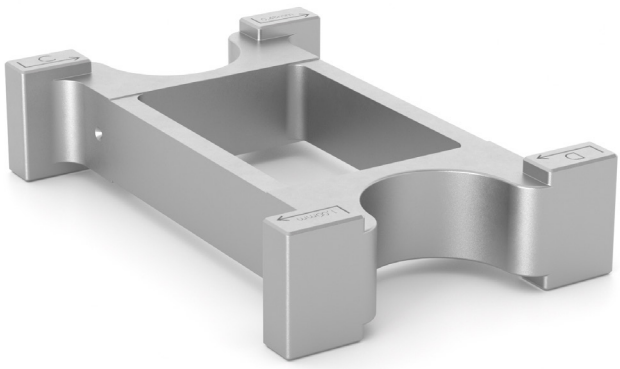


Figure 3. FagronLab™ FILM-Rx Applicator.

2.2 FILM-Rx Glass Plate

The **FILM-Rx Glass Plate** (Figure 4) provides a clean, stable, and chemically resistant surface for casting and drying pharmaceutical films. Manufactured from tempered safety glass, it combines durability, scratch resistance, and enhanced safety with reliable thermal performance. Its smooth surface allows easy removal of dried films, while engraved graduations support accurate measurement and standardized dimensions. Resistant to chemicals, and capable of withstanding temperatures up to 300 °C, the plate promotes even drying and helps reduce brittleness or edge curling, contributing to a more precise and controlled compounding process.

- Flat, stable surface for precise film preparation
- Tempered safety glass for durability and reliability
- Chemically resistant and non-reactive material
- Engraved markings for standardized sizing
- Promotes controlled drying and reproducible results
- Easy to clean and ideal for routine use

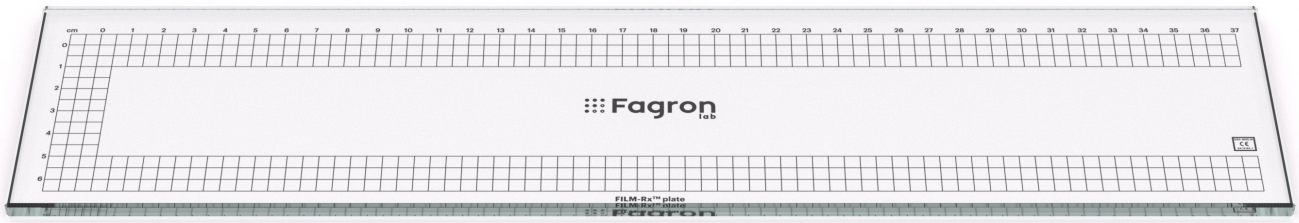


Figure 4. FagronLab™ FILM-Rx Glass Plate.

2.3 FILM-Rx Cutter

The **FILM-Rx Cutter** (Figure 5) enables fast, precise, and reproducible cutting of dried films directly on the glass plate. Designed for safe, effortless handling, its compact, ergonomic format and predefined guides ensure stable alignment and consistent film dimensions. Clear markings match the engraved measurements on the glass plate, allowing standardized sizing with pharmaceutical-grade precision. Moisture- and chemical-resistant, with low-maintenance, the cutter supports clean, accurate, and repeatable film preparation, helping translate uniform film thickness into precise unit dosing.

- Fast, precise, and reproducible cutting
- Guided alignment for consistent sizing
- Compact, ergonomic design for safe handling
- Supports dose uniformity and standardization
- Durable, moisture-resistant construction
- Easy to clean and ideal for routine use

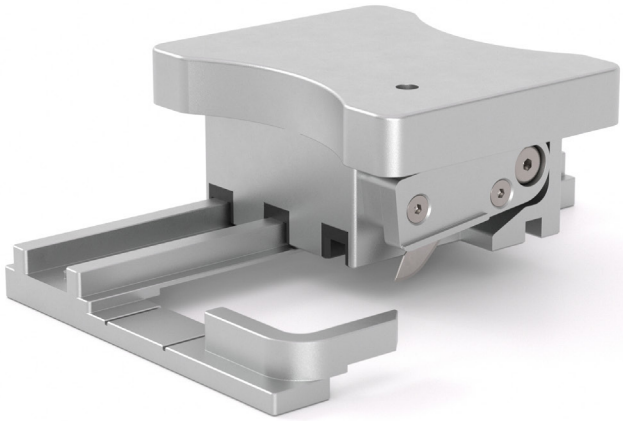


Figure 5. FagronLab™ FILM-Rx Cutter.

2.4 FILM-Rx Mat

The **FILM-Rx Mat** (Figure 6) is a foldable, anti-slip support surface that keeps the glass plate firmly in place throughout the compounding process. By reducing slipping and micro-vibrations, it supports more uniform spreading and greater precision during film casting and cutting. Resistant to moisture and chemicals, the mat also protects the plate and workbench, contributing to a cleaner, safer, and more controlled workflow. Easy to clean and low maintenance, it is a practical support tool for routine film preparation.

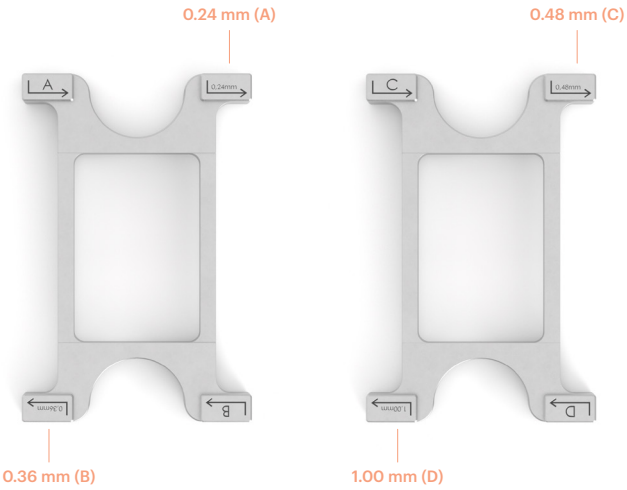
- Anti-slip support for better process stability
- Helps improve precision during casting and cutting
- Protects the glass plate and workspace
- Durable silicone with chemical resistance
- Easy to clean and reuse
- Flexible, lightweight, and easy to store

