

Quick Guide

Unguator Technology - Competence from the Start

Determinate mixing parameters, based on traditional pharmaceutical compounding:

1. Classification of the formulation according to its appropriate compounding

- 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 carbomergel 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**

2. Compounding method and mixing parameters according formulation type

Suspension ointments

Formulations containing one or more micronized solids suspended in one or more foundations.

The Unguator Technology differs between two manufacturing types of suspension ointments by active substance content.

→ **Suspension ointment with an active substance content < 2 %**

The manufacturing of suspension ointments < 2 % is in two-parts.

- **Step 1:**

Weighing in: cover the ground with approximately 30 % of the foundation calculated of the overall formulation, add solids to the side (not into the middle) and cover with some foundation.

The use of the standard mixing blade is recommended.
Move the jar bottom up to diminish air.

We recommend following mixing parameters for the pre-grinding process:

pre-grinding - Level 4 (1290 rpm)				
Jar size	15 - 30 ml	50 - 100 ml	200 ml	300 - 500 ml
Time (min.)	2:30	3:30	5:00	9:55
Stirrer	SMB	SMB	SMB	SMB

- **Step 2:**

Weigh in possible remaining solids and cover it with the remaining foundation. Possible liquid components can be added on top.

We recommend following mixing parameters for the main mixing process:

main mixing process - Level 8 (1930 rpm)				
Jar size	15 - 30 ml	50 - 100 ml	200 ml	300 - 500 ml
Time (min.)	1:30	2:00	3:30	4:40
Stirrer	SMB	SMB	SMB	SMB

→ **Suspension ointment with an active substance content > 2 %**

For suspensions with ingredient content above 2 % the pre-grinding process is not required.

Weighing in: Add 50 % of the required foundation ground-covering, the micronized solids to the middle and the remainder of the foundation on top.

The use of the standard mixing blade is recommended.
Move the jar bottom up to diminish air.

We recommend following mixing parameters:

Level 9 (2100 rpm)				
Jar size	15 - 30 ml	50 - 100 ml	200 ml	300 - 500 ml
Time (min.)	3:00	3:50	6:45	9:30
Stirrer	SMB	SMB	SMB	SMB

Emulsion/Solution ointment

An aqueous and an oily phase are mixed together. The same parameters can be used for solution ointments.

The Unguator Technology differs between two manufacturing types of emulsions ointments.

→ Emulsion ointment at room temperature

Weighing in: First add the oily, firmer phase ground-covering. The fluid components add onto the top.

The use of the disp. Blade is recommended up to 200 ml, for 300-500 ml the standard mixing blade.

Move the jar bottom up to diminish air.

We recommend following mixing parameters:

Level 9 (2100 rpm)				
Jar size	15 - 30 ml	50 - 100 ml	200 ml	300 - 500 ml
Time (min.)	2:00	2:20	4:10	5:30
Stirrer	Disp. Blade	Disp. Blade	Disp. Blade	SMB

→ Emulsion ointments with heat application

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

Weighing in: Add all components to the jar and melt them in a hot water bath (up to 85°C / 185° F). Formulation containing an aqueous phase can also be melted in the microwave (up to 85°C / 185° F).

The use of the disp. Blade is recommended up to 200 ml, for 300-500 ml the standard mixing blade.

Move the jar bottom up to diminish air.

We recommend following mixing parameters:

Step 1: combining phase - Level 0 (650 rpm)				
Jar size	15 - 30 ml	50 - 100 ml	200 ml	300 - 500 ml
Time (min.)	0:30	0:30	0:30	1:00
Stirrer	Disp. Blade	Disp. Blade	Disp. Blade	SMB

Step 2: emulsion phase - Level 8 (1930 rpm)				
Jar size	15 - 30 ml	50 - 100 ml	200 ml	300 - 500 ml
Time (min.)	1:00	1:00	1:00	2:00

Step 3: cool down phase - Level 0 (650 rpm)				
Jar size	15 - 30 ml	50 - 100 ml	200 ml	300 - 500 ml
Time (min.)	9:55	9:55	9:55	9:55
Use cool down phase and emulsion phase alternativ until compound reaches room temperature.				

Gel

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

Weighing in: Add the liquid phase into the jar, dissolvable solids can be added and dissolved. Spread the gelling agent onto the top. Embed the gelling agent between two layers of the semi-solid foundation.

The use of the disp. Blade is recommended up to 200 ml, for 300-500 ml the standard mixing blade. Move the jar bottom up to diminuate air.

We recommend following mixing parameters:

Step 1: moistening phase - Level 9 (2100 rpm)				
Jar size	15 - 30 ml	50 - 100 ml	200 ml	300 - 500 ml
Time (min.)	0:30	0:30	0:30	1:00
Stirrer	Disp. Blade	Disp. Blade	Disp. Blade	SMB
Step 2: swelling phase - Level 0 (650 rpm)				
Jar size	15 - 30 ml	50 - 100 ml	200 ml	300 - 500 ml
Time (min.)	8:30	9:30	9:55	9:55
Alternate the mixing steps at least twice or until a homogeneous gel structure is reached!				

Soft in Soft

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

Weighing in: Layer two or more semi-solid components into the jar.

We recommend following mixing parameters:

Level 8 (1930 rpm)				
Jar size	15 - 30 ml	50 - 100 ml	200 ml	300 - 500 ml
Time (min.)	1:40	2:10	4:10	5:10
Stirrer	Disp. Blade or SMB	Disp. Blade or SMB	Disp. Blade or SMB	SMB

Specialites

Formulations containing surface-active, temperature sensitive or sensitive active substances or force sensitive foundations.

Weighing in: review formulation type.

We recommend following mixing parameters:

Level 3 (1130 rpm)				
Jar size	15 - 30 ml	50 - 100 ml	200 ml	300 - 500 ml
Time (min.)	5:00	7:30	9:55	2 x 8:30
Stirrer	Disp. Blade or SMB	Disp. Blade or SMB	Disp. Blade or SMB	SMB

3. gako unguator notes

- All gako unguator devices guarantee good pre-grinding results if micronized solids are used. Be aware, the particle size will not be changed.
- Always diminuate air by moving the jar bottom up before mixing.
- Every compound has to be free of agglomerates after the mixing process.
- Observe the general notes from the operation manual

4. Abbreviation

- disp. Blade - Disposable Blade
- SMB - Standard Mixing Blade
- rpm - rounds per minute

5. Liability

The gako unguator mixing parameters are an assistance in the right handling of the Unguator Technology. The manufacturing with the gako unguator devices lies in the responsibility of the pharmaceutical personal.