

SECRO® 3000 DOSING TUBE

Questions and Answers

What is the purpose of the dosing tube?

- The dosing tube is a novel packaging in the shape of a plastic tube. It has been developed to contain liquid preparations which are to be dispensed by the user in the form of drops of specific size. Thus, its area of application corresponds essentially to current vertical dropper bottles which are customarily being utilised in many countries. Based on the superior operation, it offers, in addition, the possibility of not only easy metering but the targeted application of the filling medium.

How is the dosing tube designed / assembled?

- The dosing tube consists of a tube body, a dropper and a screw cap. These components are assembled by us to form a pre-fabricated primary packaging medium which our customers can fill and seal directly without taking any intermediate steps. As a result they receive a ready-for-use primary packaging.
- The tube body which holds the filling medium is closed by means of a thin plastic membrane. There is a small opening made in this membrane, the so-called choke. The dimensioning of this choke is calibrated to the properties of the filling medium and the desired dosage; as a result this has a decisive influence on the operation of the dosing tube.
- The dropper is located in the neck finish of the dosing tube and meters the liquid in drops of the corresponding size.
- The closure protects the tube from the external environment and secures its tamper-evidence until initial application. On request the tube can be supplied with a child-resistant screw cap making it difficult for young children to gain access to the tube contents.

Which products/preparations are suitable to be used with the dosing tube?

- Fundamentally, all solutions can be packaged and metered using the dosing tube, which enable administration in the form of drops owing to their viscosity and surface tension. For liquids containing solid particles, the applicability must be tested in individual cases to see if the choke becomes clogged.

How is the dosing tube utilised?

- After removal of the screw cap, the dosing tube is held in such a manner so that the dropper is positioned downwards vertically.
- Using pressure on the side of the tube body, the drop sequence is started and continued until the desired number of drops has been dispensed from the tube.
- The dropping action ends as soon as the pressure on the tube body is reduced accordingly or released entirely. Liquid still remaining in the dropper is sucked back into the tube body as a result of the release of pressure on the tube body. The liquid discharge channel is thereby emptied.
- Should a large number of drops need to be dispensed, the steps mentioned above should be repeated as required.
- After the dispensing of the desired dosage amount, the screw cap is replaced and tightened. In this way, the dosing tube is securely closed.
- The application of the dosing tube is generally carried out in the proper manner intuitively without the need for complicated directions for use. We should however, point out that to attain the highest possible metering precision when dispensing the drops, care should be taken to hold the tube in a vertical position. In addition, the proper handling of the child-resistant cap when re-closing the package should be explained in greater detail. Especially in

relationship to the importance of guaranteeing child safety. Samples texts are available from us.

Which general advantages are offered by the dosing tube?

- Generally speaking, the dosing tube increases the convenience and acceptance by the user owing to its simple and intuitive operation. The easy handling of the packaging is transmitted by the user to the packed product.
- Since comfort and ease of use is combined with the most precise metering, one can also reckon on an increased compliance from patients.
- Safety – the dosing tube is virtually unbreakable.

Which particular advantages does the dosing tube have for the consumer in comparison to customary dropper bottles?

- The advantages already begin immediately after opening the package: Since the dosing tube only has one opening and this opening is securely sealed by a screwed cap, the space under the cap remains always free of liquids. In addition, this also applies to the dosing tube when the packing has been subject to severe acceleration during transport.
- Of course the most important benefit is that in the case of the dosing tube, the delayed or complete absence of drop action which is often observed in customary dropper bottles does not occur. Some pressure on the tube body suffices to start the dropping action.
- The consumer decides the speed of the drop sequence themselves by determining the pressure to be exerted on the tube body. The specified drop size is, as a consequence, not influenced to any appreciable degree. The accordance with the requirements of the European Pharmacopoeia in relationship to the maximum drop speed and metering precision does not represent a problem for the dosing tube.
- Even small amounts of drops can be metered without any problem. As soon as the pressure on the tube body is reduced correspondingly or completely stopped, the dispensing of the drops ends. Liquid which still clings to the dropper is sucked back into the container when releasing the pressure on the tube body. Any remaining liquid in the discharge channel is thereby removed. This prevents any smearing or clogging of the discharge opening.
- Since the consumer can turn and position the dosing tube without haste before starting the drop sequence, he can target the application of the liquid to be dosed. This enables him in certain circumstances, to dispense with the use of spoons or other dosing aids. Especially, this also opens the possibility of applying the drop preparation directly onto the skin. In this case it is advantageous to be able to stop dispensing the filling medium without having to tilt the package. Releasing pressure on the tube suffices for the operation which is carried out in an entirely intuitive manner.
- The complete package consists of plastic and is therefore unbreakable. Initial experience has shown that the user is more apt to carry a dosing tube rather than a dropper bottle around with him. Users perceive this as an advantage over glass packing materials.
- And last but not least. The dosing tube can be completely drained, literally down to the last drop.

