

# Operating Instructions and Production Recommendations



UNGUATOR® Q

***Dear UNGUATOR<sup>®</sup> user,  
thank you for choosing the UNGUATOR<sup>®</sup> Mixing Technology,  
a quality system  
for advanced prescription compounding.***

***Please read the operations manual carefully.  
For additional information about the use  
and operation of the  
UNGUATOR<sup>®</sup> Mixing Technology,  
please feel free to contact us at  
[contact@unguator.com](mailto:contact@unguator.com)***

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## 1. Installation information

Select a suitable location for the UNGUATOR® Q.

**CAUTION!** The UNGUATOR® Q weighs almost 30 lbs (16,5 kg). It is recommended to have an assistant while carrying and moving the equipment to the final destination.

Ensure that there is enough space to operate the UNGUATOR® Q. This must include sufficient space around the UNGUATOR® Q to provide proper ventilation.

Select a proper environment:

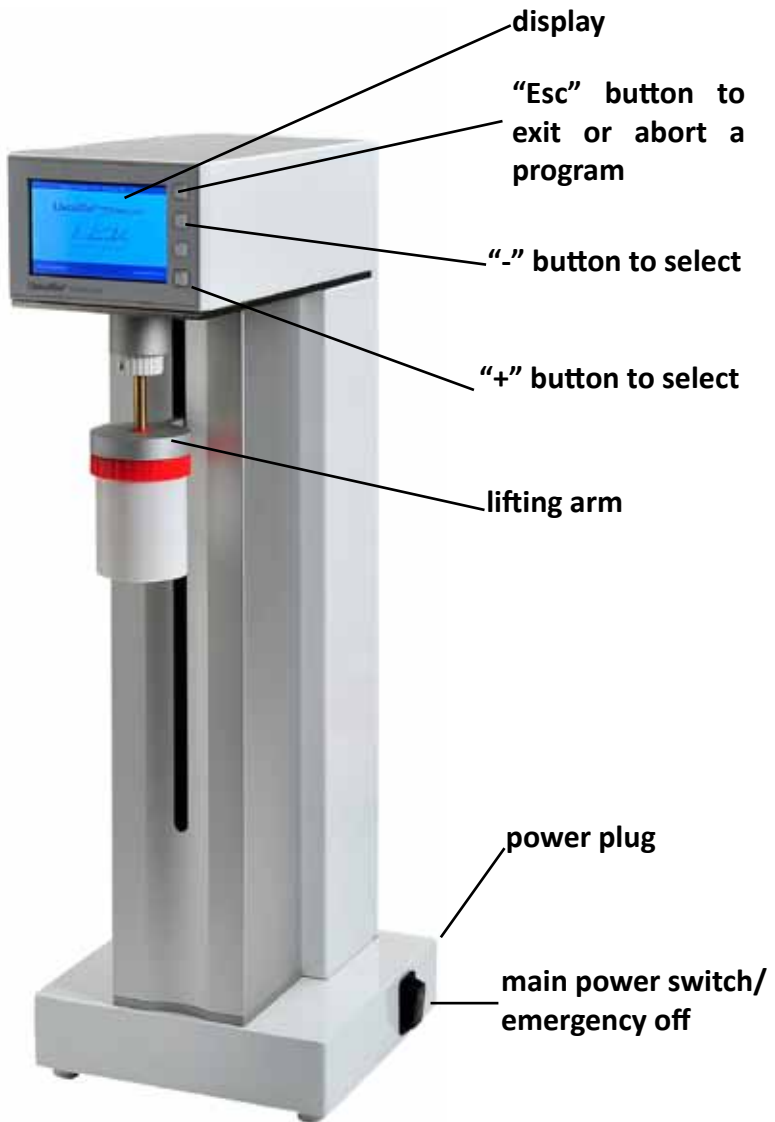
- Solid, horizontal surface
- Away from direct air flow from air conditioning systems, heaters, open windows or fans.
- Keep the temperature between 15°- 30° C (59°- 86°F) and maximum humidity of 80%.
- Clean, dry and dust-free.

Remove all components from the cardboard box. Check to ensure that the following components are included in your shipment:

- UNGUATOR® Q mixing device
- Power cable
- Operating instructions

Please contact your responsible UNGUATOR® dealer and/or supplier immediately in case that components are missing or arrived damaged. Afterwards, we will not accept any claims regarding missing or defect items, they will be for your account!

Please hold on to the original cardboard box and packing material in case you have to send the UNGUATOR® Q in for service.



Pic.1: UNGUATOR® Q

## 2. Initial Operation

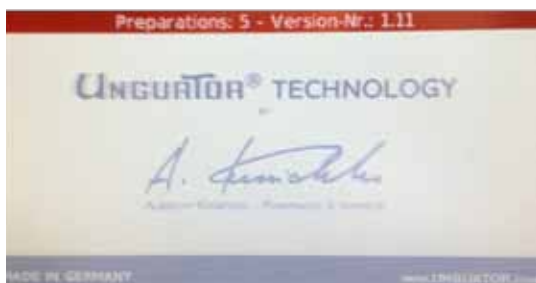
On the back of the UNGUATOR® Q you will find the interface for the power cord. The power switch “O/I” is also the emergency switch and it is located at the base of the machine, on the right side. Initially check if the power switch of the Unguator® is switched off. Second, connect the power cable to the device, and finally connect the power cable to the outlet.

Now you can turn the power switch of the UNGUATOR® QMS on using the “I / O”. The device is ready to be used.

During cold weather condition, plan in advance 30 minutes to allow the UNGUATOR® Q to acclimate.

## 3. Display-operation

The face of the UNGUATOR® Q device shows both a panel with four keys “Esc”, “-”, “+”, “ok” for manual control or command input and a display screen. After turning the UNGUATOR® Q on pressing the main power switch, a splash screen appears on the display. The splash screen of your device might vary from below picture 34. The top bar shows the total number of preparations and current software version code of the device. By pressing any key the “Start Menu” will appear.



Pic. 2: Display with splash screen

## 4. Menu guide

On the right of the UNGUATOR® Q face you will find a panel with keys “Esc”, “-”, “+” and “ok”. By operating the keys “+” or “-” you may move up and down the navigation bar. Pressing “ok” you may select and confirm. Pressing the “Esc” key you move back one step.

Additional options...





Pic. 3.: Select “display”, “language”, and “key sound”

Pressing the “Esc” key you will move from the “Start Menu” to the setting options. Here, you may change the background color of your display, the operating language and activate or deactivate a key sound.

Changes in the language or in the color background might take a few seconds loading prior being activated. After pressing the “Esc” key you will reach the “Start Menu” again.

You will find descriptions of the “Start menu” programs in the following chapter 6.3, “Formulation programs”.

## 5. UNGUATOR® Technology

The UNGUATOR® Technology reduces the mechanical preparation of formulation ointments to the least common denominator. The core of UNGUATOR® Technology consists of the patented arrangement of the UNGUATOR® Mixing Blade adapted to the requirements of prescription ointments and the UNGUATOR® Jar that serves as both a hygienic mixing jar and a hygienic dispensing jar.

The principle of the preparation method using UNGUATOR® Technology in the closed UNGUATOR® Mixing System is quick and easy to learn, true to the motto.

### learning by doing

A little experience will make it easy to prepare ointments though they may seem rather complicated at first. Using the UNGUATOR® Technology enables the pharmacy to better prepare prescription ointments in a shorter period of time compared to conventional methods that were used prior to the invention (1994). For the first time, it is possible to not only standardize ointments, but also validate them.

## 5.1 UNGUATOR® mixing machines

The current UNGUATOR® mixing machines - UNGUATOR® B/R, UNGUATOR® e/s, UNGUATOR® 2100 and UNGUATOR Q - are useful and advanced improvements on the first UNGUATOR® launched in 1994. They are designed for a working capacity of approx. 500 work hours which corresponds to approximately 15,000 to 20,000 preparations.

The UNGUATOR® mixing machines feature a high safety standard and were tested by TÜV-Rheinland, Germany for safety. The devices are manufactured under license and maintained by defined service partners.

Product quality, product uniformity and reproducibility of ointments prepared individually and in batches were improved with the increasing automation of the UNGUATOR® units starting with the individual model B/R- through e/s-, Q- and 2100 model.

Method of ointment preparation	Pharmaceutical Quality	Uniformity of ointment	Lifting arm	Mixing parameters
Mortar and pestle	++	+	n/a	manual
UNGUATOR® B/R	+++	++	manual	manually adjustable
UNGUATOR® e/s	+++	+++	automatic	individually programmable
UNGUATOR® Q	++++	++++	automatic	Totally automatic
UNGUATOR® 2100	++++	++++	automatic	fully automatic

Tab. 1: Quality improvement with increasing automation

### 5.1.1 UNGUATOR® B/R

The UNGUATOR® B/R is the basic machine with controlled mixing motor and manual jar guidance.



Pic. 4: UNGUATOR® B/R

## 5.1.2 UNGUATOR® e/s

The UNGUATOR® e/s machine was developed for efficient individual and batch preparations. The automated stroke enables the user to leave the UNGUATOR® e/s during the mixing process to serve a customer for instance or to prepare the next formulation at the same time.

The precisely set sensor for the automatic oscillation arm will always ascertain at each upward or downward stroke the exact position of the UNGUATOR® Jar bottom or lid. This guarantees that the UNGUATOR® Jar is always accessible to the UNGUATOR® Mixing Blade despite the inevitable vertical motion during the mixing process. If the stroke length of the first stroke was taken as a constant value, then the active ingredient weighed out in the lower region of the UNGUATOR® Jar might not be included in the mixing process by the UNGUATOR® Mixing Blade, getting „lost“ at the bottom. The lifting technique of the UNGUATOR® Mixing System prevents this from happening, so that the result of the mixing process is not just a homogeneous ointment, but also one with the desired ratio of active ingredients.



Pic. 5: UNGUATOR® e/s

## 5.1.3 UNGUATOR® 2100

The UNGUATOR® 2100 shows all the advantages of its predecessors and can therefore automatically control the mixing parameters for each UNGUATOR® Jar size and different types of ointments. The user may program individual mixing parameters with a maximum of 180 additional programs that may be individually saved. The UNGUATOR® 2100 can be connected to a PC via USB interface.

