FagronLab™ PM140

User Manual

Version 3.0

www.fagronlab.com

Fagron lab

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1. An All-in-One Solution: FagronLab™ PM140

For pharmacists who are looking for a simple, fast, and affordable solution for mixing, deaeration, and melting, the **FagronLab™ PM140** is a revolutionary device that combines those multiple functionalities to standardize the compounding process, ensuring safety, quality, and efficacy for compounded preparations while saving time and money for the pharmacy (Figure 1).

Moreover, it can be used on its own or in a combined workflow with other compounding equipment, such as the **FagronLab™ EMP*** or other devices or molds required for the preparation of semi-solids or molded and melted solids.

Figure 1. FagronLab™ PM140 device.

1.1. Mechanism of Action

Due to its ingenious mechanism, the preparation inside the PM jar (mixing jar) simultaneously spins and rotates around an axis in opposite planetary motion while keeping all the components at an angle of 40°. This promotes a centrifugal force caused by the rotational movement making particles in the mixture move toward the edges of the PM jar. As a result, the mixing process can be conducted in an enclosed environment without blades (Figure 2), reducing the number of items to be cleaned afterwards and enabling the pharmacist to **mix** and **deaerate** formulas within a simple one-step process (a process in less than 60 seconds). This centrifugal motion is accompanied by uniform and gradual heat release, facilitating the **melting** of substances such as suppository bases, gelatin bases, or gelling agents in the preparation (a process that requires around 15 minutes depending on the base).

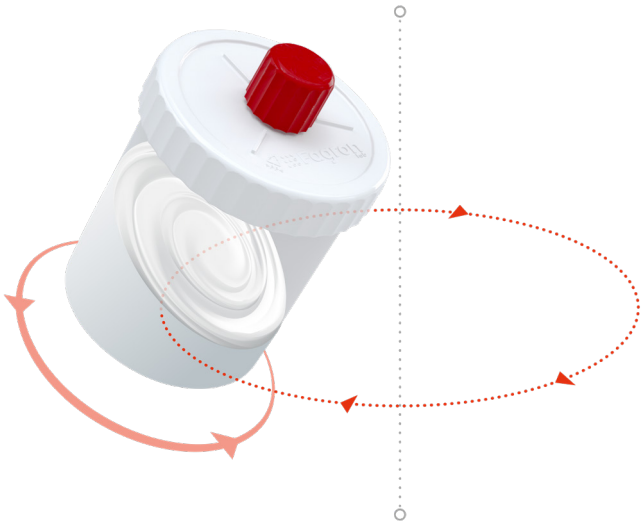


Figure 2. The working mechanism of FagronLab™ PM140.

For optimal results, we are continuously developing suitable accessories including jars and dispensers for the **FagronLab™ PM140** (see section 3. Accessories). The PM jars and dispensers provide a closed environment to reduce microbial contamination and eliminate spilling and spreading problems. They can be used in negative pressure cabinets to prevent hazardous drug exposure. The disposable ones that are also used as primary packages, help avoiding material loss that would otherwise occur during the transfer step from the preparation cup into the package.

* **FagronLab™ EMP** is a product line of fully automatic, semi-automatic, and manual versions devices, designed for mixing and the homogenization of semi-solid preparations (gels, creams, ointments, and suppositories) using blades.

1.2. Application and Use

Mixing

FagronLab™ PM140 is a user-friendly and practical device that allows the preparation of formulas in less than a minute, in a closed mixing jar, with no need for mixing blades (Figure 3). The studies conducted by our laboratories show the content uniformity in all portions of the formulations produced. The standardized mixing allows for greater stability of emulsions, therefore eliminating formulation issues such as creaming, sedimentation, flocculation, and coalescence. An adequate homogenization also ensures correct rheological properties, such as the formulation's viscosity and flow.

