FagronLab™ PM140

The next step in compounding mixing technology

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Contents

1. The Importance of Standardized Processes in Compounding Pharmacy

Standardizing techniques and procedures is essential to guarantee high-quality and safe preparations in the compounding pharmacy. Compounded preparations without a standardized process may lead to potential changes in the active pharmaceutical ingredient (API) activity, influence the formulation aspect, and cause chemical alterations that potentially trigger reactions of different severity or inefficiency in treatments.[1,2]

According to the United States Pharmacopeia (USP)[3], the safety, quality, efficacy, and/or benefit of compounded preparations depend on a number of factors that should be monitored as part of the quality assurance process.

Those factors are:

- correct ingredients and calculations;
- accurate and precise measurements;
- appropriate formulation, facilities, equipment, and procedures (appropriate compounding equipment needs to be selected and inspected for cleanliness and correct functioning);
- and prudent pharmaceutical judgement.

To ensure accuracy and completeness, the compounder shall observe the finished preparation to ensure that it appears as expected, investigate discrepancies and take appropriate corrective action before dispensing the prescription to the patient.[3] In this sense, critical processes (including but not limited to weighing, measuring, and mixing) are verified by the compounder to ensure that procedures, when used, consistently result in the expected quality in the finished preparation.[4]

When a process is standardized[5]:

- Batch variation is reduced/eliminated;
- The quality of the product is assured;
- Regulatory risk (non-compliance) is reduced;
- Consistency of the compounding operation and process reproducibility is ensured;
- Quality Management System within the organization is ensured;
- Equipment maintenance is facilitated;
- Employee/compounder awareness is improved.

Health systems
are constantly challenged to ensure formulations
are prepared safely and accurately while complying with increasingly
complex regulations.

Standardization of processes
creates traceability and helps to eliminate or spot
formulation process deviations and errors.

Automated compounding solutions
provide pharmacists and technicians with the tools to improve
dose accuracy and product safety.
It also can reduce costs and enable compliance.

2. Critical Challenges in Focus: Mixing, Deaeration, Melting and Wet Milling

Mixing

Mixing is a pharmaceutical operation to achieve total homogeneity of the components in a formulation: the essential condition for a final compliant product in terms of cream content is to be perfectly mixed.[5]

Mixing significantly affects the final characteristics of the compounded preparation, including physicochemical stability and dosage variation, compromising the safety and effectiveness of the treatment. Adequate mixing is crucial in preparing dosage forms within the compounding pharmacy.

Ensuring the efficiency and reproducibility of the mixing process is essential for reducing operational risks and batch variation and improving the pharmacy's quality management system.[5] Therefore, using equipment that can assist and enhance the safety and reproducibility of processes is highly important to pharmacists in their daily compounding practice[6].

This is also true for semi-solid formulations where the active ingredients are dose-dependent, especially hormones dispensed in dosing packages. Therefore, each dose should reproduce the remaining doses regarding active ingredient content.

Deaeration

Emulsion droplet/air interaction can have significant consequences for its stability.[7] Entrapped air increases the risk of dose inaccuracy in the final preparation, and it can alter the texture of an emulsion or gel, affecting its stability by absorbing the emulsifier molecules at the air-liquid interface.[8] The final pH of the formula can also be impacted since the bubble formation interferes with fluid-flow patterns. Moreover, microorganisms grow in media with water and air, making most semi-solid dosage forms an ideal environment for their proliferation. Increased oxidation can also be seen due to the oxygen in the entrapped air.[9]

A substantial risk related to the presence of entrapped air as microbubbles or macrobubbles is the dosage variations they can cause, especially while working with small volumes, low dosages, or hormone replacement therapy (HRT) preparations.

A high degree of air entrapped in a cream may lead to changes in its density. Therefore, the precise dosing required for HRT can be compromised as it will affect the doses dispensed by the calibrated packaging, potentially causing underdoses and overdoses throughout the treatment.

