

Operating Instructions and Production Recommendations



UNGUATOR® B/R

*Dear UNGUATOR® user,
thank you for choosing the UNGUATOR® 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® Mixing Technology,
please feel free to contact us at
contact@unguator.com*

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1. Installation information

Select a suitable location for the UNGUATOR® B/R

CAUTION! The UNGUATOR® B/R weighs almost 15 lbs (6,8 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® B/R. This must include sufficient space around the UNGUATOR® B/R to provide good ventilation.

Select a suitable 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® B/R 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® device in for service.

UNGUATOR B/R

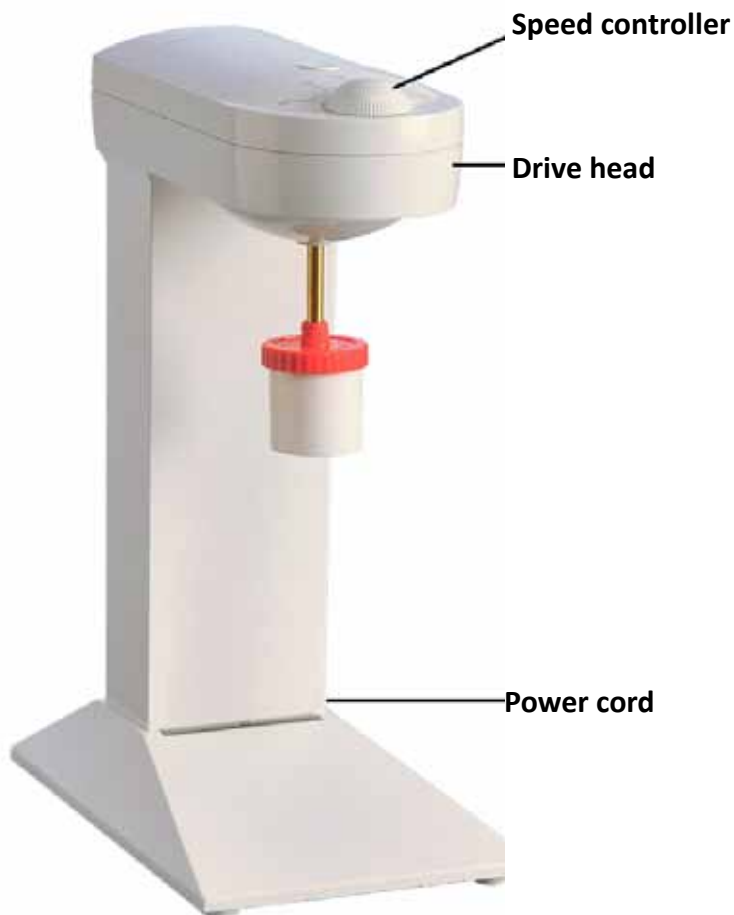


Fig. 1: UNGUATOR® B/R description

2. Initial operation

You will find the power switch “O/I” located at the rear of the UNGUATOR® B/R on its base. This is also the emergency switch. Please check that the UNGUATOR® B/R power switch is set to off. Connect the power cord to the socket outlet. You may now switch the UNGUATOR® B/R on using the power switch. The device is now ready for operation.

3. 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 the conventional methods that were used prior to the invention (1994). For the first time, it is possible to not only standardize ointments, but validate them too.

3.1 UNGUATOR® mixing machines

The current UNGUATOR® mixing machines - the UNGUATOR® B/R, the UNGUATOR® e/s, the UNGUATOR® 2100 and the UNGUATOR Q - are useful and advanced improvements on the first UNGUATOR® from 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 the e/s-, Q- and 2100 models.