An integrated microprocessor measures the actual revolutions of the UNGUATOR® Mixing Blade carried out by the UNGUATOR® 2100. This guarantees that the selected mixing program will always be identical, even for paste-like preparations, which usually might demand more power from the mixing motor. This makes it easy to develop new formulations, cosmetics, etc. using the UNGUATOR® 2100, since only the composition would change but not the mixing program. As a result, ointments can now finally be reliably reproduced even in smaller quantities.



Pic. 6: UNGUATOR® 2100

The adjustable stroke speed, or the speed of the upward or downward motion of the automated oscillation arm, is another unique feature of the UNGUATOR® 2100. This allows

the UNGUATOR® Mixing Blade to rotate at lower speed while the UNGUATOR® Jar quickly travels up and down and vice versa. This new function is particularly useful using a low rotating speed of the UNGUATOR® Mixing Blade since it allows the UNGUATOR® Mixing Blade to mix an ointment homogeneously with a slow stroke.

## 5.1.4 UNGUATOR® Q

The UNGUATOR Q is the result of continuous improvement of the UNGUATOR® e/s from the year 2003.

It combines both the mixing functions of the UNGUATOR® e/s and the operating concept of the UNGUATOR® 2100. The basic functionality of the e/s - System, with the setting parameters of the mixing rotation speed and time are retained. A significant innovation of the UNGUATOR® Q is the possibility of scaling one mixing program already created automatically to another jar size. This enables a constant quality of the formulations and as a consequence, has a tremendous time saving result, since recalculation can be very time consuming and complex.



Pic. 7: UNGUATOR® Q

## 5.2 UNGUATOR® Assortment

Appart from the UNGUATOR® Standard Mixing Blade (SMB), the UNGUATOR® Disposable Blade (Disp. Blade) and the UNGUATOR® Jars, the UNGUATOR® Assortment provides additional and useful components. These include dosing aids such as the UNGUATOR® Varionozzles and UNGUATOR® Applicators, removal or transfer aids such as the UNGUATOR® Spindle, the UNGUATOR® Coupling and the patented AirDynamic® Pumpball System. All UNGUATOR® products are compatible with all currently available UNGUATOR® Mixing devices.

### 5.2.1 UNGUATOR® Mixing Blade (MB)

The UNGUATOR® Standard Mixing Blade and the UNGUATOR® Disposable Blade are designated UNGUATOR® MB's. The UNGUATOR® MB's are steadily guided up and down inside the UNGUATOR® Jar. Their special design results in a tight contact between the mixing blade and the inside wall of the UNGUATOR® Jar, which serves, primarily, for comminuting the substances during the mixing process. Additionally forced mixing in the whole mixing unit is achieved through the shape and vibration of substances while preparing the ointment.

The lubricating effect of the ointment and substances generally protects the UNGUATOR® Jars and the UNGUATOR® MB against abrasion. Discolorations of the mixing blade are mostly irreversible and therefore harmless. All UNGUATOR® MB's are dishwasher safe.

## UNGUATOR® Standard mixing blade (SMB)



Pic. 8: UNGUATOR® SMB

UNGUATOR® SMBs are adjusted to the size of each individual UNGUATOR® Jar. While the UNGUATOR® SMBs for 100 and 200 ml and for the 300 and 500 ml jars have the same mixing blade diameter, their shaft length differs. This must be taken into consideration, particularly when using the UNGUATOR® e/s and the UNGUATOR® 2100, since the use of the wrong length may cause problems with the automated stroke.

Always make sure the UNGUATOR® MB used is the right length, and that it is clean prior use. (e.g. with isopropanol 70%).

The UNGUATOR® SMB is suitable for the production of all formulations. For suspension ointments and glass cleaning operations, we recommend the use of the UNGUATOR® Disp. Blade.

## UNGUATOR® Disposable Blade (Disp. Blade)



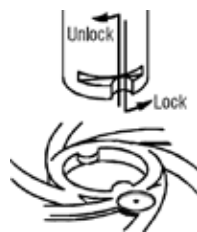
Fig. 9: UNGUATOR® disposable blade

The UNGUATOR® Disp. Blade is suitable for all UNGUATOR® devices. The mixing blade of UNGUATOR® Disp. Blade is connected to the UNGUATOR® Disp. Blade shaft by twisting the blade counterclockwise and can be disconnected after the mixing process with a clockwise turn.

The material contact in the ointment is three times as high as when using the Disp. Blade compared to the UNGUATOR® SMB at the same mixing speed. The counter rotating twist of the mixing blades causes intensive material vibration in the material to be mixed and achieves good product quality faster than using the UNGUATOR® SMB. We do however recommend using the same mixing time as for the UNGUATOR® SMB.

In the process of final quality control the mixing blade can be picked up and discarded with the small end of the shaft, or left inside the jar. Cleaning is limited to the UNGUATOR® Disp. Blade shaft. We recommend using the UNGUATOR® Disp. Blade for substances that may

discolor the regular blade. This type of UNGUATOR® MB also comes with different shaft lengths. The range of UNGUATOR® Jar sizes that can be used for the application is marked for orientation on the weak end of the shaft. (15-100 ml and 200 ml respectively)

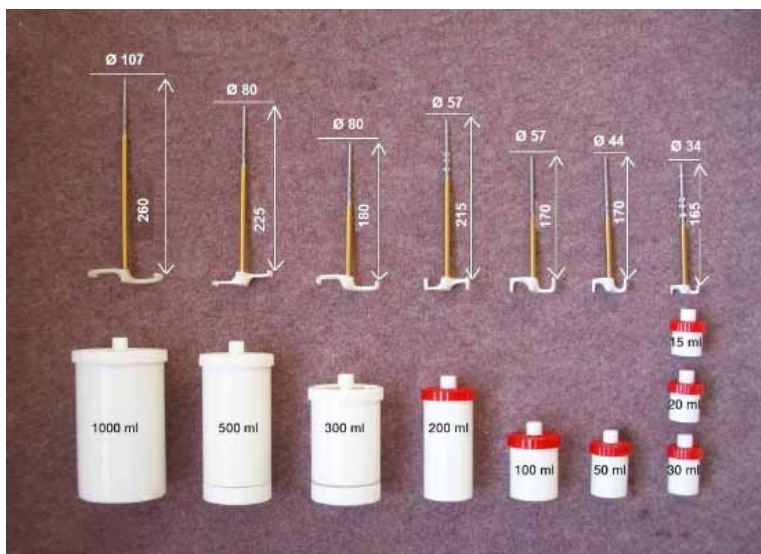


Pic. 10: Handling the UNGUATOR® disp. blade

## Assignment of the UNGUATOR® MB

Please take care to use the correct UNGUATOR® SMB for the corresponding UNGUATOR® Jar (see Pic. 8). Selecting the wrong shaft/blade may cause problems and failure messages.

Please also ensure that the right shaft is used when working with the UNGUATOR® Disp. Blade. Both available shafts are marked for use with sizes 15–100ml or 200ml in the UNGUATOR® Jar. They have to be combined with the correct UNGUATOR® Disp. Blade, and while the same UNGUATOR® Disp. Blade is used for the 100 and 200ml UNGUATOR® Jar sizes, it still needs a different shaft for each. See also the operating instructions that come with the disposable blade shafts.



Pic. 11: Assignment of the UNGUATOR® SMB with different length of shafts

## Flowing recesses of the UNGUATOR® SMB

The flow-adapted shape of the UNGUATOR® SMB generally cleans itself during the rotating penetration of the ointment. Unmixed ingredients may adhere to recesses of flow of the UNGUATOR® SMB depending on ointment's ingredients' compatibility of weighted formulation and also if the UNGUATOR® Jar is considerably under filled (e.g. large volumes of powder). These remnants should be transferred into the UNGUATOR® Jar using a spatula when about half of the mixing time is complete. The air should be decreased again following this process. When using the UNGUATOR® Disp. Blade, however, there are no recesses of flow and no remedial work is generally required.

## Heating

The heat that develops from the friction between the UNGUATOR® MB and the inside wall of the UNGUATOR® Jar is required. Decreased viscosity increases the wettability of powders and accelerates the penetration of potential powder pockets. Even the emulsifying readiness of fats and oils is benefited by heat. A temperature of 54°C/129°F was the maximum taken after 6 minutes of mixing a highly pasty preparation made of vaseline and zinc oxide aa at full speed. This temperature increase is generally safe for the substances used in the pharmaceutical field. Ointments of low viscosity only heat slightly [2]. Volatile substances such as ethereal oils or alcohol do not evaporate from the closed UNGUATOR® Mixing System.

## Cleaning the UNGUATOR® MB

The UNGUATOR® MB is normally cleaned with a paper towel and, if necessary, held under a hot water faucet and then dried with the paper towel. UNGUATOR® MBs can also be cleaned in a dishwasher.

The UNGUATOR® devices as well as the UNGUATOR® line of products should never be treated with sharp-edged objects or abrasive cleaning agents.

### 5.2.2 UNGUATOR® Jar

The UNGUATOR® Jar is both the mixing and the dispensing jar and is therefore designed as an expendable or disposable jar. The UNGUATOR® Jar guarantees evaporation-free and contamination-free preparation in the air-reduced mixing space.

The UNGUATOR® Jar Lid closes the UNGUATOR® Jar to ensure no loss of active ingredients.

Used as a dispensing jar, the UNGUATOR® Jar corresponds to the guidelines for quality assurance from the German Chamber of Pharmacists ("Apothekerkammer").

With its small dispensing opening, comparable to a tube and without an environmental contamination surface, the UNGUATOR® guarantees the minimization of negative quality interference demanded by section 13, ApBetrO (Pharmacist Operating Regulations); including those caused by germs on the fingers when dispensing the ointment. Consequently, the user can remove the prescription ointment from the UNGUATOR® Jar very hygienically.



Pic. 12: UNGUATOR® Jar

The UNGUATOR® Jar is resistant to hot-water baths and microwaves with temperatures below 85°C/185°F. Higher temperatures may alter the tightness of the UNGUATOR® Jar and the displaceability of the bottom (“push-up process might be negatively impacted).

The UNGUATOR® material becomes brittle at temperatures below 0 °C/32 °F. UNGUATOR® Jars are available in the following sizes: 15/28 ml, 20/33 ml, 30/42 ml, 50/70 ml, 100/140 ml, 200/280 ml, 300/390 ml, 500/600 ml and 1000/1250 ml (rated volume/filling volume).