This is also relevant for molded dosage forms that undergo melting during preparation, as in suppositories and vaginal inserts. Indeed, this is a phenomenon that creates the need for the calculation of displacement factors (df). The molds for those dosage forms contain a known, invariable volume. Still, the weight of the unit produced by the mold varies with the type of base used and the air incorporated throughout the compounding process. Also, the base is mixed with the drug, but the base and drug may have different bulk densities. Therefore, a low-density drug will displace a larger amount of the base than a similar weight of a higher-density drug – and this is, of course, also influenced by the density of the base, which is affected by the amount of air entrapped within it.[5]

Melting

The most commonly used method for pharmaceutical compounding of molded dosage forms is the Solidification Method: the excipient (the base mass) is melted, the ingredients in the formulation are added, and the mixture is poured into appropriate molds that have been greased with liquid petrolatum or mineral oil (for metal molds) – if packing molds (disposable molds) are used, they do not need to be greased.

During this process, time and temperature play an essential role. Although time can be easily controlled, temperature is a more complex parameter to standardize if the compounding facility does not possess a suitable device for this purpose. Fluctuations in the average temperature are, making it challenging to keep the whole formulation at the same temperature. Also, the multiple steps in the process can lead to significant loss of materials throughout it.[5]

Wet milling

Wet milling plays a crucial role in the preparation of suspensions and colloidal solutions by reducing particle size, leading to improved distribution and solubility profiles. Smaller particles exhibit reduced settling in the liquid phase, enhancing suspension stability and ensuring a more accurate dose distribution.

Wet milling is particularly advantageous when the active substance is unavailable in powder form, necessitating the compounding of formulations from whole tablets. The dry grinding of entire tablets can be challenging, as tablets are designed to maintain their integrity under pressure, making the process time-consuming and requiring considerable strength to apply sufficient pressure. Moreover, it often results in the dispersion of powders, posing health concerns for the person involved, especially if the pharmaceutical includes hazardous drugs. While capsules provide an alternative, opening them individually to

extract APIs is a time-consuming process that compromises dosage accuracy since static electricity causes powders to adhere to the capsule shell, preventing the extraction of the entire API content.

To address these concerns, it is important to conduct wet milling processes in closed environments, employing devices that handle whole tablets and capsules. This not only prioritizes safety and process efficiency but also ensures reproducibility and compliance with Good Manufacturing Practices (GMP). Nevertheless, the limited space in pharmacy labs can pose a challenge when utilizing such equipment. Thus, the adoption of versatile devices capable of integrating multiple processes, including wet milling, becomes an additional advantage. This innovative approach optimizes compounding practices, aligning with the stringent requirements of pharmaceutical standards and enhancing efficiency within confined laboratory spaces.

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

For pharmacists who are looking for a simple, fast, and affordable solution for mixing, melting, wet milling and deaeration, 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 dosage forms.

3.1. Mechanism of action

Due to its ingenious mechanism, the preparation inside the FagronLab™ 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 FagronLab™ PM jar. As a result, the mixing process can be conducted in an enclosed environment without mixing 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). The operation is naturally accompanied by uniform and gradual heat release, reaching up to 45°C within 15 minutes when started at room temperature. The device's low-temperature rise, even over extended periods, ensures safe usage with formulations containing thermolabile substances. This feature is also advantageous for maintaining the physical state of previously melted bases, such as suppositories and gel bases, during the mixing process.

Figure 1. The FagronLab™ PM140 device.