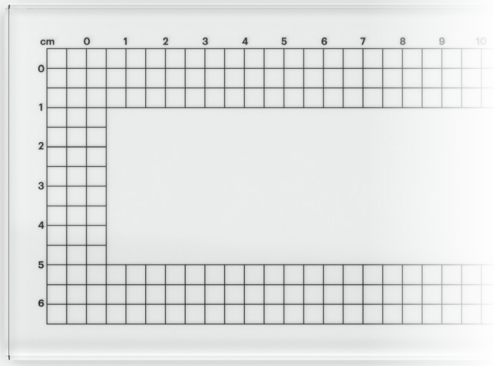
Figure 6. FagronLab™ FILM-Rx Mat.

3. Technical Information

3.1 FILM-Rx Applicator

Material	Aluminum–magnesium alloy (N-AW-6061 (AlMg1SiCu)
Dimensions (L x W x H)	110 × 72 × 24 mm
Weight (g)	128.95 g
Thickness options	0.24 mm (Side A) / 0.36 mm (Side B) 0.48 mm (Side C) / 1.00 mm (Side D)



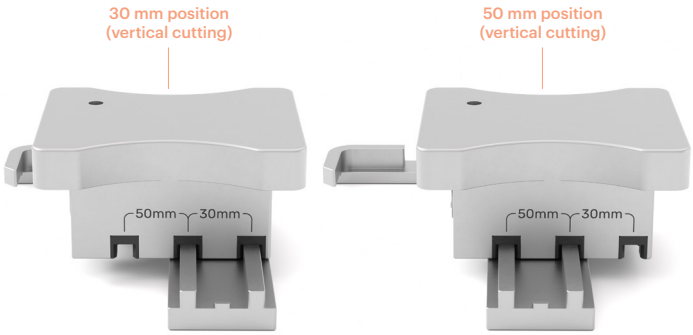


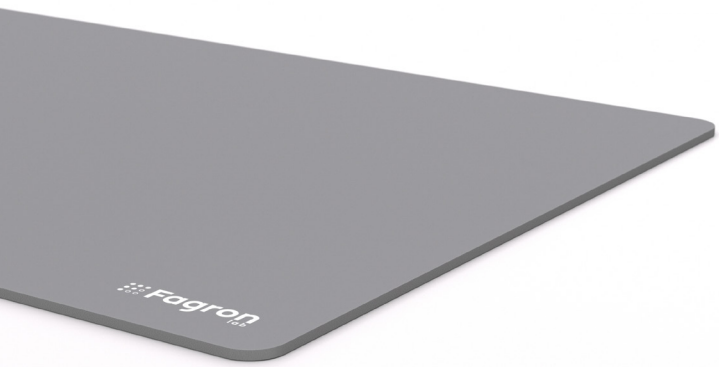
3.2 FILM-Rx Glass Plate

Material	Tempered soda-lime silicate glass
Dimensions (L x W x H)	400 × 90 × 6 mm
Weight (g)	536 g
Maximum casting length	320 mm
Temperature resistance	Up to 300 °C
Surface features	Engraved metric ruler; smooth, low-adhesion surface

3.3 FILM-Rx Cutter

Material	Aluminum–magnesium alloy (EN-AW-6061 (AlMg1SiCu)
Cutting tool dimensions (L × W × H)	90 × 70 × 40 mm
Slider dimensions (L × W × H)	100 × 144 × 13 mm
Weight (g)	465 g
Compatible blade	Surgical blade No. 10
Cutting modes	Horizontal and vertical (30 mm / 50 mm guide positions)





3.4 FILM-Rx Mat

Material	Silicone – FDA compliant (21 CFR 177.2600)
Dimensions (L x W x H)	600 × 400 × 1 mm
Weight (g)	320 g
Properties	Nonslip surface, flexible, vibration dampening

4. How to Use

The compounding process of pharmaceutical films involves several precise steps to ensure consistency and quality. The **FagronLab™ FILM-Rx** delivers a superior film compounding experience by providing a controlled casting process that ensures perfectly smooth, uniform, and consistently reproducible films in 4 simple steps (Figure 7).