Method of ointment preparation	Pharmaceutical QUality	Uniformity of ointment	Lifting arm	Mixing parameters
Bowl and pestle	++	+	(-)	manual
UNGUATOR® B/R	+++	++	manual	manually adjustable
UNGUATOR® e/s	+++	+++	automatic	individually programmable
UNGUATOR® Q	++++	++++	automatic	fully automatic
UNGUATOR® 2100	++++	++++	automatic	fully automatic

Tab.1: Quality improvement with increasing automation

3.1.1 UNGUATOR® B/R

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



Pic. 2: UNGUATOR® B/R

3.1.2 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.



Pic. 3: UNGUATOR® e/s

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.

3.1.3 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 can be stored. The UNGUATOR® 2100 can be connected to a PC via an 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 ointments, cosmetics, etc. using the UNGUATOR® 2100, since only the composition changes and not the mixing program. As a result, ointments can now finally be reliably reproduced even in smaller quantities.

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, or 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.



Pic. 4: UNGUATOR® 2100

3.1.4 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. 5: UNGUATOR® Q

3.2 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 UNGUATOR® Mixing devices.

3.2.1 UNGUATOR® Mixing blade (MB)

The UNGUATOR® Standard Mixing Blade and the UNGUATOR® Disposable Blade are designated as UNGUATOR® MBs. The UNGUATOR® MBs 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® MBs are dishwasher safe.

UNGUATOR® Standard mixing blade (SMB)



Pic. 6: 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 recipes. For suspension ointments and glass cleaning operations, we recommend the use of the UNGUATOR® Disp. Blade.

UNGUATOR® Disposable blade (Disp. 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.



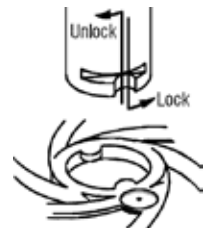
Fig. 7: UNGUATOR® Disposable Blade (HD)

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)

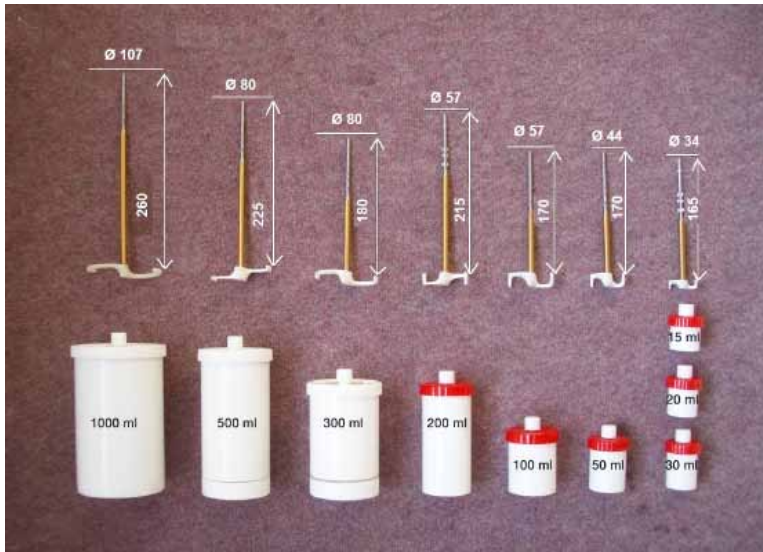
Assignment of the UNGUATOR® MB

Please make sure to use the correct UNGUATOR® MBs for the corresponding UNGUATOR® Jar (Fig. 6). Mixing up may cause failure messages.

Please also ensure that the right shaft is used with the UNGUATOR® Disp. Blade. Both available shafts are marked for use with sizes 15–100 ml or 200 ml 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 200 ml UNGUATOR® Jar sizes, it still needs a different shaft for each jar size. Please also mind the operating instructions that come with the shafts.



Pic. 8: Handling the UNGUATOR® Disp. Blade



Pic. 9: 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 the ointment's ingredient's compatibility sequence of weighted sample but also if the UNGUATOR® Jar is considerably underfilled (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 and no remedial work is 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 jet and then dried with dispensing pulp. UNGUATOR® MBs can also be cleaned in a conventional dishwasher.