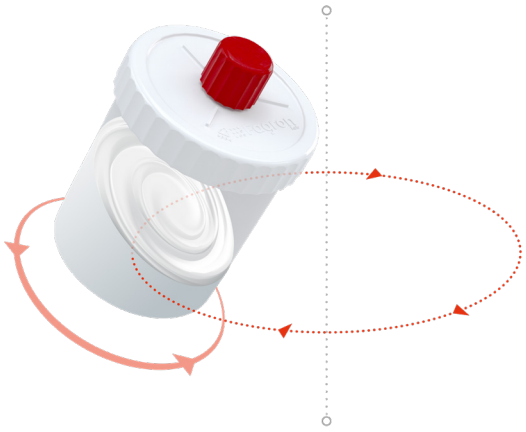

Figure 2. The working mechanism of the FagronLab™ PM140.

* **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.

For optimal results, we are continuously developing suitable accessories including various FagronLab™ PM jars and dispensers for the **FagronLab™ PM140** (see section 3.6. Accessories). The FagronLab™ 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 vessel into the package.

3.2. Application and Uses

Mixing

The **FagronLab™ PM140** is a user-friendly and practical device that allows the preparation of formulations in less than 60 seconds, 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

The **FagronLab™ PM140** deaerates emulsions and gels in just 45 seconds, ensuring the removal of macrobubbles from those formulations (Figure 4).

Melting

As the **FagronLab™ PM140** is not designed for melting, it does not incorporate heat-emitting parts or a thermal insulation system to mitigate ambient temperature changes, so direct use for the melting process is not recommended. For the formulations requiring heat treatment, it is necessary to apply external heat to conduct the melting process. This approach also ensures compounding standardization by fixing the parameters.

Figure 4. Deaeration process using the FagronLab™ PM140.

The external heat can be directly administered to the substances within the **FagronLab™ PM jar 125 mL HV+LV** (see section 3.6.2. FagronLab™ PM jar 125 mL HV+LV) through a hot water bath, as the jar can withstand temperatures of up to 85°C (Figure 5). Thus, the melting process is conducted in a closed environment, protecting the substances from external contaminants such as water vapor.

Following the melting process, the **FagronLab™ PM jar 125 mL HV+LV** is directly inserted into the **FagronLab™ PM140** for mixing. This eliminates the need to transfer substances from a melting vessel to the FagronLab™ PM jar, preventing any substance loss.

The **FagronLab™ PM140** preserves the physical state of the previously melted suppository and gelatin bases through the natural heat release during operation. This approach contributes to the melting process, ensuring efficient mixing and deaeration.

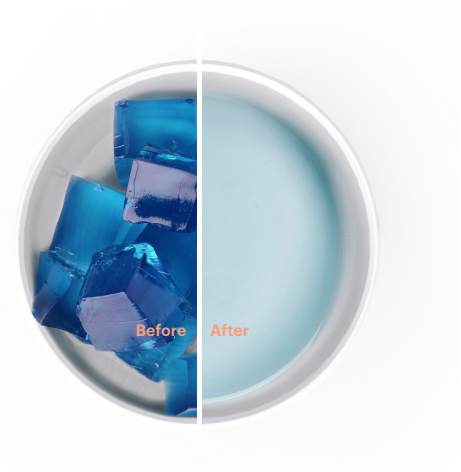

Figure 5. Melting process in the FagronLab™ PM jar 125 mL HV+LV using a hot water bath.

Wet Milling

The preparation of colloidal solutions and suspensions is effortlessly streamlined by the **FagronLab™ PM140** through a one-step process that integrates mixing, deaeration, and wet milling. This is achieved by utilizing the innovative **FagronLab™ MillBottle** (see section 3.6.3. FagronLab™ MillBottle), enabling milling whole tablets, capsules or capsule contents, and bulk powders (Figure 6). For suspension preparation, simply place the whole tablets, capsules, or powdered APIs into the **FagronLab™ MillBottle** in the required formulation amount. Add the necessary quantity of water or liquid suspension base and securely close the lid of the **FagronLab™ MillBottle**. After inserting the **FagronLab™ MillBottle** into the **FagronLab™ PM140**, set the time and start the operation. As the base generates a centrifugal force during high-speed operation, medications added to the bottle crush against the strips inside this bottle. This milling process results in the reduction of particle size, dispensing particles in the base, and achieving a homogeneous preparation.

