



gako PM140

FAQ

1. What are the main applications for the PM140?

The main application areas of **gako PM140** are deaeration, mixing, and melting. Moreover, it combines those functions in a single step to standardize the compounding process, ensuring safety, quality, and efficacy for compounded preparations while saving time and money for the pharmacy.

2. What types of pharmaceutical dosage forms can I prepare with the gako PM140?

With **gako PM140**, it is possible to prepare:

- Creams
- Ointments
- Gels
- Vaginal inserts
- Suppositories
- Gelatin gum

3. Can I use the gako PM140 to mix powders?

Many factors can influence the powder mixing efficiency, such as particle size, shape, and density. Because of their specific characteristics, the adequate choice of mixing technique and equipment can play an important role in the stability and quality of the powder mixture. Although the centrifugal mixing technique with the planetary movement of **gako PM140** can be used to mix semi-solid preparations, it is not a sufficient way to mix powders. For optimal and effective powder mixing, we recommend using InvoMatic™, which creates a 3D-movement cycle with a robotic mixing arm that allows complete diffusive mixing.

4. Can I prepare suspensions with the gako PM140?

As a characteristic of the suspensions, the active pharmaceutical ingredient (API) cannot dissolve inside the base but needs to be dispensed homogeneously. However, **gako PM140** is not a suitable device to dispense insoluble APIs in the base. To mix and prepare a homogeneous semi-solid suspension, we recommend using the gako unguator devices, since they can dispense the particles homogeneously during the mixing process. Afterward, **gako PM140** can be used for the deaeration of the compounding to provide dosage accuracy and increase stability, ensuring the preparation of a high-quality formulation.

If a colloidal solution needs to be prepared, we recommend gako WetMill Compact to distribute API homogeneously inside the suspension vehicle.

5. Is gako PM140 suggested for hazardous drugs?

Yes, it is possible to work in negative pressure cabinets, which in addition to mixing within the closed environment, increases safety for the compounding of hazardous APIs (such as antineoplastics, cytotoxic medications, and hormones).

6. How do I decide whether I should use gako PM140 alone or in combination with other equipment while preparing a formulation?

Since each API has different physicochemical characteristics, they require different handling and compounding processes. Therefore, if the compounding process requires different steps such as pre-grinding or pre-heating, the relevant equipment (e.g. gako InvoMatic for pre-grinding, gako unguator devices for dispensing, or a hot water bath for pre-heating) should be used, after then **gako PM140** can be used as a complementary device to operate deaeration step. However, if only mixing, melting, or/and deaeration steps are required for the compounding and the API is soluble inside the base, **gako PM140** can be used alone.

7. What is the difference between the gako PM140 and unguator devices?

Although both **gako PM140** and unguator devices are used to combine the APIs with ointment, cream, gel, and suppository bases, certain differences make them unreplaceable by each other. The most important difference is mixing blades. The gako unguator devices use mixing blades to be able to conduct emulsification and suspending processes. On the other hand, the mixing blades generate rapid empty areas and alter the flow direction by exerting pressure on the substances within the container. Consequently, the substances swiftly shift positions inside the mixing jar, occupying the newly formed empty spaces. However, this process also leads to the entrapment of air within the mixture as it becomes obstructed. If emulsification and suspending steps are required for the compounding process, they can be conducted by unguator devices and then, **gako PM140** can be used for deaeration to achieve advanced quality preparation. Another difference is the production size. The **gako PM140** allows the preparation of up to 100 ml compounding. On the other hand, gako unguator devices are used for large batches, enabling the production of up to 2000 ml of compounding when gako unguator PRO is used and up to 500 ml when gako unguator EMP and BASIC are used. Afterward, the batches can be divided into 100 ml jars for the deaeration step with **gako PM140**.



8. Which jar can I use with the gako PM140?

Only PM jars can be used with **gako PM140**. There are two types of PM jars: gako PM jar 100ml HV and gako PM jar 125ml HV+LV.

The gako PM jar 100ml HV is a sterile and disposable jar, 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. The 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 gako unguator 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 unguator jar to the PM jar 100ml HV.

The gako PM jar 125ml HV+LV is a sterile and 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 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 gako PM jar 125ml HV+LV, up to 85 °C by using a hot water bath.

9. How can I choose the correct jar?

If the compounding process includes melting or requires a longer mixing time than 1 minute, the suggested jar is gako PM jar 125ml HV+LV.

If the **gako PM140** is intended to be used for mixing and deaeration for less than 1 minute, gako PM jar 100ml HV.

10. Can I use PM jars also as a primary package for the delivery of compounding to the patient?

Yes. Both gako PM jar 100ml HV and gako PM jar 125 ml HV+LV are disposable jars that can also be used as a primary package.

11. Can I use the PM jars with EMP devices?

Only gako PM jar 100ml HV can be used with unguator devices. The gako PM jar 125ml HV+LV is not suitable for unguator devices.

12. Can I use the unguator jars with the PM140?

No. Although they look similar, there are slight differences between unguator jars and PM jar 100ml HV. The inner bottom of the unguator jar is more slightly oval than the PM jar. Therefore, the mixing blades fit snugly against the walls of the unguator jar and ensure homogeneous mixing, preventing the formulation from accumulating in areas inaccessible to the blades. However, this feature can affect the mixing process negatively when an unguator jar is used with the PM140 by causing compounding accumulation at the edges due to centrifugal movement. The bottom of the PM jar 100ml HV is slightly oval than the unguator jar, so it is suitable for both PM140 and unguator devices.