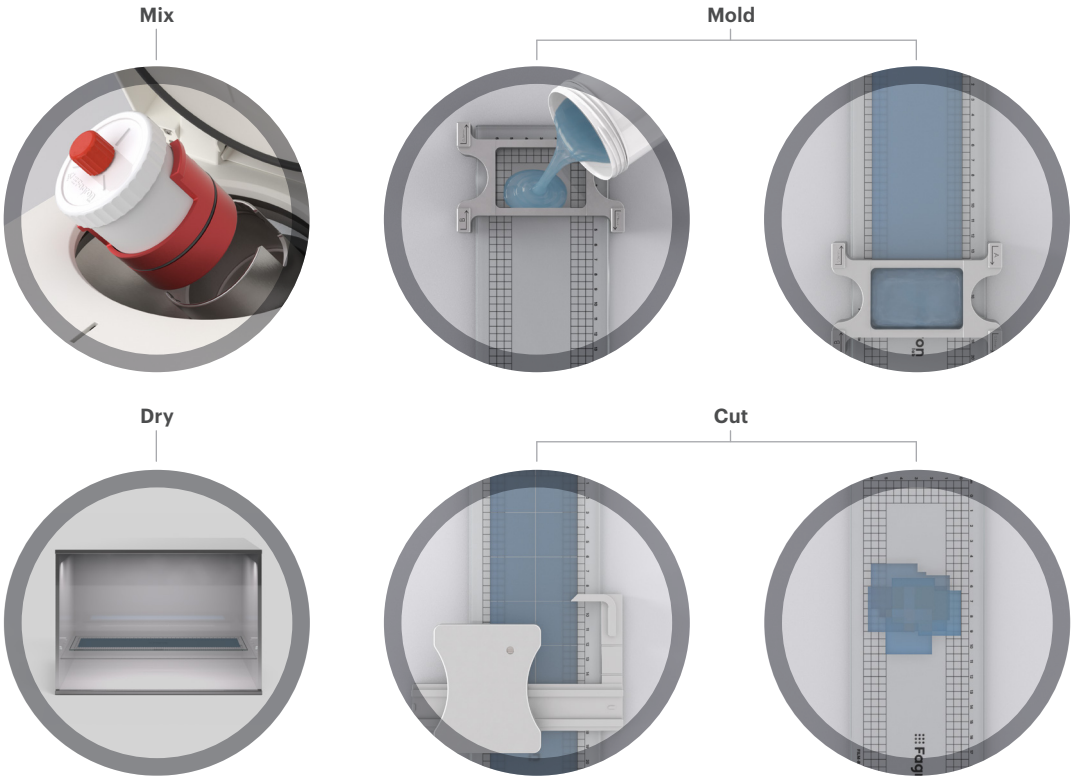


Figure 7. 4-step compounding procedure of pharmaceutical films.

4.1 Mix

1.
Weigh all active pharmaceutical ingredients (APIs), the film base and excipients. A **10% excess** is recommended to compensate for losses during molding and cutting. Micronize the powders in a mortar and pestle and premix with the base.

2.
Add the mixture into a FagronLab™ PM jar.

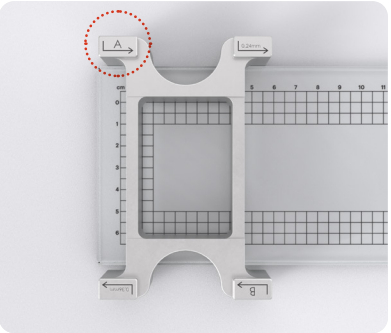
3.
Insert the FagronLab™ PM jar into the FagronLab™ PM jar holder.

4.
Place them to the FagronLab™ PM140, and process the formulation for **30 seconds** for final mixing and deaeration.

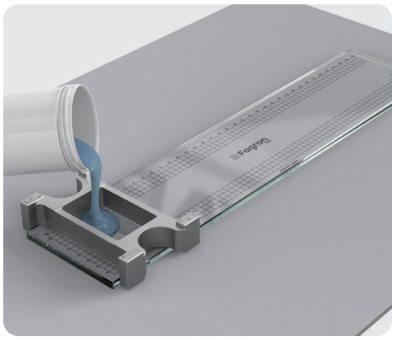
4.2 Mold

1.
Lay the FILM-Rx Mat on your workbench area.

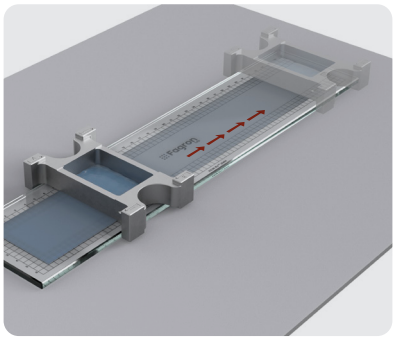
2.
Place the FILM-Rx Glass Plate on the FILM-Rx Mat.



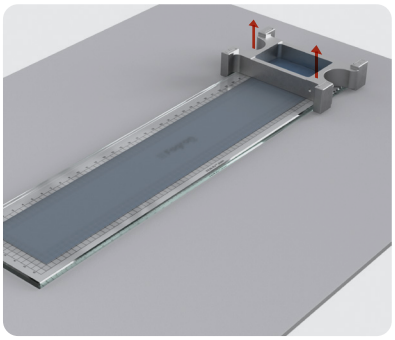
3.
Place the FILM-Rx Applicator onto the FILM-Rx Glass Plate, aligning it from above and from the left. Ensure that the desired thickness of the FILM-Rx Applicator is facing upwards.



4.
Pour the film mixture into the FILM-Rx Applicator, adding only the amount needed for the batch you want to prepare. For example, to produce around **20 films**, dispense approximately **10-12 g** of the formulation (adjusting as needed according to your final film thickness).



5.
With a steady hand, gently slide the FILM-Rx Applicator across the FILM-Rx Glass Plate, until there is no base left in the FILM-Rx Applicator. Do not stop or reverse the movement.



6.
Remove the FILM-Rx Applicator from the FILM-Rx Glass Plate, taking care not to damage the film layer

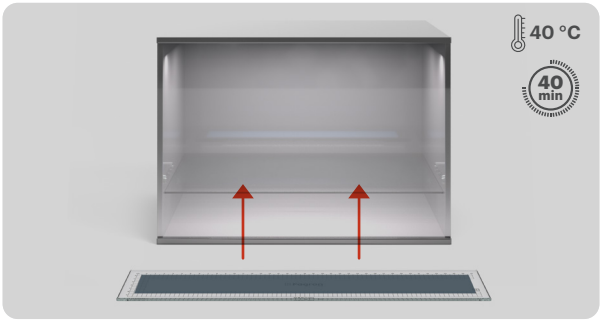
Observe the ergonomic requirements for setting up workplaces to enable fatigue-free use of the equipment.

The FILM-Rx kit is intended for indoor use only

Improper placing the device on inclined or unstable surfaces can lead to injury due to cuts and/or crushing.

Always use the FILM-Rx Mat as a base to avoid injuries caused by the device slipping during handling.

4.3 Dry

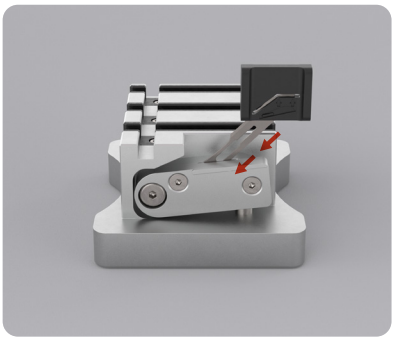


1.
Place the FILM-Rx Glass Plate with the compounded mixture inside a positive pressure laminar flow cabinet or in a ventilated drying cabinet. The films can be dried either overnight in the laminar flow cabinet or at **40 °C** for about **40 minutes** in the drying cabinet.