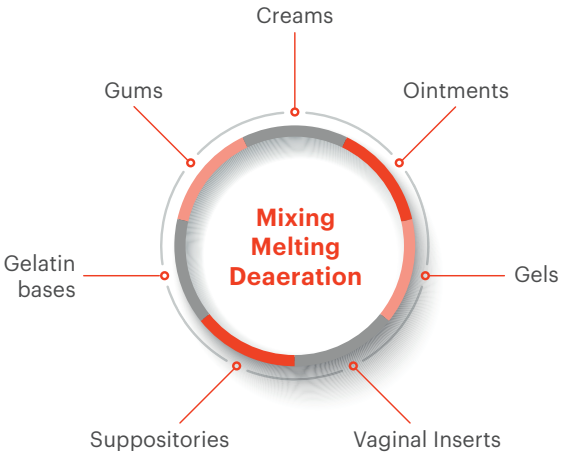


Figure 3. Mixing process using the FagronLab™ PM140.

Deaeration

FagronLab™ PM140 deaerates emulsions and gels in just 50 seconds, ensuring the removal of macrobubbles from those formulations (Figure 4).

Melting

FagronLab™ PM140 can melt gelatin, suppository, and vaginal inserts bases in one simple step: the base can be placed together with the APIs and other necessary ingredients in the PM jar (Figure 5).

Figure 4. Deaeration process using the FagronLab™ PM140.

Figure 5. Melting process using the FagronLab™ PM140.

1.3. Key Features

Single-Step Process

FagronLab™ PM140 combines mixing, melting, and de-aeration processes in a single step. Therefore, it simplifies the compounding of pharmaceutical preparations and saves time while ensuring high-quality formulations. As demonstrated in studies conducted by our scientific expert team, the temperature rise is limited to 45°C, making it suitable for most heat-sensitive ingredients.

Time-Saving

The high mixing speed of **FagronLab™ PM140** is fixed to 2800 rpm, allowing the preparation of formulations in less than 60 seconds.

Dosage Accuracy

In volume-dependent doses, as in HRT creams, a reliable mixing process that deaerates the formulation improves API distribution and ensures dosage accuracy for each application.

Material-Loss Prevention

In traditional mixing processes, material loss occurs during the transfer to the final package after mixing. Even if the exact amounts are calculated and weighed, the compounded preparation is never completely transferred from the mortar into the package, especially when working with semi-solid dosage forms. To prevent material loss, the **FagronLab™ PM140** is designed to mix the formulation in a disposable PM jar, also used as a final package to be delivered to the patient.

Conservation of Resources

The **FagronLab™ PM140** contributes to water conservation, as it does not require subsequent washing and rinsing steps of spare parts such as blades and mixing rods.

Low-Maintenance

The **FagronLab™ PM140** is distinguished by quality materials that allow for a low-maintenance and durable service, improving cost-efficiency. Due to its compact and functional design, the device can be easily integrated into lab furniture or used on the workbench. It also eliminates issues when compounding colored ingredients, such as coloring the blades or wearing them out by changing color and avoiding cross-contamination in a hormone preparation through the edges.

Compounding Hazardous Drugs

The term "hazardous drug" (HD) was first described by the American Society of Health-System Pharmacists (ASHP) in 1990 and has also been used by Occupational Safety and Health Administration (OSHA) for compounds that display the following characteristics: genotoxicity; carcinogenicity; teratogenicity or loss of fertility; and severe toxic manifestations at low doses in experiments with animals or treated patients. An API is considered hazardous if it features one or more of these characteristics, and new APIs with structure and toxicity profiles that mimic those of hazardous APIs are also classified as HDs.