Beyond its role as a mixing and wet milling vessel, this patent-pending bottle also serves as a storage and dispensing container for the final compounded formulation.

Figure 6. The FagronLab™ MillBottle.

3.3. Key Features

Single-Step Process

The **FagronLab™ PM140** combines mixing, wet milling, and deaeration processes in a single step. This enables the preparation of various dosage forms with a single device, simplifies the compounding process, and saves time while ensuring high-quality formulations.

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, e.g. 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 packaging after mixing. Even if the exact amounts are calculated and weighed, the compounded preparation is never completely transferred from the mortar into the packaging, especially when working with semi-solid dosage forms. To prevent material loss, the **FagronLab™ PM140** is designed to mix the formulation in a disposable FagronLab™ PM jar or FagronLab™ Millbottle, also used as a primary packaging 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 mixing blades and 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.

The **FagronLab™ PM140** decreases the risk of exposure to HDs as it works in a closed environment provided by the FagronLab™ PM jars. Additionally, the FagronLab™ 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, the **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.

3.4. Instructions for Use

The **FagronLab™ PM140** enables the pharmacist to wet mill, mix, and deaerate formulations within a simple one-step process, as easy as just pressing one button; after placing the formulation ingredients into the FagronLab™ PM jar, setting the time, and pressing the start button, the device is ready to operate the mixing process. Figure 7 shows how straightforward the process is and how the device can be used from multiple starting materials and combined with other devices to achieve optimal results. Table 1 also shows how the **FagronLab™ PM140** can help standardize the compounding processes.