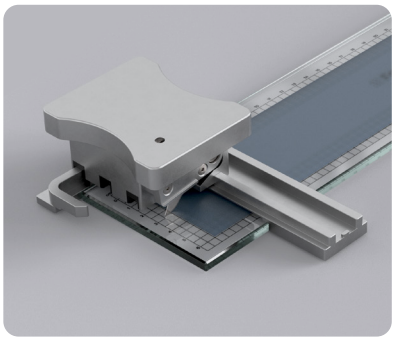
2.
Allow the films to dry completely before removing them from the cabinet. When the film is clearly dry, proceed to cutting.

4.4 Cut

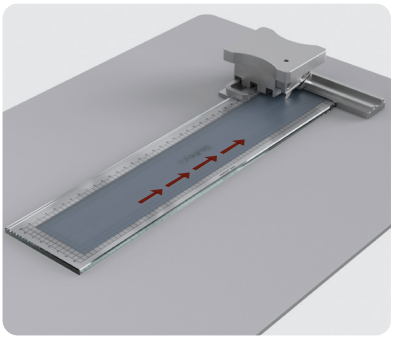
1.
Place the FILM-Rx Glass Plate with the dry film over the FILM-Rx Mat.



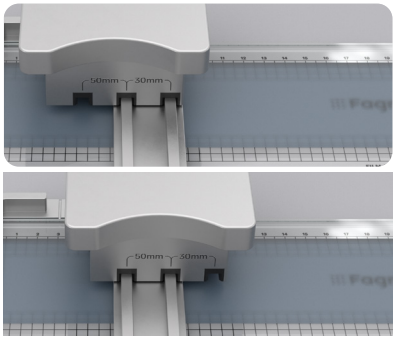
2.
Prepare the FILM-Rx Cutter by inserting the blade using the Blade Holder.



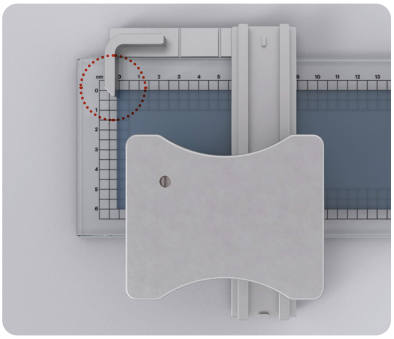
3.
For horizontal cutting, place the FILM-Rx Cutter in the horizontal cutting position, as shown above.



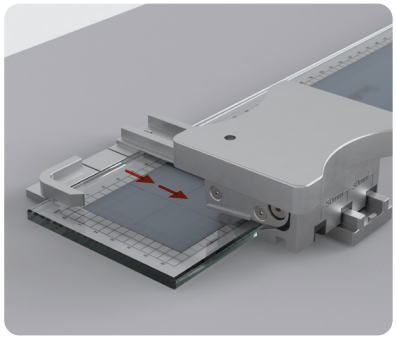
4.
Once placed, move it across the FILM-Rx Glass Plate with the slider.



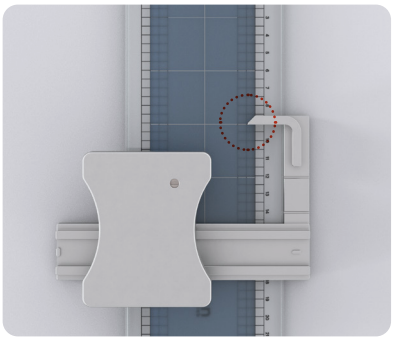
5.
For vertical cutting, place the FILM-Rx Cutter in the **30 mm** or **50 mm** vertical cutting position.



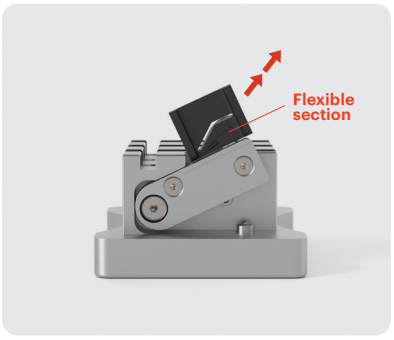
5.
When in the vertical cutting position, always set the slider indicator to "**0**".



6.
Slide the FILM-Rx Cutter vertically to perform the cut.



7.
Repeat as required to obtain target film dimensions using the indicator on the slider for an accurate and consistent result.



8.
For safety reasons, remove the blade after use by applying pressure to the flexible section of the Blade Holder and pulling the blade up as shown above.

Please give all components a visible inspection upon every usage. If there are any visible damages to any of the components don't put them to use and replace them.

Use only spare parts and accessories that have been supplied by the original manufacturer or approved for use by them.

4.5 Packaging

After cutting, the films should be packaged individually to prevent moisture uptake and deformation. FagronLab™ Sachets offer ideal barrier protection and professional presentation.

Unit-Dose Packaging

Non-reclosable, tight sachets tailored for single administration. Ensure optimal protection and stability for each film, facilitating precise dosing and patient compliance. To prevent the film from sticking to the packaging, a parchment paper sheet should be used to wrap the film (Figure 8).

Multi-Dose Packaging

Reclosable, tight sachets, designed for multiple doses. Provide convenient and secure storage, maintaining the efficacy and quality of films over time (Figure 9).

Figure 8. FagronLab™ Sachets and parchment paper for unit-dose packaging.

Figure 9. FagronLab™ Sachets and parchment paper for multi-dose packaging.

5. Troubleshooting

Even with a standardized workflow, variations in handling or environmental conditions may affect film quality. The following guide helps identify common issues, their likely causes, and the recommended corrective actions.