According to the United States Pharmacopoeia (USP), pharmacists can be potentially exposed to HDs while compounding when:

- Weighing or mixing components;
- Crushing or splitting tablets or opening capsules;
- Pouring oral or topical liquids from one container to another;
- Constituting or reconstituting powdered or lyophilized HDs;
- Withdrawing or diluting injectable HDs from parenteral containers;
- Expelling air or HDs from syringes;
- Contacting HD residues present on Personal Protective Equipment (PPE) or other garments;
- Deactivating, decontaminating, cleaning, and disinfecting areas contaminated with or suspected to be contaminated with HDs;
- Maintenance activities for potentially contaminated equipment and devices.

FagronLab™ PM140 decreases the risk of exposure to HDs as it works in a closed environment provided by the PM jars. Additionally, the PM jars can be placed in negative pressure cabinets, which increases safety for the compounding of HDs.

Volume-Adjustable Jar

For the preparation of smaller batches than 100 mL, FagronLab™ PM jar 100 mL HV enables the reduction of the jar volume by pushing the bottom upwards after the operation. This eliminates the requirement of acquiring multiple jar sizes and additional jar holders/adaptors to accommodate them with the device. Additionally, it minimizes air contact by removing excess space, resulting in improved quality.

2. Technical Parameters

Model	FagronLab™ PM140
Width (mm)	205
Height (mm)	295
Depth (mm)	265
Weight (kg)	17.3
Table-Top Model	Yes
Electrical requirements	100 VAC - 230 VAC, 50 / 60 Hz
Power Consumption (W)	250
Feed Line	3 x 1.5 mm^2
On-Time	%15
Fuse Protection	2 x 4 AT
Revolutions	2800 rpm
Time-range	Seconds 10, 20, 30, 40, 50, 60, 90
	Minutes 2, 3, 4, 5, 10, 15

3. Accessories

FagronLab™ PM jar 100ml HV is a sterile and disposable jar composed of polypropylene, and it is specifically designed to be used in the deaeration and mixing processes of gels, creams, and ointments. Although its capacity is up to 100 mL, the internal nominal volume is 140 mL. This extra volume is necessary to allow the particles to move through the process, and promote its features. This PM jar presents a movable bottom. After the preparation, the remaining volume can be eliminated by pushing the bottom upwards, reducing air contact. It is also compatible with **FagronLab™ EMP** devices, enabling it to be used with low-soluble APIs and to prepare suspension formulas. It, therefore, eliminates the need to transfer the compound from the EMP jar to the **FagronLab™ PM jar 100 mL HV**. Since the PM jars are made of a disposable material, they can also be used as a primary package to deliver to the patient, reducing the tools to be cleaned, saving time, and avoiding material loss during the transfer phase.

The **FagronLab™ PM jar 125 mL HV+LV** is a disposable jar with a fixed bottom, designed to be used mainly for the melting of the suppository preparation, and mixing more fluid formulas – but it can also be used for other preparations like creams, ointments, and gels. The capacity of this PM jar is 125 mL with a 180 mL nominal volume. When the device is operated in room temperature, the content can reach up to 45 °C. In case the prescription requires higher temperature, the external heat can be applied to the **FagronLab™ PM jar 125 mL HV+LV**, up to 85 °C by using a hot water bath.

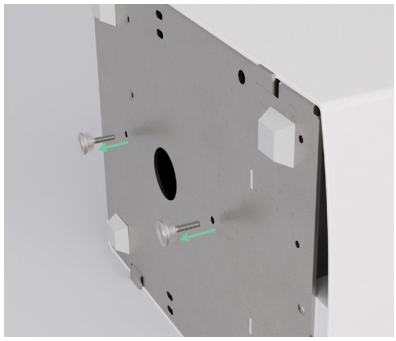
Table 1. Comparing FagronLab™ PM jars.