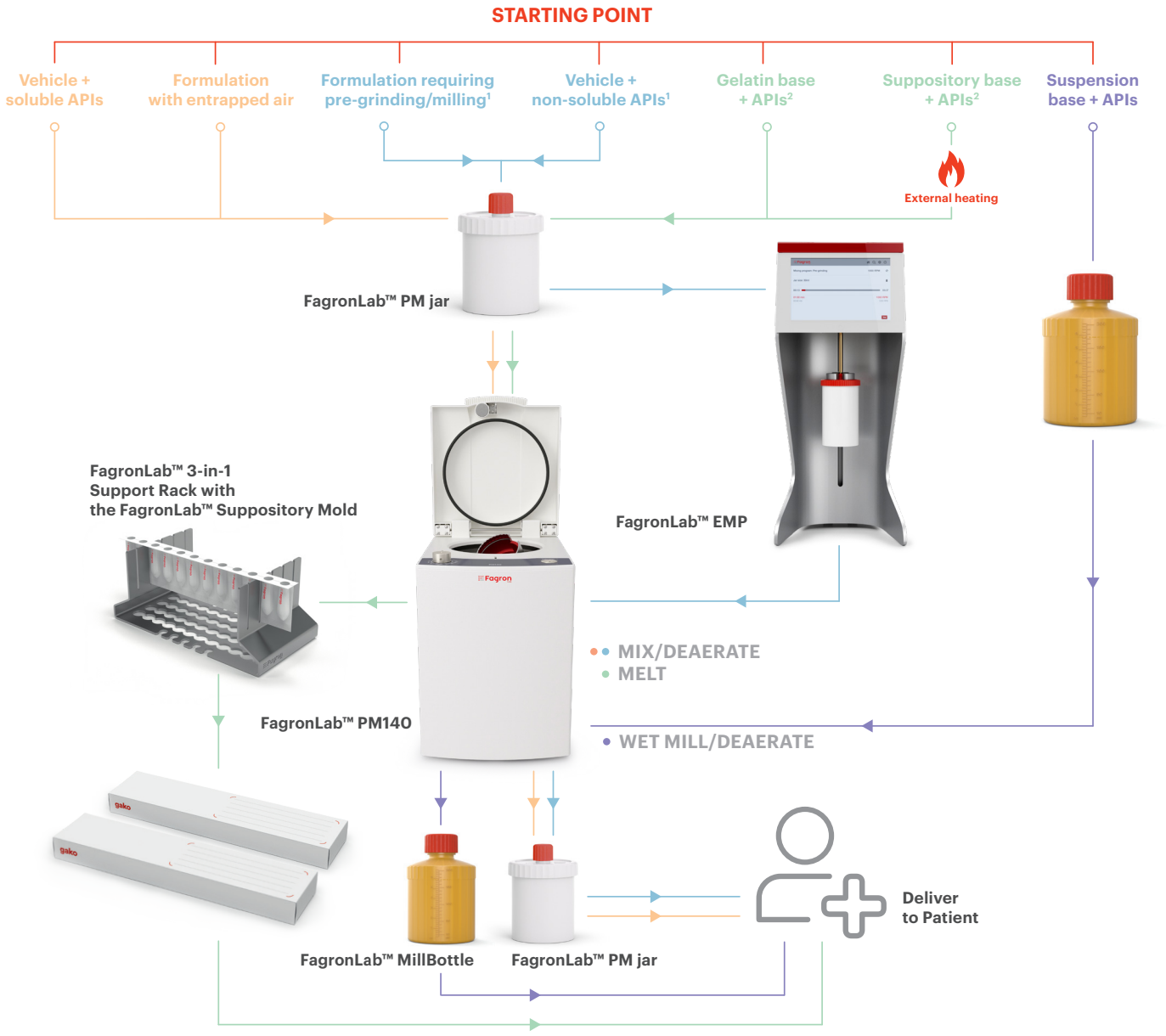

Figure 7. Workflow for FagronLab™ PM140 used standalone and in combination with other devices.

1. If the formulation contains non-soluble APIs, the use of FagronLab™ PM140 together with FagronLab™ EMP is recommended. Primarily, the FagronLab™ EMP can pre-grind and disperse all the components in the base. Afterward, the formula can be placed into FagronLab™ PM140 for final mixing and deaeration. Both processes can be carried out using the same PM jar, which can also be the dispensing package.
2. For suppositories and vaginal inserts, FagronLab™ PM140 maintain the physical state of the previously melted substances, however pre-heating is necessary to conduct melting and standardize the compounding process. The pre-heating can be applied to the substances directly in a closed FagronLab™ PM jar 125 mL HV+LV with using a hot water bath. FagronLab™ 3-in-1 Support Rack is also available; together with FagronLab™ Suppository Molds, a single-use strip used as final packaging, so the pharmacy can have a practical solution to combine molding and packaging functions.

NOTE: The FagronLab™ EMP devices can prepare ointments, creams, and gel vehicles of up to 2.000 mL at once in a homogeneous formulation (500 mL for FagronLab™ EMP BASIC and Standard, and 2.000 mL for FagronLab™ EMP PRO). This makes it an ideal choice for producing vehicles/bases or large batches to be later split into smaller amounts.

Table 1. Critical processes in preparation of compounded formulations and the role of the FagronLab™ PM140.

Critical process steps	Variable to monitor	Possible to standardize with FagronLab™ PM140?
Mixing/homogenization	• Time • Speed	Yes
Wet milling	• Speed • Friction • Dispersion	Yes
Addition ingredients incorporation	• Mixing method • Time • Speed • API accuracy of dose	Yes
Packaging	Closure of the jar / bottle Absence of reactions with formulations	Yes

3.5. FagronLab™ PM140 Standardized Protocols

3.5.1. Mixing with Low-Viscosity Bases

The mixing process of ingredients with low-viscosity bases is summarized in Table 2.

Table 2. Mixing protocol for low-viscosity bases using the FagronLab™ PM140.

