

Using the Unguator Technology

Thank you for your interest,

Following we provide a comprehensive summary for you in how to operate our Unguator Technology.

Are you already a gako unguator user? Maybe you find some information you want to integrate into your manufacturing process.

If you have additional questions please contact us, the gako competence center:

contact@unguator.com

Concept

The Unguator Technology differs compounds by manufacturing method. The knowledge from compounding by hand is transferred to the Unguator Technology.

Classification of the compound by manufacturing method

- The formulation contains solids which do not dissolve in the foundation and are suspended
→ review **Suspension Ointment**
- The formulation contains an oily phase, an aqueous phase and an emulsifier, without any suspended solids (water in oil, oil in water and quasi-emulsions)
→ review **Emulsion / Solution Ointment**
- The formulation contains a swelling or gelling agent and an oleo-, hydro- or carbomer gel will be manufactured
→ review **Gels**
- The formulation contains semi-solid components
→ review **Soft-in-Soft**
- The formulation contains a sensitive active component or an sensitive foundation
→ review **Specialities**

Assignment of the gako unguator Stirrer

The gako unguator **Standard Mixing Blade** was particularly developed for semi-solid compounds and acts like pestle and spatula together with the mortar.

If micronised solids are incorporated, we recommend always the gako unguator Standard Mixing Blade to moisten the solids with foundation and prevent agglomerates.

Due to the wide contact area of the gako unguator Standard Mixing Blade onto the inside jar wall agglomerates break apart. At the same time, the innovative S-shape accelerates all ingredients into a vortex and they are incorporated into the mixing process.

The gako unguator **Disposable Blade** was particularly developed for emulsion/solution ointments and gels. The material contact is more intensive due to the three times higher amount of blades.

The gako unguator Disposable Blade has almost no contact to the inside jar wall, insoluble solids are **not** distributed homogeneously into the foundation.

Preparing the mixing unit

The mixing unit consists of the gako unguator Jar and the matching gako unguator Stirrer.

1. Remove the gako unguator Jar from the hygienic foil packaging and move the jar bottom down, using the disinfected gako unguator stirrer. Do not touch the golden area of the stirrer and the mixing blade.
2. Leave the stirrer inside the jar and remove the small white jar cap from the jar lid.
3. Slide the lid over the stirrer shaft and move it down with both thumbs. Please note, do not damage the sealing lip with the bayonet noses.
4. Remove the stirrer together with the lid from the jar, move the mixing blade all the way up into the lid. The stirrer can be hygienically set aside.
5. The component can be weighed in into the tared jar, depending on the compounding method and the formulation, review "Weighing in the components".
6. Close the jar including the stirrer and check if the lid is correctly attached. If the lid is tilted compound could leak.
7. Loosen the lid with approx. half a centimeter tilt. Diminuate air by moving the jar bottom up until resistance is felt. Close the jar tightly.
8. Mount the mixing unit into the gako unguator device.

Mounting the jar into the lifting arm

Unguator® e/s, 2100 and Unguator® QMS

- Put in the mixing parameters
- The lifting arm moves into the start position
- Insert the blade of the mixing unit from below through the lifting arm and then screw the threat of the extraction opening into the lifting arm. The jar should be fixed with approx. two to three turns. The top edge of the jar opening is to be seen above the lifting arm.
- Start the mixing process, the Unguator device loads the stirrer automatically.

gako unguator BASIC, EMP and PRO

- Put in the mixing parameters
- gako unguator EMP and PRO: the lifting arm moves into the start position, gako unguator BASIC: move the lifting arm into its lowest possible position.
- Hold the gako logo on top of the jar to the front and insert the mixing shaft directly from the front into the lifting arm. Insert the mixing unit from below and fix the jar with a slight quarter turn counterclockwise into the the lifting arm.
- gako unguator EMP and PRO: the lifting arm moves automatically up, gako unguator BASIC: move the lifting arm up manually.
- Start the mixing process, the gako unguator device loads the stirrer automatically.

Video link, how to mount the jar goo.gl/gtDmLt



Weighing in the components

The components are weighed in directly into the gako unguator jar depending their manufacturing method.

1. Suspension Ointments

Only use microfine or micronised solids. Crystalline solids, which do not dissolve in the compound, need to be prior grinded in a mortar or reworked with an ointment mill.

The Unguator Technology differs between two manufacturing methods of suspension ointments by active ingredients content.