The standard color for the UNGUATOR® Jar housing is white and the UNGUATOR® Jar Lid is red. The 300 ml, 500 ml and 1000 ml UNGUATOR® Jars come with white lids. In addition, the 20 ml to 200 ml UNGUATOR® Jars are available in the pastel colors pink, light yellow, light blue and turquoise. Furthermore, UNGUATOR® Jars from 20 to 200 ml are available with special colors lids, green, blue and white. Upon special demand and defined quantity, UNGUATOR® Jars from 20 to 200ml may also be ordered in customized colors.

All UNGUATOR® Jars come sealed in plastic packaging. Cleaning or disinfection prior usage could put the certified asepsis at risk. We would recommend storing the UNGUATOR® Jars in its plastic packaging after opening for protection against possible dust contamination. The UNGUATOR® Jar sizes 300 to 1000 ml are particularly well suited as storage and transfer vessels for semisolids and other preparations. Since the contents dispensed using the movable jar bottom are always close to the lid, the UNGUATOR® Jar solves the problem of the unsightly contents in traditional porcelain vessels used previously. Evaporation, formation of crust, contamination and oxidation processes can thereby be avoided to a great extent. Furthermore, the contents of the UNGUATOR® Jar can be moved close to the lid after spatula dispensing using the UNGUATOR® Spindle or the AirDynamic® Pumpball System.

The body of the UNGUATOR® Jar sizes 300 to 1000 ml can be cleaned in a dishwasher as long as it has not left the pharmacy. Asepsis has to be ensured before reuse though. The movable bottom of the UNGUATOR® Jar is not suitable for the dishwasher and the sealing lip of the UNGUATOR® Jar Lid may be destroyed after repeated mixing. The corresponding UNGUATOR® Jar Lids or jar bottoms can be ordered in sets of five and used for the economical reuse of the body.



The UNGUATOR® Jar is subject to periodic inspections in accordance to the German “ZL” packing regulation DK II/94. All plastic materials, which come into contact with food are manufactured according to the legal requirements of the EU plastic regulation N° 10/2011 and N° 1935/2004 (version 01/2013).

A certificate of analysis is issued after batch-defined examinations. The documentation of primary packaging materials at the pharmacy stipulates that the manufacturer’s test certificate (certificate of analysis) is retained after receiving visual inspection. This certificate is affixed to the plastic packaging of the UNGUATOR® Jars. It may be removed from the plastic packaging as needed and added to the records.

Analysenzertifikat / Certificate of Analysis		Dat. 01.03.2012
<b>UNGUATOR® Kruke / Jar</b>		
EINWEGEFÄSS VOR GEBRAUCH NICHT SPÜLEN		
DISPOSABLE / DO NOT RINSE BEFORE USAGE		
NENN- / FÜLL- / NOMINAL- / FILLING -VOL.: 50/70 ml		
PZN: 0471975 * INHALT / PACKING UNIT:10 ST / pcs		
ART. / PROD.-NR.: 808 CHARGE: 1234/56P78		
Geprüft nach ZL-Verp.-Vorschrift: DK II/94		
Examined acc. to central lab. pack. regul.: DK II/94		
Lichtdurchlässigkeit / Opaqueness	:	OK
Partikelgehalt / Particle Concentration	:	OK
Farbbeständigkeit / Color Fastness	:	OK
Dichtigkeit / Seal Integrity	:	OK
Mikrobiologie / Microbiology	:	OK
gez/signed: Grieser (head of quality assurance)		
<b>GAKO® Konietzko GmbH * <a href="http://www.unguator.com">www.unguator.com</a></b>		



Plc. 13: Certificate of Analysis for the UNGUATOR® jar of 50 ml

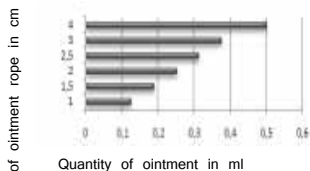
## Notes on Dispensing Ointment

Each customer should be given specific instructions at how to apply the UNGUATOR® Jars when handing to the individual client. The use of the UNGUATOR® Spindle should be explained for large UNGUATOR® Jars. Low viscosity ointments should be equipped with an UNGUATOR® Applicator or an UNGUATOR® Varionozzle to reduce the dispensed volume. Medium viscosity ointments can easily be extracted through the regular opening of the UNGUATOR® Jar. Very pasty ointments (e.g. pasta zinc) may not necessarily be pressed through the regular opening, even by using a spindle.

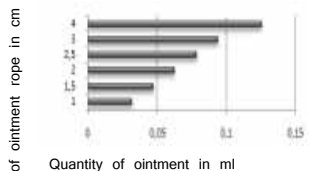
In this case, once the UNGUATOR® Jar lid has been removed, the ointment can be extracted with the help of a spatula, similar to handling conventional jars with a regular lid. If the UNGUATOR® Jar Lid has been removed, the ointment should be pushed up close to the lid after each dispensing process, using the UNGUATOR® Spindle or the AirDynamic® System.

The diameter of the dispensing nozzle allows simple dosing of the quantity of ointment to be applied using approximate values. The regular dispensing nozzle in the screw lid of each UNGUATOR® Jar has a diameter of 8mm. The varionozzles or applicators reduce the

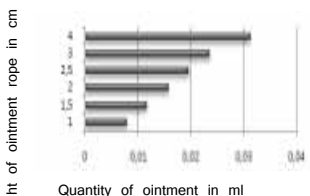
diameter to 4, 2 or 1 mm. The approximate values represented in the following diagrams may also be helpful to weight out concentrated active substances or regular trituration from the UNGUATOR<sup>®</sup> Jar.



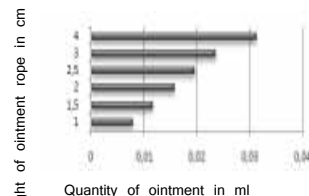
Pic. 14: Dispensing with regular UNGUATOR<sup>®</sup> varionozzle



Pic. 15: Dispensing with UNGUATOR<sup>®</sup> 1mm varionozzle or UNGUATOR<sup>®</sup> applicator short



Pic. 16: Dispensing with UNGUATOR<sup>®</sup> 2mm varionozzle or UNGUATOR<sup>®</sup> applicator long



Pic. 17: Dispensing with UNGUATOR<sup>®</sup> varionozzles 4 mm

## 5.2.3 UNGUATOR<sup>®</sup> Varionozzles

The UNGUATOR<sup>®</sup> Varionozzles with inner diameters of 1, 2 or 4 mm can be pressed into the dispensing opening of the UNGUATOR<sup>®</sup> jar lid. They reduce the opening size, making it possible to safely dose even low-viscosity formulations. The viscosity of the finished product normally specifies the diameter of the UNGUATOR<sup>®</sup> Varionozzles. The softly rounded surface allows ointment to be pleasantly distributed on the skin.



Pic. 18: UNGUATOR<sup>®</sup> Varionozzles

The coloring was selected corresponding to the wavelength of light:

- 4 mm: red (long-wavelength light)
- 2 mm: yellow
- 1 mm: blue (short-wavelength light)

## 5.2.4 UNGUATOR® Applicators

The UNGUATOR® Applicators reduce the dispensed quantity of low-viscosity formulations and are particularly helpful in cases where the ointment must be applied precisely.

### UNGUATOR® Applicator short

The UNGUATOR® Applicator short with a diameter of 1mm is obligatory for nose and ear ointments. The UNGUATOR® Applicator short comes with a cap to close the applicator



Pic. 19: Applicator short

### UNGUATOR® Applicator long



The UNGUATOR® Applicator long with a diameter of 2 mm allows formulations to be introduced into large orifices of the body or probes. Moreover, the UNGUATOR® Applicator long also comes inside each UNGUATOR® 200 ml Jar to help pushing up the bottom of this jar size in full. The UNGUATOR® Applicator long is generally available both with and without cap.

Pic. 20: Applicator long

## 5.2.5 UNGUATOR® Spindle

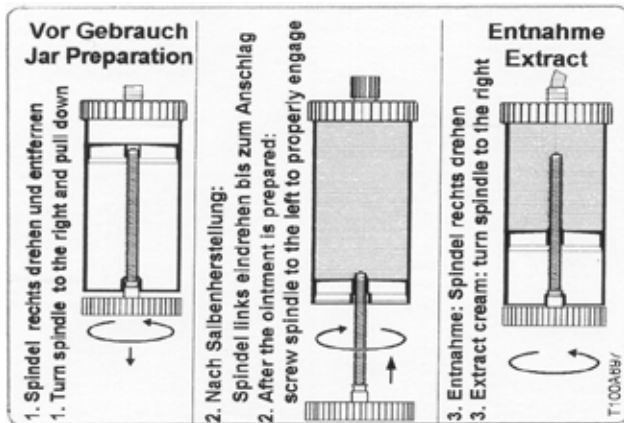
The UNGUATOR® Spindle serves as a dispensing system for UNGUATOR® jar sizes 300 ml or 500 ml UNGUATOR® Jars that come with UNGUATOR® Spindles. The spindle has to be removed by rotating it clockwise prior the mixing process. The bottom can be slid up and down when the UNGUATOR® Spindle is screwed slightly (1/2 to max. 1 turn) counterclockwise without perforating the movable bottom (a slight resistance can be felt before the bottom is perforated).

Air can be decreased by placing the UNGUATOR® Jar onto the table and using both hands pushing the jar against the table.

Before giving the UNGUATOR® Jar to the customer, the UNGUATOR® Spindle must be screwed in the UNGUATOR® Jar counter clockwise from the bottom till it locks into place. The UNGUATOR® Spindle must be turned clockwise to extract the ointment. To remove

the ointment the UNGUATOR® Spindle must be twisted to the right. One turn dispenses approx. 20 ml of the contents of the UNGUATOR® Jar.

**Caution!** If the movable bottom is accidentally perforated or the spindle is permanently locked in the bottom of the jar, the UNGUATOR® Jar may only serve as dispensing or storage vessel and can no longer be used for the mixing process.