All the UNGUATOR® devices as well as UNGUATOR® line of products must not be treated with sharp-edged objects or abrasive cleaning agents.

3.2.2 UNGUATOR® Jar

The UNGUATOR® Jar is both the mixing and dispensing jar and is therefore designed as an expendable or disposable jar. The UNGUATOR® Jar guarantees evaporation and contamination-free preparation in an 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 (Apothekenkammer) [11]. With its small dispensing opening, comparable to a tube and without an environmental contamination surface, the UNGUATOR® Jar 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 extract the ointment from the UNGUATOR® Jar very hygienically.

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



Pic. 10: UNGUATOR® Jar

All UNGUATOR® Jars come sealed in plastic packaging. Cleaning o

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.

Analysezertifikat / Certificate of Analysis		Dat. 01.03.2012
UNGUATOR® Kruke / Jar		
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)		
GAKO® * www.unguator.com		

Pic. 11: Certificate of Analysis for the UNGUATOR® jar of 50 ml

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 made with the legal requirements of the EU plastic regulation N° 10/2011 and N° 1935/2004 as of January 2013.

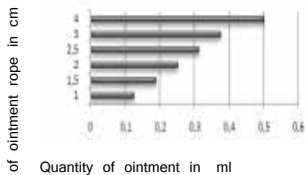
A certificate of analysis is issued after batch-defined examinations. The documentation of primary packaging materials at the pharmacy stipulates that the manufacturer's test certificate (certificate of analysis) is retained after receiving visual inspection. This certificate is affixed to the plastic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

Notes on dispensing ointment

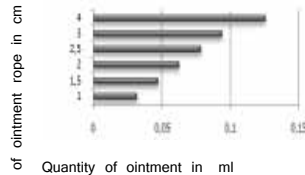
Each customer should be given specific instructions at how to apply the UNGUATOR® Jars when handing to the individual client. The use of the UNGUATOR® Spindle should be explained for large UNGUATOR® Jars. Low viscosity ointments should be equipped with an UNGUATOR® Applicator or an UNGUATOR® Varionozzle 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.

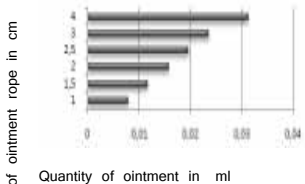
The diameter of the dispensing nozzle allows simple dosing of the quantity of ointment to be applied using approximate values. The regular dispensing nozzle in the screw lid of each UNGUATOR® Jar has a diameter of 8mm. The varionozzles or applicators reduce the diameter to 4, 2 or 1 mm. The approximate values represented in the following diagrams may also be helpful to weight out concentrated active substances or regular trituration from the UNGUATOR® Jar.



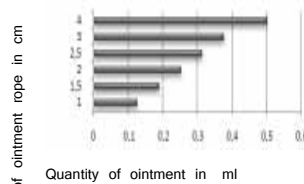
Pic. 12: Dispensing with regular UNGUATOR® Jar Nozzle



Pic. 13: Dispensing with UNGUATOR® 1mm varionozzles or UNGUATOR® applicator short



Pic. 14: Dispensing with UNGUATOR® 2mm ovarionozzle or UNGUATOR® applicator long



Pic. 15: Dispensing with UNGUATOR® varionozzles 4mm

3.2.3 UNGUATOR® Varionozzles

The UNGUATOR® Varionozzles with inner diameters of 1, 2 or 4 mm can be pressed into the regular nozzle of any UNGUATOR® jar. They reduce the opening size, making it possible to safely dose even low formulations. The viscosity of the finished product normally specifies the diameter of the UNGUATOR® Varionozzles. The softly rounded surface allows ointment to be pleasantly spread directly on your skin.



Pic. 16: UNGUATOR® Varionozzles 1, 2, 4 mm

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)

3.2.4 UNGUATOR® Applicators

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

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



Fig. 17: Applicator UNGUATOR® short

UNGUATOR® Applicator long



Pic. 18: Applicator UNGUATOR® 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.