Accessory	FagronLab™ PM jar 100 mL HV	FagronLab™ PM jar 125 mL HV+LV
Internal Nominal Volume	140 mL	180 mL
Maximum capacity for Mixing	100 mL	125 mL
Bottom	Movable	Stable
Sterility	STERILE|EO*	STERILE|EO*
Applications	Deaeration Mixing	Deaeration Mixing Melting
EMP Suitability	Suitable	Not suitable
Mixing Period	Up to 1 minute	Up to 15 minutes for melting Up to 1 minute for mixing and deaeration
Suitable Dosage Forms	• Ointment • Cream • Gel	• Ointment • Cream • Gel • Lotion • Suppository • Insert
Usability as Dispensing Primary Packaging	Applicable	Applicable

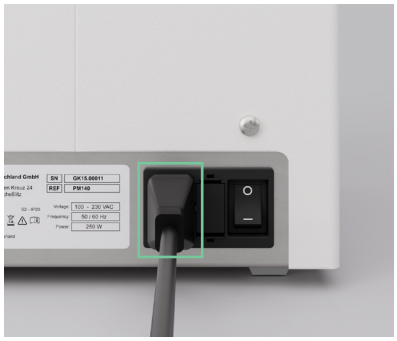
* **STERILE|EO**: Sterilized with ethylene oxide.

4. Functions and Use

4.1 Installation



1.
Remove the safety screws from the bottom, turn the device back to its rubber feet, open the cover and remove the cardboard tube.



2.
Connect the device to the local power supply using the provided connection cable.

3.
Turn the device on using the power switch at the back of the device.
I → ON **O** → OFF

4.2. Operation

1.
After turning the device on, and when the lid is closed, the LED light is flashing.

2.
Open the lid to insert the PM jar.

3.
Select the time (min/sec).

4.
Put the PM jar holder on the table.

5.
Insert the PM jar in the PM jar holder.

6.
Turn the PM jar slightly clockwise to ensure it is placed inside the PM jar holder completely.

7.
Place the PM jar with the PM jar holder into the well. Make sure the PM jar lid is completely closed, the shape is complementary with the well and the PM jar is pushed all the way down.

8.
Close the lid.

9.
Press **START**. The device automatically stops after the mixing process is completed.

10.
After the operation is completed, open the lid to remove the PM jar.

11.
Place the PM jar holder on the table.

12.
By holding the PM jar holder, take the PM jar out of it while turning slightly clockwise and pulling out.

5. Safety Shutdown

- The safety shutdown protects individuals from injury and the device from damage.
- Any attempt against the opening of the lid during mixing procedures leads to an immediate safety shutdown, which may lead to mechanical damage to the device and requires customer service support.
- Mixing procedures are immediately interrupted and stopped when pressing **START**.

6. Maintenance

6.1. Cleaning

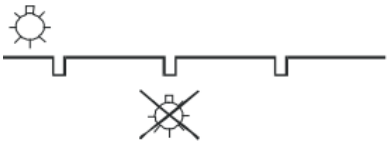
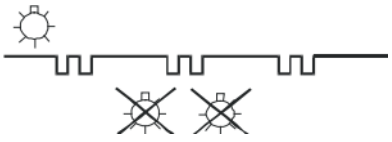
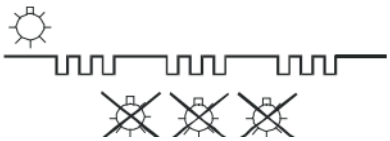
- Clean the surface with a soft fabric or cloth soaked with warm water and a non-abrasive household cleaning agent.
- Afterward, wipe the surface with another soft fabric or cloth soaked with warm water and clear it.
- In the end, rapidly wipe the entire surface with a dry cotton cloth or towel.
- Heavy scaling may be cleaned with a standard liquid cleanser.
- Do not use scratching sponges or abrasive cleaning agents such as nitro or synthetic resin thinner.
- Since it may cause irreparable damage, ensure no fluids enter the device.
- Use mild surface disinfectants.
- Do not use thermal disinfection.