Suspension ointments with an active substance content < 2%

There are two steps to manufacture suspension ointments with less than 2 % active ingredients.

1. Step

Weighing in: Approx. 15% of the foundation (based on the total amount of the preparation)

ground-covering into the jar, add the active ingredient(s) to the side (not in the middle) and cover with 15% foundation (based on the total amount of the preparation) to prevent powder residue sticking on the blade. Important is the use of the standard mixing blade. Move the jar bottom up and diminish air. After the pre-grinding check the compound for agglomerates and repeat the pre-grinding if necessary.

2. Step

Weigh in the remaining active substances (if applicable) cover with the remaining foundation or add the remaining foundation.

Important is to use the standard mixing blade. Move the jar bottom up and diminish air.

Suspension Ointment with more than 2% active ingredients

The amount of active substances is high enough, the pre-grinding is not necessary. The moistening of the solids is ensured due to a longer mixing process.

Weighing in: Approx. 50% of the foundation into the jar, add solids and top it with the remaining foundation. Important is to use the standard mixing blade. Move the jar bottom up and diminish air.

Emulsions/Solution Ointments

Emulsion (Emulsion Ointment at Room Temperature)

Weighing in: Weigh the firmer or oily phase groundcovering in the jar first. Add the liquid components on top.

We recommend to use the disposable blade up to 200 ml. Move the jar bottom up and diminish the air.

In some cases emulsifying refrigerated foundations can cause difficulties.

In this case the process of emulsification can be accelerated by adding the required liquid warmed.

Emulsion+ (Emulsion Ointment with heat application)

If one or more components need to be melted or warm incorporated.

Weighing in: All components are weighed into the jar and melted on a hot-water bath (up to 85 °C). Formulation containing an aqueous phase can be melted in a microwave (up to 85 °C), control the temperature with a thermometer in short intervals to ensure the compound is not overheating.

We recommend to use the disposable blade up to 200 ml. Move the jar bottom up and diminish the air.

Gel

Formulations containing a gelling agent incorporated into liquids or semi-solid foundations. The liquid phase can contain dissolved active and/or inactive substances.

Pre-grinding with glycerol or propylene glycol is not necessary. Manufacturing polyacrylate gels, the base can be added to the liquid.

Weighing in:

- The liquid component will be weighed out first into the jar. Soluble active substances can be administered directly into the jar and dissolved. The gelling agent will be dispersed on top of the liquid component.
- The gelling agent is embedded between two layers of foundation.

We recommend to use the disposable blade up to 200ml. Move the jar bottom up and diminish the air.

Soft-in-Soft

Mixing two or more semi-solid components together, as an example, combining two foundations.

Weighing in: Weigh the two or more semi-solid components in layers into the jar. Move the jar bottom up and diminish the air.

Specialities

Formulations containing surface-active or sensitive active substances or force sensitive foundation.

Therefore, with suspension ointments < 2%, first use the pre-grinding parameters and for the main mixing process use the parameters/program Specialities.

Weighing in: The weighing in depends which formulation type is manufactured.

The Mixing Process

The mixing parameters/mixing program is different according to the formulation type. Review the manual and quick guide of the device.

After the Mixing Process

- Remove the mixing unit from the lifting arm:
 - BASIC, EMP and PRO: remove the mixing unit with a quarter turn clockwise.
 - Q, 2100, 2000 and e/s: remove the mixing unit clockwise.
 - B/R: remove the mixing unit with a quarter turn clockwise.
- Open the lid of the gako unguator Jar and check the compound for consistency, appearance

- rance and homogeneity.
- Removing the mixing blade:
 - gako unguator Standard Mixing Blade:
After the quality check, remove the SMB from the lid downwards.
Adhering compound can be removed into the jar with a spatula.
 - gako unguator Disposable Blade:
After the quality check the disposable blade can stay in the compound. Unlatch the mixing shaft by turning it clockwise and remove it. If desired, the disposable blade can be removed like the SMB and not stay in the compound.
 - Screw the lid loosely onto the jar, if necessary add a gako unguator Varionozzle, gako unguator Applicator or gako unguator ExactDose and close it with the small white lid or the applicator cap. Move the compound close to the lid to prevent a squirting out of the ointment when first dispensed and to reduce the contamination surface. Then close the jar tightly.
 - Label the jar properly and explain the handling of the jar to the patient when dispensed.