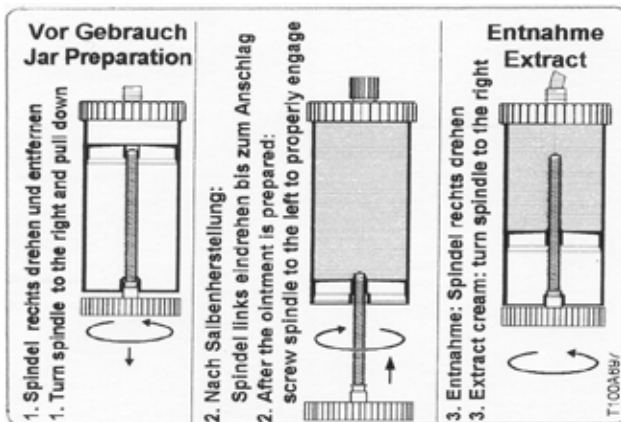
3.2.5 UNGUATOR® Spindle

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. 19: How to operate the UNGUATOR® Spindle



Pic. 20: UNGUATOR® Spindle

3.2.6 UNGUATOR® Coupling



Pic. 21: 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 200 ml 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.

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 1000 ml 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.

3.2.7 Air Dynamic® Pumpball System

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 300 ml to 1000 ml 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.



Fig. 22: UNGUATOR® AirDynamic® Pumpball system

By pumping air into the lower chamber of the UNGUATOR® Jar using the pumball, the pressure thus generated moves the bottom upward. Thanks to the AirDynamic® Pumball System, even thick pastes can be dispensed via the small dispensing opening in the screw cap or transferred to small UNGUATOR® Jars using the

4. General Guidelines for the UNGUATOR® Technology

4.1 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.

4.2 Weighed 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 200 ml 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.

4.3 Preparing the mixing process

Together with the UNGUATOR® Jar Lid, the UNGUATOR® MB should be loosely screwed onto the UNGUATOR® Jar body after the components of the formulation have been weighed out. By pushing up the UNGUATOR® Jar bottom with your thumb or, for large UNGUATOR® Jars, with the help of the UNGUATOR® Spindle or the AirDynamic® Pumpball System, the air will escape between the UNGUATOR® Jar Lid and the UNGUATOR® Jar body. Then the UNGUATOR® Mixing System should be tightly screwed down. This process is called air diminuation.

Air diminuation will prevent ointment exudation at the sealing zones of the UNGUATOR® Jar through reduction of any overpressure that may have developed. The mixing result is also optimized since there is no trapped air. We recommend, mainly in the case of intermingling large quantities of powder, that air diminuation be repeated after 15 seconds of the mixing process.

When pregrinding by pasting the solids with ointment base in the UNGUATOR® Jar, we recommend positioning the movable UNGUATOR® Jar Bottom as far downward as possible. This will guarantee that the large surface area of the inside wall of the UNGUATOR® Jar also including the lid and bottom can be used for dispersion between the friction surfaces of the UNGUATOR® MB and the inside surface area of the UNGUATOR® Jar body. Consequently, no air diminuation need be carried out prior pegrinding.

At this point of the mixing process, device-specific settings will need to be implemented and the UNGUATOR® Mixing System connected to the UNGUATOR®.

4.4 The Mixing process using the UNGUATOR® B/R

The UNGUATOR® B/R is an improved version of the first ever UNGUATOR® from 1994. The UNGUATOR® B/R meets the minimum requirements of the ointment quality management system (QMS) that represents the basic function of an UNGUATOR®. The powerful motor and the integrated controller also guarantee constant speed during the mixing process. The UNGUATOR® B/R name is the result of these properties: B stands for basic device and R for contRoller.