1. Uneven film thickness

How it appears	Possible causes	Corrective actions
• Some areas of the film are thicker or thinner than others; • Visible streaks or lines appear after casting.	• The FILM-Rx Applicator was stopped during spreading; • Pressure or angle was inconsistent during casting; • The FILM-Rx Glass Plate was not fully stable on the FILM-Rx Mat.	• Cast the mixture in one continuous, uninterrupted motion; • Ensure the FILM-Rx Mat is correctly positioned under the FILM-Rx Glass Plate; • Confirm that the selected FILM-Rx Applicator thickness side is correctly oriented.

2. Bubbles or pinholes in the film

How it appears	Possible causes	Corrective actions
• Small air pockets are trapped in the dried film; • Tiny holes are visible when the film is held against the light.	• Air was incorporated during mixing; • The mixture was spread too quickly; • Drying took place under excessive heat or turbulent airflow.	• Mix gently to avoid incorporating air; • Use FagronLab™ PM140 to process the formulation and remove entrapped air; • Spread the preparation steadily, without abrupt movements; • Dry under laminar flow or in a ventilated cabinet at a maximum of 40 °C; • Avoid direct drafts or airflow onto the Glass Plate.

3. Film does not release cleanly from the Glass Plate

How it appears	Possible causes	Corrective actions
• The film sticks to the FILM-Rx Glass Plate; • The film tears during removal; • Residue remains on the plate surface.	• The film is not fully dry or is excessively dry; • Excessive force was used during removal; • The FILM-Rx Glass Plate surface is scratched or damaged; • The FILM-Rx Glass Plate was not completely clean.	• If not fully dry, allow additional drying time before removal; • If overdried, gently spray anhydrous/absolute ethanol over the film; • Peel the film carefully from one corner using minimal force; • Inspect the FILM-Rx Glass Plate and replace it if scratches are present; • Ensure the plate is clean and completely dry before each batch.

4. Curling or warping of film edges

How it appears	Possible causes	Corrective actions
• Film edges lift after drying; • Corners curl or twist	• Drying occurred too quickly; • Airflow was uneven during drying; • The film layer was too thin for the formulation.	• Use the recommended drying conditions: in a laminar flow or at 40 °C in a drying cabinet; • Avoid direct drafts and maintain constant airflow; • If suitable for the formulation, use a thicker Applicator side setting.

5. Film cracking or breaking

How it appears	Possible causes	Corrective actions
• The film fractures during cutting; • The film splits during removal from the plate; • The texture is brittle.	• The formulation was insufficiently hydrated; • The film was overdried; • The film was stored in an excessively dry environment.	• Verify the correct mixture consistency during preparation; • Reduce drying time slightly if overdrying is suspected; • Place the films in protective sachets immediately after cutting.

6. Irregular cutting or uneven doses

How it appears	Possible causes	Corrective actions
• Film units are not the same size; • Cuts are jagged or slanted; • Thickness varies at the cut edges.	• The FILM-Rx Cutter was not aligned with the engraved markings on the FILM-Rx Glass Plate; • The blade is dull or incorrectly installed; • The FILM-Rx Glass Plate was not fully stabilized on the FILM-Rx Mat.	• Align the FILM-Rx Cutter with the measurement marks before each cut; • Replace the blade regularly and always use blade No. 10; • Confirm that the FILM-Rx Mat is correctly positioned and the plate is stable.

7. Film too soft or sticky after drying

How it appears	Possible causes	Corrective actions
• The film sticks to the fingers during handling; • The texture remains soft, wet, or overly flexible.	• Drying was incomplete; • Environmental humidity was too high; • The casting layer was too thick.	• Extend the drying time; • During periods of high humidity, use a ventilated drying cabinet at 40 °C; • If compatible with the formulation, use a thinner FILM-Rx Applicator side setting.

8. Film margins are uneven or with a different thickness

How it appears	Possible causes	Corrective actions
• The film margins present irregularities after casting; • The margins appear to be thinner or thicker than the rest of the film.	• The FILM-Rx Applicator calibrated thickness might be damaged; • Residues may have accumulated in the calibrated corners.	• Check for damages in the FILM-Rx Applicator and, if necessary, replace the equipment; • Make sure the device is stored clean and free from residues and humidity.

9. Film is not cut or cut with gaps

How it appears	Possible causes	Corrective actions
• The film is not fully cut after processing • Cuts appear incomplete or discontinuous • Visible gaps where the film should be cleanly separated	• The blade height is set too high and does not properly contact the glass • The blade may be worn or damaged	• Adjust the blade height following the blade adjustment procedure • Ensure the blade makes proper contact with the glass surface • Replace the blade if it is worn or damaged

6. Cleaning and Maintenance

6.1 Cleaning

Proper cleaning and routine inspection are essential to ensure accurate film preparation, preserve batch quality, and extend the lifespan of the FILM-Rx components. Although the system does not require technical maintenance, all parts should be cleaned immediately after use, before residues dry. In general, use a mild detergent and warm water; avoid harsh chemicals, abrasive pads, metal brushes, or acidic cleaning agents; and always dry each component thoroughly before storage to prevent marks, moisture damage, or material degradation. All tools should also be inspected regularly for residue buildup, scratches, cracks, or blade wear.

FILM-Rx Applicator

The **FILM-Rx Applicator** should be hand-washed with mild detergent and lukewarm water, then wiped with a soft, non-abrasive cloth, paying special attention to keeping all four thickness edges completely clean. It should not be placed in a dishwasher, as dishwasher chemicals may react with the aluminum-magnesium alloy, causing discoloration or damage over time.

FILM-Rx Glass Plate

The **FILM-Rx Glass Plate** should also be cleaned with mild detergent and lukewarm water, and any film residue removed gently with a soft plastic scraper, if needed. It should be dried completely before reuse. Abrasive pads, metal tools, and dishwasher cleaning should be avoided, as scratches may affect film release, create unwanted surface texture, and compromise dosage uniformity.