Formula type	Emulsion/Gel + Liquid API	Emulsion/Gel + Powder API*
Jar	FagronLab™ PM jar 125 mL HV+LV	FagronLab™ PM jar 125 mL HV+LV
Quantity	50 g to 125 g (max)	50 g to 125 g (max)
Time	30 seconds	45 seconds
Temperature	The maximum temperature reached is 25 °C.	The maximum temperature reached is 25 °C.

* When a powder API is used in the **FagronLab™ PM140**, we recommend using a levigating agent to facilitate the incorporation of the APIs. It can be pre-mixed together, forming a paste, or the levigating agent can be placed above the powder, covering it completely. It is crucial to keep in mind the compatibility of the components with the base. This process is necessary before starting the **FagronLab™ PM140** to avoid an accumulation of the powder in the bottom or the top of the FagronLab™ PM jar.

3.5.2. Mixing with High-Viscosity Bases

Some creams may present a high-viscosity characteristic, e.g., transdermal creams in general, such as Pentravan®. Those may require an extended mixing time, as described below. This mixing process is summarized in Table 3.

Table 3. Mixing protocol for high-viscosity bases using the FagronLab™ PM140.

Formula type	Pentravan® + Liquid API	Pentravan® + Powder API*
Jar	FagronLab™ PM jar 100 mL HV / FagronLab™ PM jar 125 mL HV+LV	FagronLab™ PM jar 100 mL HV / FagronLab™ PM jar 125 mL HV+LV
Quantity	50 g to 100 g (max)	50 g to 100 g (max)
Time	30 seconds - 1 minute	2 - 3 minutes
Temperature	The maximum temperature reached is 25 °C.	The maximum temperature reached is 25 °C.

* When a powder API is used in the **FagronLab™ PM140**, we recommend using a levigating agent to facilitate the incorporation of the APIs. It can be pre-mixed together, forming a paste, or the levigating agent can be placed above the powder, covering it completely. It is crucial to keep in mind the compatibility of the components with the base. This process is necessary before starting the **FagronLab™ PM140** to avoid an accumulation of the powder in the bottom or the top of the FagronLab™ PM jar.

3.5.3. Deaeration

The deaeration process of formulations with entrapped air is summarized in Table 4 and Figure 6.

Table 4. Deaeration protocol for formulations containing entrapped air using the FagronLab™ PM140.

Formula type	Emulsion/Gel + Liquid API	Emulsion/Gel + Powder API
Jar	FagronLab™ PM jar 100 mL HV	FagronLab™ PM jar 100 mL HV
Quantity	50 g to 100 g (max)	50 g to 100 g (max)
Time	30 seconds	45 seconds
Temperature	The maximum temperature reached is 25 °C	The maximum temperature reached is 25 °C

3.5.4. Melting

The melting process involves applying external heat to the substances in the **FagronLab™ PM jar 125 mL HV+LV** using a hot water bath. The duration for melting depends on the material, environmental temperature, and hot-water temperature. Following this, the **FagronLab™ PM jar 125 mL HV+LV** is placed in the **FagronLab™ PM140**, where the mixing process takes place. This process not only prevents re-solidification of the melted base but also maintains its physical state due to the slight heating released during mixing. Table 5 provides a summary of the mixing parameters for the **FagronLab™ PM140** following the melting process of the substances.

Table 5. Mixing protocol for vaginal inserts, suppository bases, or other bases (gelatin or gum) using the FagronLab™ PM140 after melting externally.

Formula type	Supposiblend™ + Liquid API	Supposiblend™ + Powder API*
Jar	FagronLab™ PM jar 125 mL HV+LV	FagronLab™ PM jar 125 mL HV+LV
Quantity	125 g (max)	125 g (max)
Time	30 seconds	45 seconds
Temperature	The maximum temperature reached depends on the initial temperature.	The maximum temperature reached depends on the initial temperature.