The prepared UNGUATOR® Mixing System is inserted into the bayonet holder of the UNGUATOR® B/R from below and pushed up as far as it will go. The UNGUATOR® Jar Lid and the UNGUATOR® Jar housing should be held simultaneously in one hand. When the UNGUATOR® B/R is switched on, the bayonet receptor will grip immediately by actuating the rotating knob, continuing until the mixing process is completed. The UNGUATOR® B/R is switched off by turning the rotating knob back into the initial position. Then the UNGUATOR® Mixing System can be removed by twisting the UNGUATOR® MB counterclockwise from the bayonet receptor and pulling it down.

We recommend moving the UNGUATOR® Jar up and down steadily from the stop on the UNGUATOR® Jar bottom to the stop on the UNGUATOR® Jar Lid every second, while holding the UNGUATOR® Mixing System tightly with at least one hand. The number of revolutions per minute (rpm) of the UNGUATOR® MB can be read from the scale on the operating head and continuously set using the rotating knob. The speed should already be set to the highest stage (2000 rpm) after a couple of strokes. The minimum quantity of strokes should not fall below 50 to ensure an optimal mixing result. Keep in mind that the required mixing time will increase with the size of the UNGUATOR® Jar.

The UNGUATOR® Mixing System can be switched to free spin motion as a special step with manual stroke movement.

Size of the UNGUATOR® Jar

Type of formulation	15-30 ml	50-100 ml	200 ml
Suspension	02:00	02:30	04:30
Normal	01:40	02:10	04:00
Emulsion	02:00	02:20	04:10
Suppositories	01:40	02:10	04:00

Tab. 2: Minimum values for mixing time at speed level 9 in min:sec

Size of the UNGUATOR® Jar

Type of formulation	15-30 ml	30-100 ml	200 ml
Suspension	03:00	03:50	06:45
Normal	02:30	03:20	06:10
Emulsion	03:00	03:50	
Suppositoires	02:30	03:20	06:10
Gel	4 x 1 min. with 1450 rpm with a break of 5 min. each		

Tab. 3: Minimum values for mixing time at speed level 5 in min:sec

The UNGUATOR® Mixing System is removed from the UNGUATOR® B/R after the required mixing time and the UNGUATOR® Jar Lid needs to be slightly untwisted as with air diminuation. The UNGUATOR® Jar bottom should then be pushed into the full down position using the UNGUATOR® MB. Then the UNGUATOR® Jar Lid should be retightened. The UNGUATOR® Mixing System can now be inserted back into the bayonet receptor of the UNGUATOR® B/R from below and pushed up as far as it will go. The UNGUATOR® MB can now clean itself through high-speed rotation in a position close to the lid. This process is called freespin. Most of the ointment is removed from the UNGUATOR® MB and the mixing process is complete.

4.4.1 Emulsion

(Emulsifying semisolid substances with water at room temperature).

Example: Eucerin c. aqua aa

Up to 200ml. we recommend using the UNGUATOR® Disp. Blade.

Cold stored foundations make the emulsification more difficult. Heating up the liquid to be added may accelerate the emulsification. Sometimes the heat that occurs during the mixing process inside the jar may already be sufficient and formation of emulsions.

4.4.2 Emulsion +

(Emulsifying of semisolid substances to be melted).

Examples: Emulsific. aquosa, Lanette, Cera

Up to 200ml. we recommend using the UNGUATOR® Disp. Blade.

Emulsions should always be heated then when UNGUATOR® Jars of 300 ml to 500 ml

are used.

Melting semisolid substances using max. 85°C/185°F hot water can be achieved by three methods:

1. Addition of hot water ($\leq 85^{\circ}\text{C}/185^{\circ}\text{F}$)
2. Covering with cold water – heat up to 200 ml in the hot-water bath $\leq 85^{\circ}\text{C}/185^{\circ}\text{F}$.
3. Covering with cold water – careful heating in the microwave (mind max. temperature)

To attain an even structure, heated emulsions should be stirred until they have cooled to room temperature with a few intervalled strokes using a water jacket or by using cooling phases at medium speed during which the UNGUATOR® Jars are placed in the refrigerator, if necessary.