Pic. 21: How to operate the UNGUATOR® Spindle



Pic. 22: UNGUATOR® Spindle

## 5.2.6 UNGUATOR® Coupling

The UNGUATOR® Coupling connects two UNGUATOR® Jars by the threads of their dispensing openings and is very useful when preparing ointments in larger batches. Transferring a formulation from a larger UNGUATOR® Jar into a smaller UNGUATOR® Jar using the UNGUATOR® Coupling will ensure hygiene from the mixing process to the end user.

The 200ml UNGUATOR® Jar becomes a convenient transfer device to smaller UNGUATOR® Jars when their UNGUATOR® Jar bottoms are carefully pressed towards the work surface using an UNGUATOR® Applicator (long) screwed on a 30 ml UNGUATOR® Jar.



Fig. 23: UNGUATOR® Coupling

In addition to the UNGUATOR® Coupling, required for transferring from a 300 ml or 500 ml UNGUATOR® Jar into a smaller UNGUATOR® Jar, both the UNGUATOR® spindle and the AirDynamic® Pumpball System may also be used. Dispensing and transferring a formulation via the regular UNGUATOR® Jar nozzle from a 1000ml UNGUATOR® Jar is practically only possible using the AirDynamic® Pumpball System.

We recommend transferring the formulation after mixing as soon as possible, since the formulation is still warm and less viscous.

## 5.2.7 AirDynamic® Pumpball System



Pic. 24: UNGUATOR® AirDynamic® Pumpballsystem

The AirDynamic® Pumpball System optimizes batch preparation within the closed system:

- Contamination-free transfer
- Contamination-free storage

The AirDynamic® Pumpball System has been designed to apply with UNGUATOR® Jars from size 300ml to 1000ml to extract mixtures. An adapter connected to a pumpball is affixed to the center hole on the body's bottom of the

UNGUATOR® Jar with an air-tight connection.

By pumping air into the lower chamber of the UNGUATOR® Jar using the pumpball, the pressure thus generated moves the bottom upward. Thanks to the AirDynamic® Pumpball System, even thick pastes can be dispensed via the small dispensing opening in the screw cap or transferred to small UNGUATOR® Jars using the UNGUATOR® Coupling. The material outlet velocity depends on viscosity which may be reduced through heating.

The air pressure that had developed in the lower chamber of the UNGUATOR® Jar can be relieved by opening the valve screw. This is mandatory after the transfer process using the UNGUATOR® Coupling **before the smaller UNGUATOR® Jar is removed**. Otherwise this may result in considerable contamination of the immediate environment, depending on the formulation viscosity.

## 6. General guidelines for the UNGUATOR® Technology

### 6.1 Preparing the UNGUATOR® Mixing System

The UNGUATOR® Mixing System consists of an UNGUATOR® Jar, an UNGUATOR® MB and the components of the formulation to be mixed.

First, the UNGUATOR® jar cap (small white screw cap) of the UNGUATOR® Jar and then the UNGUATOR® Jar lid (large red or white screw cap) must be unscrewed from the UNGUATOR® Jar.

Second, the UNGUATOR® MB is inserted into the UNGUATOR® Jar housing, sliding the UNGUATOR® Jar down. The UNGUATOR® Jar lid is then slid onto the UNGUATOR® MB standing in the UNGUATOR® Jar housing and pressed down firmly using both thumbs. Ensure that the sealing lip of the UNGUATOR® Jar lid opening is not damaged by the bayonet noses because the ointment may otherwise rise on the UNGUATOR® MB shaft during the mixing process.

Third, the UNGUATOR® MB is carefully removed from the UNGUATOR® Jar and the UNGUATOR® Jar lid will be moved all the way in the direction of the Blade. Both parts, i. e. the UNGUATOR® MB and the UNGUATOR® Jar lid are put down or possibly tarde on the balance together with the UNGUATOR® Jar.

## 6.2 Weighing portion of the formulation

Generally, oily, greasy, aqueous and pulverized ingredients can be weighed out into the UNGUATOR® Jar all at the same time. It is however advantageous to consider certain general procedures to optimize the mixing results. Generally, know-how gained from the traditional preparation of ointments is very helpful when using the UNGUATOR® Mixing System. As already mentioned at the beginning of the operating instructions, true to the motto:

### **learning by doing**

Listed below are the seven different general procedures used to produce the routine standard formulations in pharmaceutical preparation of ointments: EMULSION, EMULSION +, NORMAL, SUSPENSION <2%, SUSPENSION >2% as well as GEL and SUPPOSITORIES. Due to the rapid heat generation, powder mixtures should be processed only at very low speed. In the following, these standard formulations will be defined and the recommended procedure on weighing described. This will produce a code of practice for orientation. This does not exclude other possible methods for optimization.

For mixtures with high liquid content, ensure that the ointment base on the UNGUATOR® Jar Bottom is first carefully placed around the sealing lip. This enhances the leak tightness of the UNGUATOR® Jar when it is filled. For UNGUATOR® Jars of 200ml and up an active ingredient proportion of less than 5%, of the active ingredient can be filled alternating with the foundation ointment over two or more levels to speed up vertical intermixture.

## 6.3 The mixing process with the UNGUATOR® Q

The UNGUATOR® Q is the result of continuous improvements of the UNGUATOR® Technology.

The integrated programmable software that automates the UNGUATOR® Q Mixing System completely turns the device into a universal machine for the production of formulations!

The UNGUATOR® Q works with two quiet, high duty, permanent motors and is an intelligent ointment mixing machine for formulation from 15-500ml. You can work in the ranges of 0 to 2400 rpm and produce homogeneous formulations. It is also possible to set intervals and the device gives you the opportunity to interrupt the formula manufacturing in a controlled manner.

After selecting a program and the size of the UNGUATOR® Jar a microprocessor controls the mixing parameters for a consistent and reproducible product quality.

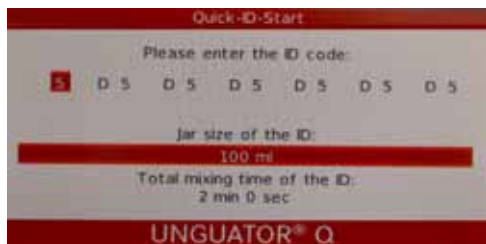
After the completion of each preparation, the UNGUATOR® Q automatically assigns an identification number. It is used for simple documentation and the accurate reproduction of the mixing process and will appear on the display after the mixing process.

## 6.4 Formulation programs

### 6.4.1 Quick-ID-Start

In the program “Quick ID-Start” you can quickly enter a defined or previously created mixing program using a certain identification (ID) code. The program automatically transforms any mixing program to different jar sizes without recalculating them. This “scaling” process is based on the original ID code in combination with the current jar size.

For this purpose enter a previously defined identification code, e.g. a pre-created or documented formulation.



Pic. 25: Program “Quick-ID-Start”

The first number of the UNGUATOR® identification code provides information about the jar size, whereby each jar size is assigned to one of the following numbers:

Unguator® Jar	1	2	3	4	5	6	7	8
Jar in ml	15	20	30	50	100	200	300	500

Tab. 2: Number/Jar size correlation

Enter the specific UNGUATOR® jar size you like to start with by pressing the “+” and “-” key, confirming your selection with the “ok” key.

For jar sizes 100ml and greater the advice “You have chosen a jar size which speed range is defined differently due to quality assurance reasons. All previous settings of the ID will be lost” appears. This is a safety feature to optimize the power exposure for all material, jars, and mixing blades particularly when using larger UNGUATOR® jars.

Proceed with the identification number by entering speed (rpm) and time (mm:ss) for each step of the six possible mixing levels.

The time is specified in upper- and lowercase letters, whereas each letter is assigned to a specific time value:

	A	B	C	D	E	F	G	H	I	J	K	L	M
mm:ss	00:05	00:10	00:15	00:20	00:25	00:30	00:35	00:40	00:45	:00:50	00:55	01:00	01:05
	N	O	P	Q	R	S	T	U	V	W	X	Y	Z
mm:ss	01:10	01:15	01:20	01:25	01:30	01:35	01:40	01:45	01:50	01:55	02:00	02:05	02:10
	a	b	c	d	e	f	g	h	i	j	k	l	m
mm:ss	02:20	02:30	02:40	02:50	03:00	03:10	03:20	03:30	03:40	03:50	04:00	04:20	04:40
	n	o	p	q	r	s	t	u	v	w	x	y	z
mm:ss	05:00	05:20	05:40	06:00	06:25	06:50	07:15	07:40	08:05	08:30	09:00	09:00	10:00

Tab. 3: Letter/Time correlation

Set with “+” or “-” the desired time interval and confirm your selection with “ok”.

The input of rpm is defined with the numbers 0 - 9, each number assigned to a specific speed level:

Level	0	1	2	3	4	5	6	7	8	9
U/min	0	600	800	1000	1200	1400	1650	1900	2150	2400

Tab. 4: Number/Rpm correlation



Set with “+” or “-” the desired rpm and confirm your selection with “ok”.

With this option you may define up to 6 mixing stages. With “Esc” you may go back to the previous step and edit if necessary. By confirming the final ID stage, you also confirmed the completed identification number in total.

In case the entered identification number shows less than 6 mixing stages, you may still conclude earlier. To do this, set the time to “0” using “+” or “-” after you defined your final mixing level. Once you confirmed with pressing “ok”, the remaining mixing level will automatically be set to “0”.

Another question regarding the desired jar size will appear. If you wish to prepare the same jar size with the entered identification number again, confirm the proposed jar size with “ok”.

If you have entered an identification number for a specific jar size but would like to prepare a formulation with a different size, enter the actual jar size with “+” or “-” and confirm with “ok”. The UNGUATOR® Q now automatically scales all previously entered mixing parameters adjusted for the actual jar size.

Scaling is limited to a minimum of 5 seconds and maximum 10 minutes for each mixing level. Hence smaller or greater time intervals cannot be processed.

**Please note:** As a professional user you are responsible for the quality of the final formulation. Please always check the quality of the final product prior delivering to the client.

After each completed mixing process the UNGUATOR® Q generates an identification number which contains all mixing parameters. You have the opportunity to save, record or reject the number. Saving the formulation enables you to individually name it. Rejecting the identification number would not allow the data being retrieved again and the information is lost.

If the mixing process has been interrupted the UNGUATOR® Q does not create any identification number. You may continue mixing on your own responsibility or starting the mixing process over.