6.2. Operational Error

Error	Troubleshooting	Solution
Insufficient mixture quality	Short mixing time	Adjust mixing-time
	The expiry date of the mixture passed	Observe expiry date
Uncombined powder after mixing	Humid powder	Store the powder according to the manufacturer's instruction
Processing and segregation time too short	Mixing time set too long	Shorten mixing time
Powder residues in PM jar holder	The PM jar is not closed properly	Close PM jar properly
The PM jar cannot be lifted easily from the PM jar holder	Powder residues in the PM jar holder	Clean PM jar holder, observe proper closing of PM jar

6.3. Technical Error

Errors are indicated by a flashing LED light on the start button. They could be reset by pressing the start button or restarting the device. If the error continues, the LED light will flash again. The device does only work after eliminating the error.

Error	Troubleshooting	Solution
The device is not running, no LED light	Defective fuse	Check the fuse and replace it if necessary
	ON/OFF switch in off-state	Activate the ON/OFF switch
Flashing LED 	The lid has not been opened after switching on the device (with a closed lid)	The lid circuit is not yet activated. Open and close the lid
	The lid has not been opened before the further mixing process	Open and close the lid
	The device cover does not close properly after pressing the start button	Close the lid, press the start button
Flash Mode: *ON 300ms / OFF 300ms, 1.6 Hz*		
Rapidly Flashing LED 	Device activated for more than recommended on-time	Let the device cool down
	Overheating	Let the device cool down
Flash Mode: *ON 100ms / OFF 100ms, 5 Hz*		
1 x Flashing LED 	Defective locking	Let a service technician check the lock
	Missing locking signal	Let a service technician check the lock
Flash Mode: *ON 2000ms / OFF 300ms / ON 2000 ms*		
2 x Flashing LED 	Defective incremental decoder	Request service technician
Flash Mode: *ON 2000ms /* ***OFF 300ms*** */ ON 300 ms /* ***OFF 300ms*** */ ON 2000ms*		
3 x Flashing LED 	The defective motor control unit	Replace motor and control (service technician)

Flash Mode: *ON 2000ms /* ***OFF 300ms*** */ ON 300 ms /* ***OFF 300ms*** */ ON 300 ms /* ***OFF 300ms*** */ ON 2000ms*

7. Transportation and Storage

The **FagronLab™ PM140** weighs approximately 17.3 kg and should only be stored on flat, leveled surfaces capable of supporting the device's weight. The device is attached to the base plate with safety screws for protection during transportation, and the cardboard tube is inserted into the PM jar holder. Transporting the device should avoid collisions.

NOTE: Do not store the device in wet or extremely damp locations.

8. Warranty

This device is under warranty and free from defects in materials under regular use and service for 12 months from the invoice date (excluding consumable accessories). The warranty is extended only to the original purchaser. The warranty is not valid on a device damaged by improper installation, connections, misuse, accident, or abnormal operating conditions. If the warranty has expired, manufacturer will still be responsible for repair with relative charges. For claims under warranty, please get in touch with your local supplier.

Annex I. Declaration of Conformity

Declaration of Conformity

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

CE

Product: Laboratory mixing device
Product type: FagronLab™ PM140

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

The manufacturer declares the conformity of the designated product with the following European guideline:

Directive 2014 / 35 / EU of the European Parliament and of the Council
26th February 2014
on the harmonisation of the laws of the Member States relating to the making available of electrical equipment designed for use within certain voltage limits on the market

Directive 2014 / 30 / EU of the European Parliament and of the Council
26th February 2014
on the harmonisation of the laws of the Member States relating to electromagnetic compatibility (recast)

Directive 2006 / 42 / EC of the European Parliament and of the Council
17th May 2006
on machinery, and amending Directive 95/16/EC (recast)

The conformity of the designated product has been proven by the complete compliance of the following directions:

DIN EN 61010-1:2020-03
DIN EN 61010-2-051:2016-02
DIN EN IEC 61326-1:2022-11
DIN EN 61000-4-2:2009-12
DIN EN 61000-4-4:2013-04
DIN EN 61000-4-5:2019-03
DIN EN 61000-4-6:2010-11
DIN EN IEC 61000-4-11:2018-08
DIN EN 55011:2022-15

For the intended use the designated product meets the requirements from European, US, British and Japanese Pharmacopeia and ROHS (EU) 2015/863 and 2011/65/EU) regulations.