4.4.3 Normal

(Mixing semisolid substances from low-viscous to pasty).

Examples: Off-the-shelf pharmaceutical ointments with base(s), concentrated active substances with base(s), liquid active ingredients in base(s)

First the ointment base should be weighed out into the UNGUATOR® Jar. Then the remaining constituents should be added accordingly.

4.4.4 Suspension <2%

(Mixing semisolid substances with a portion of microfine, agglomerated, optionally finegrained solid substances of less than 2 %).

Examples: Cortisones, antibiotics, fungicides, metronidazole

We recommend using the UNGUATOR® SMB.

If there is no concentrated active substance, we recommend a pregrinding process e.g. by use of a pregrind program in the case of a suspension with a content of less than 2% active ingredients. For pregrinding, the solids with low base content are weighed out into the UNGUATOR® Jar. The movable bottom remains in the lowest position, in order to make use of the full capacity of the jar including both lid and bottom areas for the dispersion process. The degree of dispersion reached by pregrinding should be checked to ensure that no active substance particles or agglomerates are too large, either microscopically or using a strong magnifying glass. Usually, the spreading on a glassplate (e.g. object slide) is sufficient to prevent inhomogeneity. Eventually the pregrinding process needs to be repeated depending on the examination.

Due to a high speed grinding process a warming of the formulation up to 50°C (122°F) may occur. Since this warming may not be suitable for some of the substances (e.g. metronidazole), we recommend continuously checking the temperature.

In order to gently work the substances, making use of these programs, the rpm and lifting speed can be individually selected and adjusted.

The relatively large surface of the UNGUATOR® SMB benefits the formation of an agglomerate grinding process. This can be quickly homogenized with the rest of the base even when using larger UNGUATOR® Jar sizes. After finalizing the pregrinding process both the remaining base and all substances will be weighed in.

4.4.5 Suspension >2%

(Mixing semisolid substances with a portion of microfine, agglomerated, optionally finegrained solid substances of more than 2 %).

Examples: Zincum oxydatum, acidum salicylicum

We recommend using the UNGUATOR® SMB.

For suspensions with ingredient content above 2% pregrinding is not required. For preparation please add 50% of the required base in the UNGUATOR® jar first and then include the micronized solid parts. Add the remainder of the base on top of the ingredients in order to avoid remaining powder sticking to the blades.

4.4.6 Gel

(Mixing of gel).

Example: Hydroxypropyl cellulose 400

We recommend using the UNGUATOR® Disp. Blade for up to 200 ml.

Basic gel approaches are mixed, with several intervals, at high speed during the required swell time thus preventing agglomerations and slightly reducing soaking time. Principlerelated, trapped air will normally clear after the preparation would settle for a while.

4.4.7 Suppositories

We recommend using the UNGUATOR® Disp. Blade for up to 200 ml.

The heating of fat suppository base ointment may be carried out using an infrared lamp over the open UNGUATOR® Jar. An UNGUATOR® Applicator aids the precise filling of the suppository forms. It may be reheated using a hair dryer or an infrared lamp. A batch of approximately 5 to 10% is recommended.

4.4.8 Powder

(Mixing powder to fill capsules).

We recommend using the UNGUATOR® Disp. Blade for sizes up to 200 ml.

Excellent mixing results will be achieved when using microfine powder with a high content of lubricious aerosil, which is considered as “Soft in Soft” (S/S) preparation. Please select low rpm (level 0/650 rpm), preferably applying the manual “Hand” mode (changing from “Auto” to “Hand”). Please have the mixing time extended accordingly.

4.5 Requirements for the ingredients of a prescription

Powder

If possible powders should be used as microfine substances. Powders should be added after any liquid constituents to ensure better wetting. For substances with a low proportion of powder, we recommend pregrinding by pasting the powder in minimum base inside the UNGUATOR® Jar, as already described before.