## 6.4.2 Auto-Q

With the program “Auto-Q” you may begin a mixing process directly without retrieving a previously saved mixing program.

Select with “+” or “-” the specified UNGUATOR® jar size and confirm with “ok”. From a jar

size 100ml and greater the maximum rpm is restricted. This is a safety feature to optimize the power exposure for all material, jars, and mixing blades particularly when using larger jars.

Afterwards you may choose the initial mixing time with “+” or “-“. The time is set to a maximum of 10 minutes to begin with. Enter with “ok”.

At the next step you may enter the initial mixing speed (rpm). With “ok” you may confirm your selection and the mixing process begins.

During the mixing process you may modify the mixing time if needed with pushing the “+” or “-“ key. With “ok” you can also move to the rpm setting. The speed may also be adjusted with “+” or “-“. As soon as the new rpm would not be changed for more than 3 seconds, the new speed level will automatically become effective and the mixing process will be adjusted accordingly. An additional mixing level will be started. After pushing “ok” you may go back to the time setting again.

According to this procedure it is possible to save 6 different mixing levels. Since each of the 6 mixing level can be max. 10 minutes long, the total mixing time is 60 minutes.

After each completed mixing process the UNGUATOR® Q generates an identification number which contains all mixing parameters. You have the opportunity to save, record or reject the number. Saving the formulation enables you to individually name it. Rejecting the identification number would not allow the data being retrieved again and the information is lost.

In case more than 6 mixing levels have been entered or if the mixing process was interrupted for any reason the UNGUATOR® Q does not create an identification number. You may continue mixing on your own responsibility or starting the mixing process over.

### 6.4.3 Individual

The archive of the individually created and previously saved mixing programs is listed in the “Individual” program.

With “+” or “-“ you may browse a list in alphabetical order and enter your selection with “ok”.

At the next step you may define your jar sizes with “+” or “-“, entering with “ok”. The UNGUATOR® Q scales and adjusts all previously entered mixing parameters automatically for the selected jar size.

Scaling is limited to min. 5 seconds and max. 10 minutes for each mixing level. Hence smaller or greater time intervals cannot be processed.

**Please note:** As a professional user you are responsible for the quality of the final formulation. Please always check the quality of the final product prior delivering to the client.

After each completed mixing process the UNGUATOR® Q generates an identification number which contains all mixing parameters. You have the opportunity to save, record or reject the number. Saving the formulation enables you to individually name it. Rejecting the identification number would not allow the data being retrieved again and the information is lost.

If the mixing process has been interrupted the UNGUATOR® Q does not generate any identification number.

You may continue mixing on your own responsibility or starting the mixing process over. If you wish to modify or edit any individual formulation, select the defined formulation with “+” or “-” and press down the “ok” key for min. 3 seconds. You may then adjust and modify the formulation. To save it, please press down the “ok” key again for min. 3 seconds.

To delete any individual formulation, select the defined formulation with “+” or “-” and press down the “ESC” key for min. 3 seconds. You may now delete the defined formulation. To verify, a security inquiry will appear, which you may accept or reject.

## 6.4.4 Standard

The “Standard” program allows you to choose from a list of standard mixing programs based on the galenic administration of the particular formulation to be manufactured.

With “+” or “-” you may browse the list of programs and enter with “ok”. At the next step you are prompted to define the jar sizes with “+” or “-”, which you enter with “ok”.

## Pregrinding program

The pregrinding program serves to moisten solids in the preparation of suspensions with an active substance content <2%, allowing a homogeneous distribution of the active ingredient in an ointment base.

As an example, incorporation of corticoids, antibiotics, fungicides or hormones in an ointment base. In order to ensure a homogeneous processing, we recommend using the UNGUATOR® standard mixing blade.

First, load approximately 30% of the defined ointment base in the UNGUATOR® jar embedding the micronized agents afterwards. The agent has to be integrated in the ointment base in order to avoid powder residue sticking on the blade.

The movable bottom shall remain at the lowest position during the pregrinding process in order to utilize the complete inner wall of the UNGUATOR® jar as grinding surface.

Please inspect the preparation for agglomerates or qualitative abnormalities after the grinding process is completed. If required, the pregrinding process may be repeated.

After the pregrinding process has been completed, additional components of the formulation can be added and the ointment base may fill up the jar to the desired volume.

Any additional processing of the prescription should be prepared according to the galenic nature of the composition.

## Emulsion

The “Emulsion” program offers the opportunity to incorporate liquids at room temperature in water-absorbing bases, e.g. preparation of hydrous hydrophilic- or hydrous wool wax alcohol ointment.

To ensure a homogeneous processing we recommend applying disposable mixing blades for jar sizes up to 200ml and standard mixing blades for larger batches.

In preparation, the entire ointment base should be weighed out inside the jar covering the bottom. Then add the required amount of liquid or solution in room temperature.

In some cases, you may experience difficulties emulsifying refrigerated bases. In that case the process of emulsification can be accelerated by adding heated liquid.

## Emulsion +

The “Emulsion+” program allows you to accomplish prescription bases and creams from molten individual components with a cold mixing program being integrated, e.g. preparation of DAC base cream or cold cream DAB.

To ensure a homogeneous processing, we recommend applying disposable mixing blades for jar sizes up to 200ml and standard mixing blades for larger batches.

Since the UNGUATOR® jars can be heated up to max. 85°C/185°F in either water or microwave oven, you may melt defined components of your formulation directly in the jar. Do so, all components of the formulation, including aqueous phase in the UNGUATOR® jar and heat the complete formulation up in a microwave oven at low wattage and open cap. Inspection should be done at regular and short-time intervals using a thermometer in order to avoid

overheating of the formulation.

In case the basis should not contain any water, the components that are to be melted may be softened directly in the UNGUATOR® jar on a water bath.

To support cooling off during the mixing process, attaching a cooling jacket/pad on the outside of the jar for smaller jar sizes or repeating the mixing process for larger jar sizes might be applicable.

## **Normal (soft in soft)**

The “Normal” and/or “soft-in-soft” (S/S) program may be applied to mix semi-solid substances in the range of low-viscosity to pasty, e.g. incorporation of formulation concentrates in bases or mixing two bases.

To ensure a homogeneous processing, you may use UNGUATOR® standard- or disposable mixing blades.

You may first start with 50% of ointment base and weigh the required substance on top. Afterwards cover the substance with the remaining base. At a jar size 200ml or greater, you may also implement multiple layering in order to ensure a faster mixing of the final formulation.

## **Suspension <2%**

After a pregrinding process has been completed, the “Suspension <2%” program gives you the opportunity to finalize the formulation with ointment base.

## **Suspension >2%**

Selecting the “Suspension >2%” program you may incorporate solids with a content >2% homogeneously in an ointment base, e.g. incorporation of zinc oxide, salicylic acid or bismuth gallate in ointment base.

To ensure a homogeneous processing we recommend applying a standard mixing blades.

For suspensions with an active ingredient content of more than 2% a pregrinding process is not required.

You may initially load the jar with approx. 50% of the required ointment base, embedding the micronized solids afterwards. You may now add the remaining base covering the active ingredients in order to avoid powder residue sticking on the blade.

If a formulation shows some higher content of solids, e.g. pastes, heating of the formulation during the mixing process may occur. This temperature rise may be reduced applying cooled bases or a cooling pad.

If you are processing temperature-sensitive active ingredients, we recommend selecting the “Quick-ID-Start” program (see paragraph 6.3.1), which would allow you to customize the mixing parameters accordingly.

## **Gel**

The “Gel” program allows a quick and homogeneous preparation of gels and viscous solutions and facilitate the incorporation of bulking agents in liquid and semi-solid bases, e.g. preparation of ultrasonic contact-, electrode- or antiperspirant gel.

The incorporation of a swelling agent such as Bentonit or Aarosil in a semi-solid basis is another situation for applying the gel program.

To ensure a homogeneous processing, we recommend applying disposable mixing blades for jar sizes up to 200ml and standard mixing blades for larger batches.

To prepare, please weigh out the liquid phase into the UNGUATOR<sup>®</sup> jar. Soluble solids may be added and dissolved directly in the jar. The swelling agent is then sprinkled on.

If the swelling agent is incorporated into a semi-solid base, you may embed the swelling substance between the base layers. That way you would obtain a faster dispersion of the swelling agent in the base.

After each mixing performance the UNGUATOR<sup>®</sup> Q will create an identification number (ID-code), which contains all mixing parameters. You will be prompted to either save, record or reject them. Saving the formulation allows you to also assign an individual name. Rejecting the identification number would not allow the data being retrieved again and the information is lost. The initial formulation and its parameters still remain.

If the mixing process has been interrupted the UNGUATOR<sup>®</sup> Q does not create any identification number. You may continue mixing on your own responsibility or starting the mixing process over.

## **6.4.5 Manual**

The “Manual” program offers the option to mix a formulation without the automatic lifting arm. In this case, the movement is executed manually by the operator.

With the “Manual” program you may start the process directly without retrieving any data from previously saved mixing programs.

To begin, select the UNGUATOR® jar size using the “+” or “-” key and enter with “ok”. From jar size 100ml and greater the maximum rpm is restricted. This is a safety feature to optimize the power exposure for all material, jars, and mixing blades particularly when using larger UNGUATOR® jars.

Afterwards you may choose the initial mixing time with “+” or “-“. The time is set to a maximum of 10 minutes to begin with. Enter with “ok”.

At the next step you may enter the initial mixing speed (rpm). With “ok” you may confirm your selection and the electronic mixing arm moves in the lowest position in order to lifting can be manually handled.

The prepared mixing unit and/or mixing blade shaft may now be attached to the bayonet slot. The guiding hand of the operating person shall simultaneously cover both the jar lid and jar body tightly prior starting the mixing process by entering the “ok” key.

The UNGUATOR® mixing unit shall now be evenly and at a moderate rate moved up and down all the way from the bottom to the top of the jar lid and vice versa.

During the mixing process you may modify the mixing time if needed by pushing the “+” or “-“ key. With “ok” you may also move to the rpm setting. The speed may also be adjusted with “+” or “-“. After pushing “ok” you may go back to the time setting again.

Due to the possibility of handling the jar manually the “Manual” program does not create any identification number after the mixing process has been completed.