FILM-Rx Cutter

The **FILM-Rx Cutter** should be cleaned carefully in two parts: the housing and the removable blade. The housing can be wiped with a damp cloth and mild detergent, then dried completely before storage. The blade must be removed using the Blade Holder for safe handling, cleaned gently with a soft cloth and mild detergent or suitable cleaning solution, and fully dried before reinsertion. The blade should always be kept clean, dry, and free of residue, and replaced immediately if it becomes bent, dull, or oxidized.

There is a risk of cuts, always use the provided Blade Holder when inserting or removing the blade for cleaning or while handling the FILM-Rx Cutter.

FILM-Rx Mat

The **FILM-Rx Mat** should be washed with warm water and mild detergent, then air-dried after excess water is removed. To preserve its performance, it should be stored flat or loosely rolled without folds, kept away from sharp objects, and not exposed to direct sunlight for prolonged periods. Regular cleaning helps maintain its non-slip stability during casting and cutting.

6.2 Maintenance

Visually inspect the equipment for visible damages before every use. Do not put equipment with visible damages to use as it may compromise the integrity of the final product or cause injury of the user.

Inspect the glass plate for cracks and scratches before every use as they may compromise the integrity of the final product.

Before every use check if all the equipment components are free of contaminants, particles and in a clean and sanitary condition. If there are any deviations, refer to the cleaning instructions given in this manual.

Before every use make sure the cutting blade is clean, free of contaminants and particles as well as corrosion. Replace the cutting blade, if the blades' cutting edge is bent, worn out or shows other deviations.

The **FILM-Rx Cutter** is equipped with polymer inserts designed to facilitate a smooth cutting action. These inserts are subject to operational wear.

- **Regular Inspection**: The user must check the integrity of the polymer inserts at regular intervals.
- **User-Replaceable Parts**: If inserts are damaged or worn out, they must be replaced by the user to maintain equipment performance.

There is a risk of cuts, it is recommended to remove the cutting blade using the provided Blade Holder, when servicing any of the equipment

Replacement of the polymer inserts

To replace the polymer inserts put the cutter assembly on a flat and firm surface with the inserts facing upwards (Figure 10).

Make sure your work area is clean and free of any dust or other abrasive particles to avoid scratches to the surface of the equipment.

Loosen the screws using a 1.5 mm Allen key. Check the insert holder for any dirt or particles and remove them if necessary. Install the new sliding insert in the holder using the previously removed screws. The tightening torque for the screws is **25 Ncm**. Use only spare parts and accessories that have been supplied by the original manufacturer or approved for use by them.

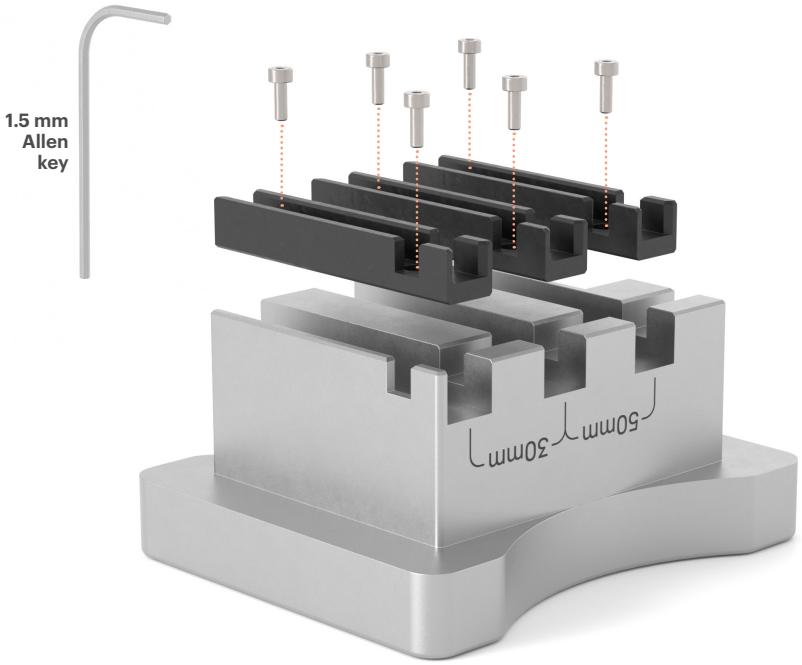
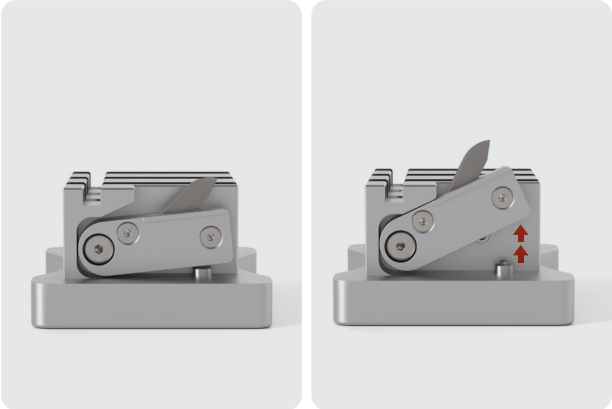


Figure 10. Replacing the polymer inserts of the FILM-Rx Cutter.

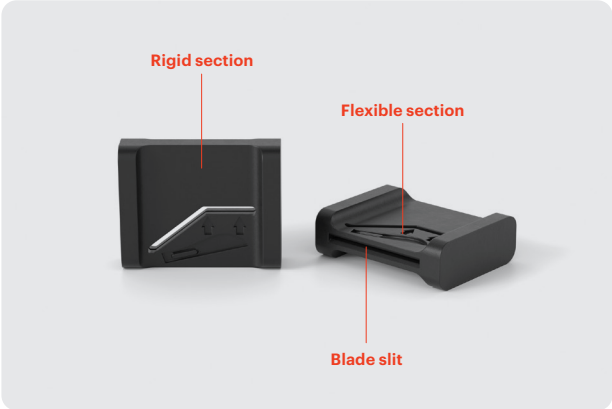
Blade removal procedure

The cutting blade installed in the **FILM-Rx Cutter** is a wear part essential for cutting precision and operational safety. A dull or damaged blade may result in uneven cutting edges and or require excessive force during use.