Crystalline Active Ingredients

We recommend pulverizing active crystalline ingredients in a mortar prior adding into 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. For example, urea with water. Then the remaining formulation ingredients can be added. The crystalline substance may also dissolve during the mixing process if the solvent is an ingredient of the ointment base.

Waxes, Hydrophilic ointment, etc.

Either pour warm water alone ($\leq 85\text{ }^{\circ}\text{C}/185\text{ }^{\circ}\text{F}$) or the heated remaining ingredients constituents over Cera, Lanette N, etc. in the UNGUATOR® Jar,
or

pour water in the substances and heat them either in a heated-water bath ($\leq 85\text{ }^{\circ}\text{C}/185\text{ }^{\circ}\text{F}$) or carefully observed in a microwave oven. Formulations without water containing components may be melted already directly inside the UNGUATOR® Jar by placing the jar in the water bath.

Please note that the UNGUATOR® MB must not go in a microwave oven. Furthermore, isolated areas of heat concentration may develop when heating in a microwave. To avoid this, we recommend coarsely blending the content of the jar during heating using a spatula at intervals. Please also keep in mind that a microwave will only heat aqueous substances. Generally it is sufficient to homogenize heated mixtures in three cooling intervals of six minutes each and apply 10 strokes each using the UNGUATOR® at high speed.

Homogenization of solid substances takes slightly longer. The cooling time and hence the cooling interval can be shortened in the refrigerator or by using a water jacket. The UNGUATOR® MB should remain in the UNGUATOR® Jar during the cooling phase. For emulsions, it makes sense in some cases to pregrind ingredients using the whole fatty phase and a low portion of water by a pregrinding. The remaining water can then be filled in the UNGUATOR® Jar in additional steps when the mixing process is interrupted. The advantage of pregrinding, where the basic ingredients are mixed evenly along the UNGUATOR® Jar wall, is a relatively fast bonding of the liquid constituents. This in turn assures an increased tightness of the sealing lips, even for large UNGUATOR® Jars and extended mixing processes.

4.6 After the mixing process is complete

The UNGUATOR® Mixing System is released and removed from the UNGUATOR® oscillation arm once the mixing process is finished. Unscrew the UNGUATOR® Jar Lid from the oscillation arm and/or twist the UNGUATOR® 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® Mixing System tightly with one hand when removing it from the UNGUATOR®.

In the next step, the UNGUATOR® Jar Lid is opened and the UNGUATOR® MB removed. Since this is also an opportunity execute a quality check, the UNGUATOR® Jar Lid should also be opened after mixing when using the UNGUATOR® Disp. Blade. Practice has proved that if the surface of the ointment looks smooth and if the minimum defined mixing time

has elapsed, homogeneity inside the UNGUATOR® Jar in fall can be expected.

Push the UNGUATOR® MB out of the UNGUATOR® Jar Lid. The ointment on the mixing blade can be fallen off into the UNGUATOR® Jar using a spatula. When using the UNGUATOR® Disp. Blade, the mixing blade can be removed from the UNGUATOR® Jar and disposed or left inside the UNGUATOR® Jar. Leaving the blade inside the jar will have no effect on dispensing the ointment through the UNGUATOR® Jar Lid. Removal of the mixing blade is recommended, particularly when giving the ointment to elderly clients, since it might otherwise cause confusion if the ointment is traditionally dispensed.

The UNGUATOR® Jar Lid is screwed back onto the UNGUATOR® Jar body and equipped with an UNGUATOR® Varionozzle as needed. Then a UNGUATOR® Jar Lid together with an UNGUATOR® Applicator is screwed on. Large UNGUATOR® Jars will be equipped with a spindle or the AirDynamic® System. Also in this case, like in the the regular mixing process, air diminution should be repeated. A “squirting out” of the ointment when first dispensed can be prevented by eliminating cavities that may have developed during the mixing process. The UNGUATOR® Jar Lid or the UNGUATOR® Applicator may now be fasten in place.