* When a powder API is used in the **FagronLab™ PM140**, we recommend using a levigating agent to facilitate the incorporation of the APIs. It can be pre-mixed together, forming a paste, or the levigating agent can be placed above the powder, covering it completely. It is crucial to keep in mind the compatibility of the components with the base. This process is necessary before starting the **FagronLab™ PM140** to avoid an accumulation of the powder in the bottom or the top of the FagronLab™ PM jar.

3.5.5. Wet Milling

The wet milling process is initiated by introducing APIs, or all tablets and capsules containing APIs, into the **FagronLab™ MillBottle** along with water or a suspension base (SyrSpend® SF PH4 e.g.) as an essential liquid carrier for the process. This carrier may be low density, like water, or high density, such as a suspension base. Subsequently, the **FagronLab™ MillBottle** is placed directly into the **FagronLab™ PM140** without using the **FagronLab™ PM jar holder**, and the operation is started according to the parameters given in Table 6.

Table 6. Wet milling protocol of the suspension formulations, using the FagronLab™ PM140.

Formula type	SyrSpend® SF PH4 + whole tablets	SyrSpend® SF PH4 + whole capsules
Jar	FagronLab™ MillBottle	FagronLab™ MillBottle
Quantity	150 mL (max)	150 mL (max)
Time	5 – 10 minutes	5 – 10 minutes
Temperature	The maximum temperature reached is 45 °C.	The maximum temperature reached is 45 °C.

3.6. FagronLab™ PM140 Accessories

3.6.1. FagronLab™ PM jar 100mL HV

The **FagronLab™ PM jar 100 mL 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 high viscosity (HV) gels, creams, and ointments. Although its mixing 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 FagronLab™ PM jar presents a movable bottom. After the preparation, the remaining volume can be eliminated by pushing the bottom upwards, reducing air contact and its mixing capacity. The mixing capacity is also compatible with the **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 FagronLab™ EMP jar to the **FagronLab™ PM jar 100 mL HV**. Since the 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.

3.6.2. FagronLab™ PM jar 125mL HV+LV

The **FagronLab™ PM jar 125 mL HV+LV** is a disposable jar designed for mainly mixing low viscosity (LV) formulations – but it can also be used for other preparations like creams, ointments, and gels.

The capacity of this jar is also 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 7 lists the differences and applications for each jar.

Table 7. 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	Closed
Sterility	STERILE|EO*	STERILE|EO*
Applications	Deaeration Mixing	Deaeration Mixing Melting
EMP Suitability	Suitable	Not suitable
Suitable Dosage Forms	• Ointment • Cream • Gel	• Ointment • Cream • Gel • Lotion • Suppository • Insert • Mucosal films
Usability as Dispensing Primary Packaging	Applicable	Applicable

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

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

3.6.3 FagronLab™ MillBottle

The **FagronLab™ MillBottle** is a graduated polyethylene bottle with a mixing capacity of 150 mL and an internal nominal volume of 220 mL designed to compound colloidal solutions and suspensions in a closed environment. Its patent-pending design enables the wet milling of whole tablets, capsules, capsule contents, and bulk powders in water or a liquid suspension base while simultaneously engaging in mixing and deaeration without using the FagronLab™ PM jar holder. The high speed capability of the **FagronLab™ PM140** makes it suitable for both high and low viscosity liquid vehicles as well as powder suspending agents. The semi-transparent orange color of the bottle allows for easy liquid volume measurement while protecting the substances from UV-light exposure.

In addition to its function as a mixing and milling vessel, this unique bottle doubles as the primary packaging for these preparations, eliminating the need for an extra packaging step. It is delivered to pharmacies in a single, ready-to-use packaging, ensuring the protection of the **FagronLab™ MillBottle** from dust, dirt, and contamination.

Figure 8. The FagronLab™ MillBottle.

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Fagron BV
Fascinatio Boulevard 350
3065 WB Rotterdam
The Netherlands

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

Fagron lab