For any UNGUATOR® jar size 200ml or greater we recommend choosing one of the programs that would apply an automatic stroke. That way you prevent any potential jam or damage of the material involved.



Pic. 26. Lifting arm in start position for the “Manual” mixing program

## 6.5 Mixing Time

When creating an individual mixing operation with either one of the programs “Auto-Q” or “Quick-ID-Start”, complying with the minimum mixing time for the selected formulation is recommended. Depending on the composition and size of the formulation, the individual

minimum mixing time for any given formulation may vary.

The following time values for each rpm serves as benchmark, which should be adjusted after each modification of rpm.

**Size of the UNGUATOR® Jar**

Type of formulation	15-30ml	50-100ml	200-300ml	500ml
Suspension	02:00	02:30	04:30	06:10
Soft-in-soft	01:40	02:10	04:00	05:10
Emulsion	02:00	02:20	04:10	05:30

Tab. 5: Minimum values for mixing time at 2150 rpm in min:s

**Size of the UNGUATOR® Jar**

Type of formulation	15-30ml	50-100ml	200-300ml	500ml
Suspension	03:00	03:50	06:45	09:30
Soft in soft	02:30	03:20	06:10	07:50
Emulsion	03:00	03:50	06:30	08:30

Tab. 6.: Minimum values for mixing time at 1650 rpm in min:s

## 6.6 Selecting the UNGUATOR® Jar Size

The maximum rpm for jar sizes 100ml and greater is restricted. This is a safety feature to optimize the power exposure for all material, jars, and mixing blades particularly when using larger UNGUATOR® jars.

## 6.7 Condition of the ingredients for any formula

### Powder

Generally powders should be used as microfine substances.

In order to ensure better wetting of powders in aqueous formulations, micronized substances should be added only after any liquid constituents.

For a solids content less than 2%, we recommend applying a pregrinding process together with approx. 30% of the ointment base (see paragraph 6.3.4 - pregrinding program).



## Crystalline active ingredients

In order to avoid complex postprocessing (e.g. w/ ointment mill), we recommend pulverizing active crystalline agents with the help of a mortar prior adding to the UNGUATOR® Jar.

Should a solvent for the active crystalline ingredient be part of the formulation, the ingredients may then also be dissolved in the UNGUATOR® Jar while mixing, e.g. urea in water. Then the remaining formulation ingredients can be added. Crystalline substances may also dissolve during the mixing process if the solvent is an ingredient of the ointment base.

## Components to be melt

Components that have been weigh out to fuse may be placed inside an UNGUATOR® jar ,douse with heated aqueous or oily phases of you formualtion constituents ( $\leq 85\text{ }^{\circ}\text{C}/185^{\circ}\text{F}$ ) to melt the content in full.

In case this process does not sufficiently melt all constituents, the formulation inside an UNGUATOR® jar might be heated in a warm water bath ( $\leq 85^{\circ}\text{C}/185^{\circ}\text{F}$ ) or carefully observed in a microwave oven. In order to ovoid overpressure, please mind having the white cap on the lid removed.

Formulations without water containing components may be melted already directly inside the UNGUATOR® Jar by placing the jar in a warm water bath.

Please be aware that UNGUATOR® MB's must **not** go in the microwave oven! Furthermore, due to irregular mixing of adipose- and water phases, reaching the melting point might happen with a delay, since only aqueous parts can be heated in a microwave oven.

Please urgently mind the operation manual of your microwave oven! An excessive temperature rise for both UNGUATOR® jar and its content must be avoided at all times!

The cooling time and hence the cooling interval decreased in the refrigerator or by using a cooling jacket/pad. The UNGUATOR® MB should remain in the UNGUATOR® jar during the cooling phase.

## Thermolabile substances

Active ingredients or substances with thermolabile characteristics should be handled with caution. To protect the substances, we recommend a maximum 1500rpm. Examine the formulation related to frictional heat, that needs to be cooled with the help of a cooling

jacket or cool-down periods in a refrigerator if required.

## **6.8 After the mixing process is complete**

The UNGUATOR<sup>®</sup> Mixing System shall be released and removed from the UNGUATOR<sup>®</sup> oscillation arm once the mixing process has been completed. Unscrew the UNGUATOR<sup>®</sup> jar Lid from the oscillation arm and/or twist the UNGUATOR<sup>®</sup> MB shaft counterclockwise. This will only require a quarter turn, which may already have happened when releasing the jar from the oscillation arm. For this reason, we recommend holding the UNGUATOR<sup>®</sup> Mixing System tightly in your hand when removing it from the UNGUATOR<sup>®</sup>.

In the next step, the UNGUATOR<sup>®</sup> jar lid is opened and the UNGUATOR<sup>®</sup> MB removed. Since this is also an opportunity to execute a quality check, the UNGUATOR<sup>®</sup> jar lid should also be opened after mixing with UNGUATOR<sup>®</sup> disposable blades. Practice has proven that if the surface of the final ointment looks smooth, complying with the minimum defined mixing time, homogeneity for the total product inside the jar can be expected.

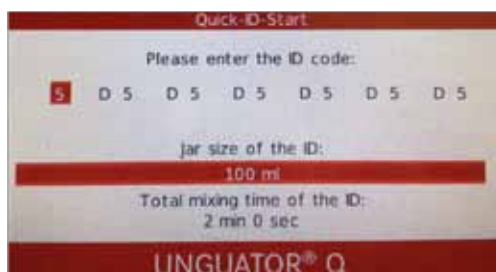
The UNGUATOR<sup>®</sup> MB shall now be pushed out of the UNGUATOR<sup>®</sup> jar lid. The ointment still attached to the standard mixing blade can be scraped off the blades using a spatula. When using the UNGUATOR<sup>®</sup> disp. blade, the mixing blade can be removed from the UNGUATOR<sup>®</sup> jar and discarded or left inside the jar. Leaving the disposable blade inside the jar will have no adverse effects in any way. Nevertheless, removing the disposable mixing blade is recommended, particularly when forwarding the ointment to elderly clients, to prevent confusion.

The lid may now be screwed back onto the jar body and equipped with an UNGUATOR<sup>®</sup> Varionozzle if required. Then the little cap and/or an UNGUATOR<sup>®</sup> Applicator would be fastened loosely. Large UNGUATOR<sup>®</sup> jars will be equipped with the spindle or the AirDynamic<sup>®</sup> System. In any case, similar to prior the mixing process, air diminution should be repeated. A “squirting” of the ointment when initially extracted may be prevented by eliminating cavities that may have developed during the mixing process. The UNGUATOR<sup>®</sup> lid and/or the UNGUATOR<sup>®</sup> Applicator may now be fastened in place.

A label may be attached prior forwarding to the client, preferably together with a short illustration of how to use and operate the UNGUATOR<sup>®</sup> jar and dispensing system. The operator also might want to individually record the mixing parameters and results of each final product validation.

## 6.9 Identification Number

The 13 digit identification number (ID code) to clearly identify each preparation has the following format:



Pic. 27: Identification number

The first number of the UNGUATOR® identification code provides information about the jar size, whereby each jar size is assigned to one of the following numbers:

UNGUA-TOR® jar	1	2	3	4	5	6	7	8
Size in ml	15	20	30	50	100	200	300	500

Tab. 7: Number/Jar size correlation

As from the second position the mixing time and the rotation speed in 6 mixing stages are represented. The time specification is represented with large- and lowercase letters, in which each letter correlates to a defined time value:

	A	B	C	D	E	F	G	H	I	J	K	L	M
mm:ss	0:05	0:10	0:15	0:20	0:25	0:30	0:35	0:40	0:45	0:50	0:55	1:00	1:05
	N	O	P	Q	R	S	T	U	V	W	X	Y	Z
mm:ss	01:10	01:15	01:20	01:25	01:30	01:35	01:40	01:45	01:50	01:55	02:00	02:05	02:10
	a	b	c	d	e	f	g	h	i	j	k	l	m
mm:ss	02:20	02:30	02:40	02:50	03:00	03:10	03:20	03:30	03:40	03:50	04:00	04:20	04:40
	n	o	p	q	r	s	t	u	v	w	x	y	z
mm:ss	05:00	05:20	05:40	06:00	06:25	06:50	07:15	07:40	08:05	08:30	09:00	09:30	10:00

Tab. 8: Letter/Time correlation

The input of the rpm is assigned to the numbers 0-9, in which each number correlates to a defined rpm value:

Level	0	1	2	3	4	5	6	7	8	9
Rpm	0	600	800	1000	1200	1400	1650	1900	2150	2400

Tab. 9: Number/Rpm correlation

## 6.10 Operating errors

The quality assurance system of the UNGUATOR® Q makes sure that operating errors shall be sensitively registered and displayed. If a problem occurs the display will show the following error message:

“Mixing tool not locked in place”, “Lifting motor overload” and “Mixing motor overload”.

If necessary switch off the device after an operating error. The UNGUATOR® Q device will generally function normally again after remedy.

Irreversible software faults caused by current transients or strong electromagnetic fields in the vicinity can only be remedied by authorized customer service points.

For functionally testing reasons the UNGUATOR® Q has to be switched off first. The device can be switched on again after 20 seconds. Please make sure that no UNGUATOR® MB is attached to the device during start up or rebooting process. We recommend changing the UNGUATOR® jar size for the initial functionality testing process, and e.g. running a mixing process with a filled UNGUATOR® jar size 30 or 50ml.

Please contact your local UNGUATOR® dealer for any malfunctions that cannot be remedied using above information to troubleshoot.

### UNGUATOR® Mixing blades (MB)

The UNGUATOR® Q has been tested with the UNGUATOR® MB’s that were initially enclosed, centered, and aligned.

All UNGUATOR® MB’s delivered after the year 1996 are compatible with the UNGUATOR® Q. Please do not use any bent or damaged UNGUATOR® MB. Other UNGUATOR® MB used, rather than the ones supplied with the UNGUATOR® Q may cause problems of coupling. If this is the case, we recommend contacting your local UNGUATOR® dealer.

The UNGUATOR® MB should not be pressed too deep in the UNGUATOR® Jar, thus the lifting arm can reach the bayonet. For this reason we recommend that after screwing the UNGUATOR® mixing unit on, the UNGUATOR® MB shaft should be manually drawn back to the jar lid.

**Error:** The UNGUATOR® jar cannot be screwed in the lifting arm because the shaft of the UNGUATOR® MB seems to be too long.