The product has been examined regarding the compliance of the direction/standards mentioned above.

gako

Gako Deutschland GmbH
96110 Scheßlitz / Germany

Dipl.-Wirtsch.-Ing. Matthias Konietzko, MBA

01.11.2022

Annex II. IQ/OQ

Functional Test FagronLab™ PM140

Assessment	Conclusion	
	OK	Not OK
Check the device label for readability.		
Check device location for stability and suitability.		
Check the device location for drafts, direct sunlight, extreme humidity, or temperature fluctuations.		
Check the device location for cleanliness, dryness, and freedom from dust.		
Check the accessibility to the power plug and power switch.		
Check the power supply for suitability and country-specific nominal voltage and frequency.		
Handling by unauthorized persons is excluded.		
Operation instructions in the user manual are available.		
Turn the device upside down and remove the safety screws from the bottom.		
Turn the device back to its rubber feet and open the lid.		
Remove the cardboard tube from the device and close the lid.		
Connect the device to the local power supply using the provided connection cable.		
Switch the power button on the back side of the device to “I”.		
Check if the red light keeps flashing after turning it on.		
Prepare a PM jar adding a transparent gel and close the lid of the jar to test deaeration (both FagronLab™ PM jar 100 mL HV and FagronLab™ PM jar 125 mL HV+LV can be used).		
Place the PM jar holder on the table, insert the PM jar into the PM jar holder, and turn the jar slightly clockwise. It is normal to be tight.		
Is the PM jar inserted in the PM jar holder?		
Place the PM jar with the PM jar holder into the well. Make sure the PM jar lid is completely closed, the shape is complementary with the well and the jar is pushed down.		
Is the PM jar fully inserted into the well?		
Close the lid of the device and set the time to 30 seconds from the button.		
Does the button move properly?		
Press “START”.		
Does the device start operation?		
Is the operation time the same as the set time?		
Does the device stop operating automatically?		
Open the lid of FagronLab™ PM140 and remove the PM jar with the PM jar holder.		
Put the PM jar holder on the table.		
Turn the PM jar slightly clockwise and take it out (it is normal to be tight).		

Assessment	Conclusion	
	OK	Not OK
Is the air entrapped in the gel removed?		
Prepare a PM jar adding a cream base and a liquid API, then close the lid of the jar to test mixing (both FagronLab™ PM jar 100 mL HV and FagronLab™ PM jar 125 mL HV+LV can be used).		
Place the PM jar into the PM jar holder and insert it by following the steps above.		
Is the PM jar fully inserted into the well?		
Close the lid of the device, set the time to 45 seconds from the button and press "START".		
Does the device start operation?		
Is the operation time the same as the set time?		
Does the device stop operating automatically?		
Open the lid of FagronLab™ PM140 and remove the PM jar with the PM jar holder.		
Take the PM jar out from the PM jar holder and check the preparation.		
Does it look homogeneous?		
Prepare a FagronLab™ PM jar 125 mL HV+LV adding a suppository base and an API, then close the lid of the PM jar to test mixing.		
Place the PM jar into the PM jar holder and insert it by following the steps above.		
Set the time to 15 minutes from the button and press "START".		
Does the device start operation?		
Is the operation time the same as the set time?		
Does the device stop operating automatically?		
Open the lid of FagronLab™ PM140 and remove the FagronLab™ PM jar 125 mL HV+LV with the PM jar holder.		
Take the PM jar out from the PM jar holder and check the preparation.		
Does the suppository base melt?		
Does the preparation look homogeneous?		

Date **Signature**

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