13. How does the device eliminate the air entrapped inside the formulation?

During the operation, **gako PM140** simultaneously spins and rotates around an axis in opposite planetary motion at a 40° angle. This promotes a centrifugal force pushing the particles through the edges from the center of the PM jar. During this movement, the air entrapped inside the compounding rises and unites with the air in the unfilled area inside the PM jar that provides a space for the particle movement (to achieve efficient mixing and prevent leakage, the PM jar should not be filled. There should be always a remaining area for the movement of the particles). While the device deaerates the compounding with this mechanism, it prevents air entrapment by working without mixing blades.

14. Why is the air entrapped inside the compounding so important? How does it impact compounding?

Air entrapment 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 adsorbing the emulsifier molecules at the air-liquid interface. The final pH of the formula can also be impacted since the bubble formation interferes with the fluid-flow patterns and can modify the nature of the API and its analytical characteristics. Moreover, microorganisms tend to grow in media with the presence of water and air, making most semi-solid dosage forms an ideal place for proliferation. An example is in extemporaneous compounding; bubble formation also may lead to microbial proliferation, increased oxidation, and stabilization problems.

In addition, the dosage variations caused by entrapped air are a high-risk issue, especially while working with small volumes, low dosages, or hormone preparations. For example, in suppositories, each unit must contain an exact dose of the API, calculated ac-



According to the volume of the suppository mold. Since each bubble has its volume, bubble formation causes a displacement of the formulation as large as the volume occupied by it, leading to inaccuracy among the units.

15. What type of APIs can I use with gako PM140?

How should I use it?

With the **gako PM140**, it is possible to mix, melt, and deaerate a wide variety of APIs. Nonetheless, the physicochemical characteristics of the API must be considered, compounding method and the operation time should be determined according to them.

- If the API is liquid and soluble in the base, the standard process will be adding all the components into the PM jar, with a max quantity of 100 g.
- When the API is soluble in the base, but in a powder form, 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 device to avoid an accumulation of the powder in the bottom or the top of the jar.
- If the formulation contains non-soluble APIs, the use of **gako PM140** together with gako unguator is recommended. Primarily, the gako unguator can form a paste and disperse all the components in the base. Afterward, the formula can be placed into **gako PM140** for final mixing and deaeration. Both processes can be carried out using the gako PM jar 100ml HV, which can also be the dispensing package.
- For suppositories and vaginal inserts, **gako PM140** can melt substances up to 45°C within a simple one-step process and is suitable for mixing most heat-sensitive ingredients. For this purpose, the ideal jar is gako PM jar 125ml HV+LV. After mixing the suppository preparation, the compound can be poured into gako Vaginal Inserts & Suppository Molds, which are disposable strips that can also be used as packaging. During this step, gako 3-in-1 Support Rack is designed to hold the strips. After the suppositories solidify, the strips can be closed with gako Sealing Tape to prevent contamination until the time of use.

16. Does the gako PM140 mix both liquids and powders with creams? Do I need to add any wetting agent?

The **gako PM140** can directly incorporate liquid APIs with the base. When a powder API is used in the **gako 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 important to keep in mind the compatibility of the components with the base. This process is necessary before starting the device to avoid an accumulation of the powder in the bottom or the top of the jar.

17. Does the melting process damage the APIs?

No, **gako PM140** operates through a centrifugal motion that is naturally accompanied by heat release, facilitating the melting of substances such as suppository and gelatin bases, or gelling agents. The temperature limit of the device is 45°C (when started at room temperature), and it is, therefore, suitable for mixing most heat-sensitive ingredients. In case higher temperatures are desired, it is possible to pre-heat the formulation externally before mixing.

18. How can I select the time for each preparation?

A brochure has been developed with information for the preparation of different types of dosage forms, containing information such as recommended time, quantity, and temperature for each preparation. Please contact gako or local gako equipment supplier to receive this material.

19. How is the maintenance of the gako PM140?

The **gako 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.

20. Is the gako PM140 noisy?

Under maximum capacity and speed at a distance of 1 m against the wall, the **gako PM140** has an operating volume of approximately 65 dB.



21. How should I place the PM jar inside the gako PM140?

- Place the jar holder on the table.
- Insert the PM jar into the jar holder.
- Turn the jar slightly clockwise.
- Place the PM jar with the jar holder into the well.
- The lid of the PM jar should be complementary to the device and should not remain above. The mixing jar should be placed into the device.

22. What should I do if the lid of the mixing jar is not complementary to the device

- Take the PM jar with the jar holder from the device and put it on the table.
- Hold the PM jar from its body, not the jar lid.
- Take the PM jar with the jar holder from the device and put it on the table.
- Hold the PM jar from the body and turn it inside the jar holder slightly clockwise.
- Make sure the PM jar lid is completely closed.
- Place the PM jar with the jar holder into the well so that the lid is complementary to the device down.

23. How can I prevent leakage?

- Use the gako PM jar 125ml HV+LV if the formulation includes liquid components, lotion base, melting step, or requires mixing time of more than 60 seconds.
- If the gako PM jar 100ml HV is used, make sure the bottom is fully down before using it.
- Do not use the device for the preparation of liquid formulations such as solutions or suspended liquids.
- Before placing the PM jar into the device, make sure its lid is completely closed.
- Do not squeeze too much the PM jar as this will cause deformation of the jar wall. The change of the round shape can lead to leakage.
- Do not fill the PM jar fully. There should always be a remaining area to ensure the movement of the particles during operation. Therefore, the capacity of the gako PM jar 100ml HV is limited to 100 ml even though its internal nominal volume is 120 ml. Similarly, the capacity of the gako PM jar 125ml HV+LV is limited to 125 ml although its internal nominal volume is 180 ml.



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