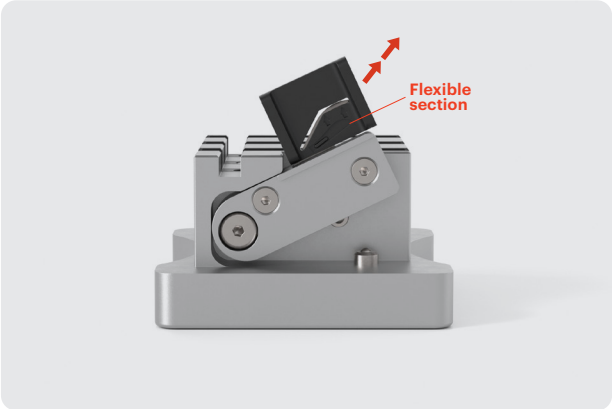


1. Positioning
Place the FILM-Rx Cutter on a flat and firm surface with the sliding inserts facing upwards, tilt the blade housing upwards until you reach the end position.

2. Attach Blade Holder
Gently slide the Blade Holder on the blade. The Blade Holder is correctly seated when the cutting edge is visible through the small slit opening.



3. Release Mechanism
The Blade Holder is designed with specific mechanical zones.
- The upper section is rigid for stability
- The slit section covering the blade is flexible



4. Removal
Apply pressure by pinching the flexible section of the Blade Holder between your thumb and index finger. While maintaining this grip, pull the blade up.

There is a risk of cuts when handling the cutting blade.

Dispose of blades exclusively in puncture-resistant, leak-proof sharps containers.

Ensure pressure is applied only to the flexible zone above the slit. Applying pressure to the rigid bottom section will not secure the blade for removal.

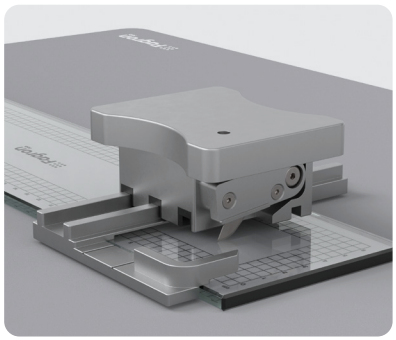
Never perform this procedure "freehand" or in mid-air. Placing the assembly on a stable, flat surface is mandatory to prevent slipping and potential injury.

If the Blade Holder is lost or damaged, a replacement can be ordered.

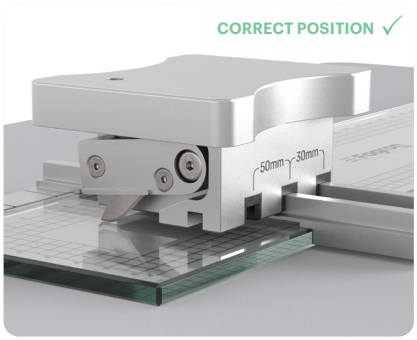
If the original Blade Holder is unavailable, the use of a suitable tool to safely grip the blade is permitted, provided that all occupational health and safety regulations are followed. The tool must prevent any direct hand contact with the cutting edge.

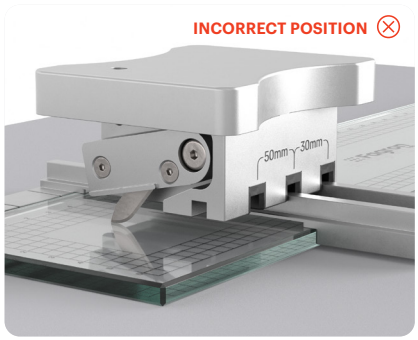
Adjusting the Blade Height

Adjustment of the blade height may be necessary for the first use or after replacing the blade or if a decline in cutting performance is observed. Follow these steps for calibration.

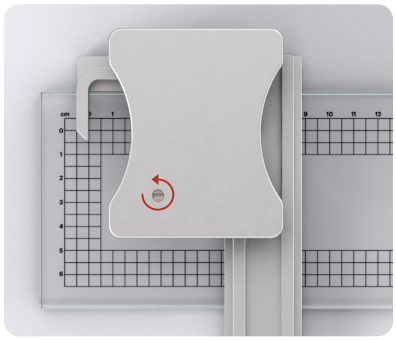


1. Preparation
Place the FILM-Rx Cutter assembly on top of the FILM-Rx Glass Plate.

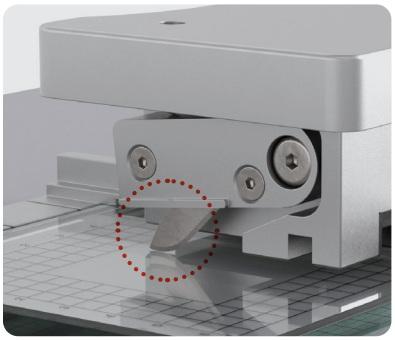




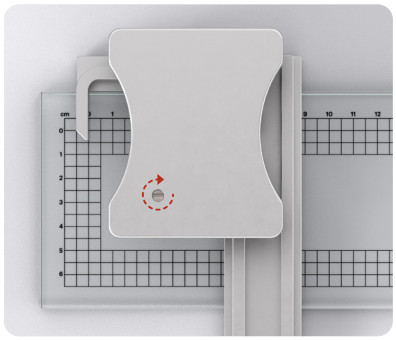
2. Positioning
Ensure the cutter is seated perfectly flat on the guide rail.



3. Zero-Point Alignment
If the assembly or the guide rail is not sitting flush on the glass plate, using a slotted screw driver, turn the spring-loaded set screw counter-clockwise until the assembly is properly seated.



4. Contact Verification
Ensure the blade is touching the surface of the glass plate.



5. Fine Adjustment
Carefully turn the set screw clockwise until you feel a slight resistance or observe the slightest displacement (lifting) of the assembly.