**Troubleshooting:** The UNGUATOR® MB must be replaced with the appropriate UNGUATOR® MB with the correct shaft length. While the UNGUATOR® SMBs for 100 and 200 ml and for the 300 and 500 ml jars have the same mixing blade diameter, their shaft length differs.

**Error:** The lifting arm is unintentionally moved with the hand too far from the starting position and the shaft is no longer aligned to the opening.

**Troubleshooting:** The shaft can be moved by hand to the start position. The shaft touches the hole and is lead into the opening.

**Error:** The UNGUATOR® MB does not penetrate completely in the mixture, since the formula is too pasty, firm, or in powder form.

**Troubleshooting:** The reverse power of the lifting arm is from 3 to 5kp intentionally low to avoid material damages. For this reason, the UNGUATOR® Q registers the resistance and the return of the stroke direction. To ensure the complete mixing of the recipe, you can for example, warm cold recipe substances in room temperature or assist pasty mixtures by hand. Further help is usually no longer necessary.

## UNGUATOR® Jar

**Error:** The jar connected to the UNGUATOR® Q is not an UNGUATOR® jar.

**Troubleshooting:** The jar has to be substituted for an UNGUATOR® jar.

**Error:** The UNGUATOR® jar lid is wrongly screwed on the UNGUATOR® jar and the UNGUATOR® MB tilted at automatic hub.

**Troubleshooting:** The UNGUATOR® jar should be unscrewed and correctly screwed together.

**Error:** The UNGUATOR® jar bottom was not pressed fully down to the stop position prior to weighing out or filling.

**Troubleshooting:** Particularly light components are not going to be accommodated in the same size UNGUATOR® jar although the filling volume is on average 40% more than the

nominal volume. Please use the next larger UNGUATOR® jar for mixing.

**Error:** The air was not removed from the jar prior mixing semisolid preparations.

**Troubleshooting:** The Mixing Blade centrifuges the ointment against the UNGUATOR® Jar wall, forming an air column inside in which the UNGUATOR® MB cannot clean itself and unmixed constituents may adhere to the UNGUATOR® MB.

**Error:** In formulations with a large amount of liquid components and cold emulsions the UNGUATOR® jar bottom does not retain liquids during the emulsifying process.

**Troubleshooting:** With cold emulsions, the basis cream must cover the complete UNGUATOR® Jar Bottom and along the lower jar wall until it is well distributed. When you prepare large quantities of liquids, for example the production of gels, it is important to use the appropriate mixing program. Those programs are constructed in order to avoid an excessive stirring speed and excess pressure on the UNGUATOR® jar.

**Error:** The sealing lip on the UNGUATOR® jar bottom does not retain liquids during the emulsifying process.

**Troubleshooting:** Please be aware that when setting up the UNGUATOR® jar lid with the UNGUATOR® mixing shaft, the sealing lip is not damaged by the bayonets of the shaft. Reduce the air prior the mixing process and use the appropriate mixing program.

**Error:** The user failed to decrease air again or to mount a UNGUATOR® Varionozzle or UNGUATOR® Applicator before dispensing. This will cause the user to first push the air out of the opening and the ointment will follow in a gush.

**Troubleshooting:** Depending on the viscosity of the formula, apply an UNGUATOR® Varionozzle or UNGUATOR® Applicator.

## UNGUATOR® Q

**Error:** The UNGUATOR® Q does not mix and the lifting arm only moves up and down.

**Troubleshooting:** The mixing motor of the UNGUATOR® Q is overloaded. Reduce the rotation speed with the “-” key until the mixing motor restarts. Overloading of the mixing motor can be avoided by using solid or stored room temperature base ointment or by reducing the starting speed.

## 6.11 Cleaning the UNGUATOR® Q

Always unplug the UNGUATOR® Q from the wall outlet before performing a cleaning. Do

not use aggressive cleaning agents or abrasive cleaners.

For cleaning, we recommend daily wiping the surface with a damp cloth with mild detergent and immediately drying it with a dry cloth. For disinfecting, the display can be lightly sprayed and wiped with isopropanol 70%.

Make sure that no liquid enters the device. If liquid enters the interior of the UNGUATOR® Q keep the device turned off and inform customer service.

An unauthorized opening of the UNGUATOR® Q device is not recommended.

## **7. General recommendations for the UNGUATOR® Mixing System**

In its quality regulations for processing any semisolid preparation, the German Chamber of Pharmacists is recommending to apply for dispensing and mixing a jar having a small dispensing nozzle since the year 2000.

### **7.1 Patent protection**

The UNGUATOR® Mixing System consists of UNGUATOR® Technology, the UNGUATOR® mixing machines and various UNGUATOR® assortment.

The UNGUATOR® Mixing System, UNGUATOR® Technology and the AirDynamic® Pumpball System integrated therein are inventions of the German pharmacist Albrecht Konietzko, Bamberg, Germany. The UNGUATOR® Technology and the AirDynamic® Pumpball System are patented in selected countries. UNGUATOR® and AirDynamic® are registered trademarks exclusively available from the company GAKO®.

The UNGUATOR® Mixing System with its versatile and comprehensive line products captivates with its simplicity. Everything the pharmacist needs for the preparation of pharmaceutical ointments and cosmetics is covered by the UNGUATOR® Mixing System.

### **7.2 Quality assurance for ointments**

Simple test methods convincingly demonstrate the good homogenizing capability of the UNGUATOR® Mixing System. Perform a homogeneity test when receiving the UNGUATOR® device and document the results. After a time period of one year or whenever needed you may repeat the test.

Use a prescription/formulation with a colored substance, e.g. iron oxide (micronized) or

“sudan red” worked in a semi-solid base. You can spread out the finished mixture on a glass plate or a microscope slide and check the solids distribution and the grain particle size.

For a short-term statement about the solids distribution in the formula basis, you can test in different levels of the UNGUATOR<sup>®</sup> Jars and examine these as described.

### **7.3 Potential sources of nonconformances**

- The UNGUATOR<sup>®</sup> jar bottom was not pressed fully down to the stop position prior to weighing out or filling. First and foremost, it is not imperative to accommodate specifically light constituents in an UNGUATOR<sup>®</sup> Jar of equal weight although the filling volume is 40 % more than the rated volume. Please use the next largest UNGUATOR<sup>®</sup> jar for the mixing.
- The air was not removed before the mixing process of semisolid preparations from the UNGUATOR<sup>®</sup> jar. Then the mixing blade centrifuges the ointment against the UNGUATOR<sup>®</sup> Jar wall, forming an air column inside in which the UNGUATOR<sup>®</sup> MB cannot clean itself and unmixed constituents may adhere to the UNGUATOR<sup>®</sup> MB.
- The UNGUATOR<sup>®</sup> jar bottom has not been moved up. The penetrating UNGUATOR<sup>®</sup> MB will generate an overpressure at high rate of speed that cannot be compensated when the movable bottom yields. Thus the overpressure may cause mixed material, mainly liquid constituents, to squeeze out of the seals on the threaded UNGUATOR<sup>®</sup> jar lid, between UNGUATOR<sup>®</sup> Jar bottom and UNGUATOR<sup>®</sup> Jar body and along the shaft of the UNGUATOR<sup>®</sup> MB [1].
- The sealing lip on the UNGUATOR<sup>®</sup> jar bottom does not retain liquids during the emulsifying process. Before starting the mixing process, particularly for large amounts of liquids, the region round the sealing lip of the UNGUATOR<sup>®</sup> Jar bottom should be carefully brushed with foundation so as to improve its sealing quality.
- The sealing lip of the UNGUATOR<sup>®</sup> jar lid has been damaged by the shaft tappets of the UNGUATOR<sup>®</sup> MB upon perforating the lid. This will cause ointment to creep up the shaft.
- The UNGUATOR<sup>®</sup> Jar Lid is not tightened correctly and not held during the manually guided stroke. This may cause the UNGUATOR<sup>®</sup> jar lid to unscrewed during the mixing process, resulting in a large mess.
- The user failed to remove air again or to mount a UNGUATOR<sup>®</sup> Varionozzle or UNGUATOR<sup>®</sup> Applicator before dispensing. This will cause the user to first push the air out of the opening and the ointment will follow in a gush [1].



## 8. Service and warranty

### 8.1 Notes on malfunctions

If the UNGUATOR® device does not work, it may be due to a little thing that you may be able to correct yourself. Before you take the unit for repair, please follow instructions below:

- If the UNGUATOR® device cannot be switched on, please check to ensure that there is electricity available and that the plug of the power cord has been correctly connected to the device and the socket.
- In any case of problems or damage of the device, please also mind the manufacturer's notes on the machines' metal foot.

### 8.2 Manufacturer's service and warranty

The manufacturer will accept independent from the obligations of the vendor against the buyer, a warranty period of twenty-four (24) months from the date of purchase. Please retain the packaging material or request its replacement from your respective representative in your individual country (please contact your local UNGUATOR® dealer).

- Deficiencies that can be related to faults in the material or manufacturing defects will be remedied free of charge within the warranty period.
- The respective representative in your individual country (please contact your UNGUATOR® dealer) must be informed of necessary warranty repairs. A cost estimate can be obtained for service repairs.
- UNGUATOR® MBs', UNGUATOR® Jars and UNGUATOR® Accessories are excluded from warranty.
- The warranty claim will lapse should an unauthorized party have tampered with the device. Damages caused by improper use as well as force majeure or other external influences are excluded from any warranty claims.
- The parts replaced at maintenance and repair will become property of GAKO®.
- Claims beyond the free rectification of faults, e.g. indemnification cannot be made within the warranty period.
- Repairs within warranty will be exclusively carried out by certified service partner.

### 8.3 Notes on maintenance

- To preserve gears and motor for continuous untroubled operation, please contact your local UNGUATOR® dealer after 20,000 preparations and/or after five (5) years for maintenance.

- After-sales service and maintenance service will be billed for expenses and wearing parts at reasonable price according to the cost estimate within the warranty period as well.
- Upon request an UNGUATOR® loaner may be provided for a one-time charge that can be used while your UNGUATOR® is away for maintenance and repair.