A label may be attached on the UNGUATOR® Jar prior forwarding to the client, preferably together with a short illustration of how to use and apply UNGUATOR® dispensing system. It is also a good idea to record the individual mixing parameters together with the results according to the final validation.

5. General recommendations on 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.

5.1 Patent protection

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

The UNGUATOR® Mixing System, and UNGUATOR® Technology and the AirDynamic® Pumpball System integrated therein are inventions of the pharmacist Albrecht Konietzko from Bamberg in 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 production of pharmaceutical ointments and cosmetics is covered by the UNGUATOR® Mixing System.

5.2 Potential sources of nonconformances

- The UNGUATOR® 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® Jar of equal weight although the filling volume is 40 % more than the rated volume. Please use the next largest UNGUATOR® jar for the mixing.
- The air was not removed before the mixing precess of semisolid preparations from the UNGUATOR® Jar. Then 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.
- The UNGUATOR® Jar bottom has not been moved up. The penetrating UNGUATOR® 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® Jar Lid, between UNGUATOR® Jar bottom and UNGUATOR® Jar body and along the shaft of the UNGUATOR® MB [1].
- The sealing lip on the UNGUATOR® 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® Jar bottom should be carefully brushed with foundation so as to improve its sealing quality.
- The sealing lip of the UNGUATOR® Jar Lid has been damaged by the shaft tappets of the UNGUATOR® MB upon perforating the lid. This will cause ointment to creep up the shaft.
- The UNGUATOR® Jar Lid is not tightened correctly and not held during the manually guided stroke. This may cause the UNGUATOR® 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® 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 [1].

5.3 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 year or when needed you can repeat the test.

Use a recipe with a colored substance, for example iron oxide (micronized) or Sudan Red and work this in a semi-solid base. You can spread out the finished recipe in a glass plate or in a microscope slide and check under the microscope the solids distribution and the grain size.

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

6. Service and warranty

6.1 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.

6.2 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 our local service partner, SMS Elap GmbH & Co. KG, Germany, or specifically authorized companies.

6.3 Notes on maintenance

- To preserve gears and motor for continuous untroubled operation, the UNGUATOR® e/s should either be sent to your representative in your individual country (please contact your UNGUATOR® dealer) or to SMS Elap GmbH & Co. KG after 20,000 preparations 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.

6.4 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® e/s: 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 UNGUATOR® e/s should pause for at least 5 minutes after a mixing period of 30 minutes.
- 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.



6.5 Technical data of the UNGUATOR® B/R

Electrical requirement	90-265 V / 45-65 Hz
Power consumption (mixing motor)	550 W
Operating mode	KB 5 (1)
Safety class	I
Type of protection	IP 21
Speed controller	electronic controlled
Timer	-
UNGUATOR® Jar sizes	15...200 ml
Weight	15 lbs (6,8 Kg)
Dimensions (L x W x H in mm)	275x 180 x 500
Testing certifications	TÜV GS

(1) KB 5: 30 minutes interval after 5 minutes' mixing operation. Please mind warning messages!

As to KB 5: Maximum load capacity will not be reached during normal operation. It is defined by 5 minutes' mixing of pasta zinci in the UNGUATOR® 100 ml jar at 2000 RPM and 30 minutes' cooling interval. A safety element may switch off the device in the case of overload condition, e.g. at 3 ointment preparations in the 200ml UNGUATOR® Jar in quick succession.

6.6 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.

7. 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]

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- [13] Mit zeitgemäßen Herstellungsverfahren rühren Pharmazeutische Zeitung (PZ) Nr.13 Jhg. 147/2002 Seite 60 Diskussion: A. Konietzko (GAKO®) und Dr. H. Reimann (NRF)

9. Manufacturer's certificate/ Declaration of Conformity

for plastic materials, which come into contact with food.

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

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

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

All the 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/dm³, 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® Germany - production control/January 2013

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

10. Distribution, manufacturing and customer service

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