7. Transportation and Storage

For transport and storage, all FILM-Rx components should be kept in their original protective packaging or properly cushioned containers to prevent movement, impact, or damage. Store the equipment in a dry, well-ventilated environment, away from direct sunlight, excessive heat, humidity, dust, powders, and residues.

Components should never be stored while still wet, as moisture may mark the **FILM-Rx Glass Plate**, degrade silicone surfaces, and reduce the lifespan of aluminum parts. Special care should be taken with the **FILM-Rx Glass Plate**, which should be stored flat or upright on a padded surface, protected from edge impact, and never placed under heavy objects. Do not stack one **FILM-Rx Glass Plate** on top of the other without proper intermediate protection. The **FILM-Rx Applicator** should be protected from pressure on its calibrated edges, the **FILM-Rx Cutter** should always be stored without the blade, and the **FILM-Rx Mat** should be kept flat or loosely rolled to avoid creasing or damage. Proper storage and transport practices help preserve the integrity, safety, and performance of the FILM-Rx kit over time.

There is a risk of cuts, always use the provided blade Holder when inserting or removing the blade or handling the device for installation, transportation or storage.

Dispose blades exclusively in puncture-resistant, leak-proof sharps containers.

8. Definitions

Used Symbols	Meaning
	General mandatory action sign
	Refer to instruction manual
	General warning sign
	Sharp element

8.1 General Warnings and Safety Instructions

Ensuring the safety of operating personnel and the integrity of the pharmaceutical product requires strict adherence to two layers of documentation:

- The technical instructions for handling, cleaning, and maintenance as outlined in this user manual.
- Compliance with the standard operating procedures (SOPs) in place at the facility (e.g., regarding cleaning intervals, PPE requirements, and process validation).

Inadequate adherence to these requirements can lead to device malfunctions, cuts, or contamination.

There is an acute risk of cuts when handling the device, changing the cutting blade, and when cleaning or disassembling the device.

- Always use the provided Blade Holder when changing the blade or handling the device
- Check the glass plate for cracks or damage before each use.

Dispose blades exclusively in puncture-resistant, leak-proof sharps containers.

Crushing hazard, beware of potential pinch points during operation, handling and cleaning.

When working with potentially chemical exposure (e.g. contact with active pharmaceutical ingredients/APIs or cleaning agents), the use of suitable personal protective equipment (PPE) in accordance with the company's risk assessment is mandatory.

Familiarize yourself with the operating instructions before operating the device, the FILM-Rx Kit may only be operated by trained and qualified personnel.

8.2 Note on Identification

To ensure seamless cleaning and minimize the risk of cross-contamination from adhesive labels or deep engravings, the equipment is identified as follows:

- **Identification via Documentation:** The device is identified through the information provided on the outer packaging and within this manual.
- **Design-Based Integrity:** The unique geometry and specific design of the individual components are engineered to prevent any confusion or incorrect assembly by design.
- **Functional Markings:** Any existing laser markings are intended solely to assist the user during operation and do not serve as identification features.
- **Identification Plate:** Full identification data (manufacturer address, CE mark, model designation) can be found on the outer packaging and in the imprint of this manual.

8.3 Quality Assurance and Documentation

To maintain maximum surface hygiene, this device does not feature a physical serial number. Identification and traceability are instead managed via the batch number provided on the outer packaging.

- **Customer Receipt and Inventory:** The operator is hereby instructed to register the device into their internal inventory and Standard Operating Procedures (SOPs) immediately upon receipt and verification against this manual.
- **Batch Traceability:** The entire delivery batch serves as the unit of identification for quality management purposes. Please retain the shipping documents and outer packaging carefully for any inquiries regarding material certification.

9. Warranty

This kit is covered by a warranty and guaranteed to be free from defects in materials and workmanship for 24 months from the date of invoice, under normal use and service conditions. The warranty applies only to the original purchaser and does not cover products damaged due to misuse, accidents, or abnormal operating conditions. If the warranty period has elapsed, Fagron will still offer repair services, subject to applicable charges. For warranty claims, kindly reach out to your local supplier for assistance.

Declaration of Product Safety and Compliance

Gako Deutschland GmbH
Is certified according
DIN EN ISO 9001:2015 &
DIN EN ISO 50001:2018

Product type: Fagronlab FILM-Rx Kit

Model/Components Included:

- **Fagronlab™ FILM-Rx Applicator**
- **Fagronlab™ FILM-Rx Glass Plate**
- **Fagronlab™ FILM-Rx Cutter**
- **Fagronlab™ FILM-Rx Mat**

Manufacturer: Gako Deutschland GmbH
Am Steinernen Kreuz 24
96110 Scheßlitz/Germany

This declaration of product safety and compliance is issued under the sole responsibility of the manufacturer.

The **Fagronlab FILM-Rx Kit** is a manual laboratory device intended for commercial use in indoor environments for the standardized manufacturing (compounding) of pharmaceutical films, including orodispersible films (ODF) and vaginal films (VF).

The object of the declaration described above is in conformity with the relevant Union harmonisation legislation:

- **Regulation (EU) 2023/988** on General Product Safety (GPSRP)

References to relevant standards and technical specifications used:

- **CENELEC Guide 32:** Guidelines for including safety aspects in standards.
- **EN ISO 12100:2010:** Safety of machinery – General principles for design – Risk assessment and risk reduction.

Additional information:

The product has been developed and manufactured in accordance with applicable material standards, established safety principles, and internal quality management procedures.
A comprehensive risk assessment has been performed in accordance with CENELEC Guide 32 and EN ISO 12100.
Relevant aspects of EU GMP guidelines (EudraLex Volume 4) have been considered, particularly regarding cleanability and material suitability.

Signed for and on behalf of:

gako

Gako Deutschland GmbH
96110 Scheßlitz / Germany

Karamperis Aris, Product manager

29.05.2026

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Together
we create the future
of personalizing medicine.

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