## 8.4 Notes on safety

- UNGUATOR® devices must only be connected to grounding type receptacles with 230V/50Hz(cps); 120V/60Hz(cps) or rated country specific voltage installed according to the regulations of DIN VDE 0100.
- UNGUATOR® devices have been designed for operation under normal room atmospheric conditions. Recommended values: Ambient temperature between 15...30 °C/ 59...86 °F and relative air humidity less than 80 %.
- The device should be allowed to acclimatize for approx. 30 minutes at commissioning and/or after extended storage time in cold rooms.
- UNGUATOR® power switch and cable must be easily accessible.
- Do not immerse UNGUATOR® devices in water
- UNGUATOR® devices should only be operated by authorized persons.
- Only operate the UNGUATOR® MB with correctly attached UNGUATOR® jars or in a plastic beaker provided for a reaction mixture.
- Do not touch rotating parts.
- Keep long hair, ties and cables away from rotating parts.
- During the automatic lifting function of the UNGUATOR®: always keep long hair, parts of the body or objects away from the lifting mechanism. Immediately turn off the power switch in an emergency or pull the power plug.
- Always keep the air vents on the driving head/back or underside of the devices free when using the device.
- Using the UNGUATOR® devices not according to these operating instructions or with line products that the manufacturer did not deliver or recommend may impair safety and will void the warranty!
- UNGUATOR® devices have not been designed for operation under hazardous conditions. Heed the relevant safety regulations when handling hazardous substances (e.g. combustible liquids such as alcohol or similar substances).
- UNGUATOR® devices correspond to the safety standards for laboratory equipment. They have to be positioned to prevent any interference or use by unauthorized persons.
- The device must not be disposed of in ordinary domestic waste. Please deliver the device to the available collecting and recycling systems at the end of its life cycle.



## 9. Technical data of the UNGUATOR® Q

Electrical requirement	no restrictions
Total power consumption	300 W
Power consumption (mixing motor)	250 W
Power consumption (lifting motor)	50 W
Operating mode continuous operation S1	Continuous operation S1
Safety class I	I
Type of protection	IP 20
Speed controller	in 10 stages electronically controlled
Timer	Program control or in stages
UNGUATOR® Jar sizes	15 ml - 500 ml
Weight	13,6 kg (30.0lbs)
Dimensions (L x W x H in mm)	320 x 220 x 600
Quality assurance	CE, TÜV-GS

Tab. 10: Technical data of the UNGUATOR® Q

### 9.1 Quality and material

Manufacturing facilities for the UNGUATOR® line of products is certified according to DIN EN ISO 9001:2008. Regular quality control, ensures both outstanding and sustainable quality of the UNGUATOR® Mixing Technology.

- The UNGUATOR® Applicators, Couplings and Jars, are made out of Polypropylen (PP) and the regular UNGUATOR® Varionozzles of Polyethylen (PE).
- The UNGUATOR® SMB is made out of Polyoximethylen.
- The UNGUATOR® Disp. MB is made out of Polyamid.
- The shaft of the UNGUATOR® MB is made of NIRO-Stainless steel (quality standard: 1.4301) and hardened titanium-nitride (golden color). The utilized material and pigments are physiologically classified as safe.

## 10. References

The advantages of the UNGUATOR® Mixing Technology and -System compared to conventional manufacturing methods with mortar and pestle are frequently mentioned

in the literatures below:

- Preparation of GMP-compliant ointments in the pharmacy is possible [2], [4]
- Formulations for ointment is standardized [4], [8]
- Excellent homogeneity [2], [4], [9]
- Improved microbiology [3], [8]
- Risk of contamination is greatly reduced in the preparation process: hygienic production in a closed system, no transfer to a separate container [2], [3], [4], [8]
- Hygienic extraction of the formulation, minimum threat of contamination by the user [2], [3], [4], [8]
- Enhanced product quality in an improved packaging ensures longer product shelf life [3], [4]

## 11. Bibliography

- [1] 1 Jahr UNGUATOR®-Rührsystem Deutsche Apothekerzeitung (DAZ) Nr. 43 Jhg. 135/1995 S. 115-117 Konietzko, A., GAKO® Konietzko GmbH, Bamberg
- [2] Der UNGUATOR® ein neuartiges Salbenrührwerk Pharmazeutische Zeitung (PZ) Nr. 30 Jhg. 141/1996 S. 30-33 Alberg et al., Pharmaz. Technologie TU Braunschweig
- [3] Keimzahl in wasserhaltigen Dermatika Pharmazeutische Zeitung (PZ) Nr. 29 Jhg. 142/1997 S. 36-40 Alberg et al., Pharmaz. Technologie, TU Braunschweig
- [4] Alternativen zum Salbenrühren im Vergleich Pharmazeutische Zeitung (PZ) Nr. 36 Jhg. 142/1997 S. 24 – 31 Zobel et al., Pharmaz. Technologie, Univ. Frankfurt a.M.
- [5] Das UNGUATOR®-Rührsystem (URSY) als Alternativverfahren für die Herstellung dermatologischer Individualrezepturen Deutscher Dermatologe: 46, Heft 6 / 1998 S. 545 – 549 Zobel et al., Pharmaz. Technologie, Univ. Frankfurt a.M.
- [6] Bedienungsanleitung UNGUATOR® Rühren im geschlossenen System (1998) A.Konietzko, GAKO® Konietzko GmbH, Bamberg
- [7] System zur Salbenherstellung im Vergleich Pharmazeutische Zeitung (PZ) Nr. 38. Jhg. 143/1998 S. 53-65 R. Eifler-Bollen, Zentrallaboratorium Deutscher Apotheker (ZL), Eschborn
- [8] Voigt, R.: Pharmazeutische Technologie (Für Studium und Beruf), Jhg. 2000, 9. Auflage., S. 314-315, Deutscher Apothekerverlag, Stuttgart
- [9] Qualitätssicherung bei Rezeptur- und Defektursalben UNGUATOR®-Technologie Apotheker & Wirtschaft Nr. 7 Jhg. 2/2001 S. 40-41 Albrecht Konietzko, 96049 Bamberg, kontakt@unguator.com Verlag: medical economics – Leipzig

- [10] Qualitätssicherung in der Rezeptur Pharmazeutische Zeitung (PZ) Nr. 14 Jhg. 146/2001 S. 42-47 R. Eifler-Bollen, NRF, Eschborn Prof. Dr. H. Möller, Zentrallaboratorium Deutscher Apotheker (ZL), Eschborn, et al.
- [11] Leitlinie zur Qualitätssicherung ... nicht sterilen Rezeptur- und Defekturarzneimittel Pharmazeutische Zeitung (PZ) Nr. 29 Jhg. 145/2000 Seiten 105–116 Deutsche Apothekerkammer
- [12] Flüssige Chlorhexidin-Cremes: Rühren ist kritisch Pharmazeutische Zeitung (PZ)Nr. 10 Jhg. 147/2002 Seiten 54 - 56
- [13] Mit zeitgemäßen Herstellungsverfahren rühren Pharmazeutische Zeitung (PZ) Nr.13 Jhg. 147/2002 Seite 60 Diskussion: A. Konietzko (GAKO®) und Dr. H. Reimann (NRF)

## 12. Manufacturer's certificate/ Declaration of Conformity

for plastic materials, which come into contact with food.

Article <sup>1)</sup>	Material <sup>2)</sup>		
		standard	cosmetic
UNGUATOR <sup>®</sup> Jar cap	Polypropylene, natural	white	colored
UNGUATOR <sup>®</sup> Jar lid	Polypropylene, natural	red, white, green, blue	colored
UNGUATOR <sup>®</sup> Jar body	Polypropylene, natural	white	colored
UNGUATOR <sup>®</sup> Jar bottom	Polypropylene, Polyethylene	-	-
UNGUATOR <sup>®</sup> Jar bottom cap	Polypropylene, natural	white	white

1) The licensed manufacturer, SMS ELAP GmbH & Co. KG, D-98544 Zella-Mehlis is DIN EN ISO 9001:2000 certified

### Further UNGUATOR<sup>®</sup> line items

UNGUATOR <sup>®</sup> Spindle	Polypropylene, natural	white
UNGUATOR <sup>®</sup> Aplicator long with cap	Polypropylene, natural	white
UNGUATOR <sup>®</sup> Aplicator short with cap	Polypropylene, natural	white
UNGUATOR <sup>®</sup> Coupling	Polypropylene, natural	white
UNGUATOR <sup>®</sup> Varionozzle blue, yellow, pink	Polypropylene, natural	blue, yellow, red
UNGUATOR <sup>®</sup> Disp. Blade	Polyamide, white	-
UNGUATOR <sup>®</sup> SMB	Polyoxymethylene	-

2) Declarations of conformity for materials and color concentrates of the materials vendors are deposited at the licensed manufacturer.

All products listed are manufactured according to the legal requirements of plastic Regulation (EU) No 10/2011 and (EU) No 1935/2004 (in their current version).

For applications according to formal specification both the overall and specific migration are under the legal limits of 10mg/dm<sup>3</sup>, according to Regulation (EU) No 10/2011.

The materials and raw materials used comply with Regulation (EU) No 10/2011. The following monomers and additives, which are subject to a specific migration limit (SML), are included according to suppliers in the used materials:

Material:		
Polypropylen natur	-	
Polyamid	Caprolactam:	SML(T) = 15 mg/kg
Polyethylen	Ref.-Nr. 68320:	SML = 6 mg/kg
	Ref.-Nr. 89040:	SML = 25 mg/kg (calculated as Zn salt)
Polyoxymethylen	-	

Color concentrate:		
white	Ref.-Nr. 46880:	SML = 6 mg/kg
white (SMB)	Formaldehyd:	SML = 15 mg/kg
	1,3-Dioxolan:	SML = 5 mg/kg
	Trioxan:	SML = 5 mg/kg
white (disposable blade)	Caprolactan:	SML(T) = 15 mg/kg
other colors	-	

Compliance with these specific migration limit is certified by the polymer manufacturers.

The traceability of Regulation (EC) No 1953/2004 of the product is ensured by the lot number and the application of manufacture.

Specification for intended use: Kind / types of food or procedures for which the material is suitable:  
aqueous media acidic media

issued by GAKO<sup>®</sup> Germany - production control (as of January 2013)

The certificate has been produced electronically and is valid without a signature

## 13. Distribution, manufacturing and customer service

**GAKO® Konietzko GmbH**  
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