What about the environmental friendliness of the dosing tube?

- The dosing tube is made exclusively out of plastic materials which belong to the polyolefin group and not of a mixture of different materials such as glass and plastics as in the case of the dropper bottles. The dosing tube represents as such a single-material packaging which fundamentally offers the possibility of material recycling without previous disassembly.
- The maintenance of the European regulations on the avoidance of waste packing materials is thereby guaranteed by means of the thermal usability of the plastic material applied.
- The absolute amount of material used in comparison with current dropper bottles is considerably lower: While a dropper bottle from the Series SECRO® including the dropper and the tamper-

evident screw cap with a 100 ml designated volume weighs approx. 91 grams, the corresponding dosing tube in comparison weighs only 11.1 grams. The empty weight amounts to only 12% of the comparable dropper bottle.

- The low weight of the dosing tube saves energy throughout the overall life cycle of the package. This is especially true for all stages of internal and external transport, for production through processing right down to retailing.
- The dosing tube represents a safe container for the filling material. Even if it falls on hard ground, there is no damage – in contrast with a dropper bottle made of glass, which in all probability will break under the same conditions.

Which plus points does the dosing tube have for the user?

- The dosing tubes offer simplification and savings to the user, firstly due to the fact that it uses only one single pre-fabricated package. That eases buying, disposition, storage, processing and documentation.
- The automatic as well as spatial costs and last but not least the personnel costs which are required to produce finished primary packaging materials are reduced. Since the only thing required is the filling and closing of the tubes. For this purpose we dispose of high-performance machines from various producers. And for pharmacists, who do not want to set up their own processing equipment, there is already the first sub-supplier with substantial practical experience in the processing of dosing tubes.
- The insertion of the droppers and fixing of the screw caps are eliminated, since these processes were already carried out during the production of the packaging material. Sealing tightness, tamper-evidence and the child-resistance of the screw cap is guaranteed by us. Especially the high demands which are set by child-resistant packaging on the maintenance of exact application torques for screw caps are eliminated for those involved in further processing measures.
- In contrast with the wide spread of weight tolerances for glass packing, the weight of unfilled dosing tubes maintain very close tolerances. This enables the precise and explicit monitoring of the filling weight.
- Not only the weight but also the dimensions of the dosing tubes are precise. This enables quick and trouble-free processing which, in addition, is considerably quieter than for glass bottles.
- And when in spite of everything something jams: due to the unbreakable plastic tubes, defects occurring during processing do not result in broken pieces of glass, the associated complex cleaning procedures and long machine downtimes.
- The low weight of the dosing tubes is clearly positive in all areas of production where packing drums with packaging materials require manual handling.

Am I entering virgin territory when I decide to pack my product using the dosing tube?

- As the first pharmaceutical company, Abbott GmbH & CO KG with their Knoll product line brought out onto the market their time-tested product Paracodin[®]N-Drops in the dosing tube containing 15 and 30 grams in November 2001 after a marketing acceptance test and numerous stability tests had been successfully carried out. In the meantime, over 1 million packages have been produced and retailed.
- The Nordmark Arzneimittel GmbH & Co. KG in Uetersen is familiar with all phases which have to be run through when introducing the dosing tube. As independent contract filler, they offer all services which could be of interest in connection with the dosing tube from testing for the fundamental suitability to sample production and stability investigations through to subsequent series production.

What is necessary to adapt the dosing tube to a new preparation and to be able to guarantee optimal drop behaviour?

- The dosing tube enables the built-in choke to adapt to almost all drop solutions without any tooling costs. This applies not only for pre-testing but also for series production.
- In contrast with current dropper bottles, it is not necessary to develop the dropper for the dosing tube using complex processes and then construct expensive injection moulds. By means of plugging together tube bodies and the simply designed droppers, the optimal functional design can be determined and attested to by samples within only a few hours. Should no existing dropper mould be able to be utilised, an adaptation of existing series moulds at minimal costs is possible within the shortest period of time.

Which cap variant can be selected for the tube?

- The time proven SECRO[®]88 closure with tamper-evident ring in standard design and as an option the child-resistant version can be utilised for the dosing tube.

Does the tube have printing capability or labelling capability?

- The tube can be printed and labelled using customary machines. Depending on requirements, the decoration or designation can, in individual cases (according to the pieces per design / batch), be effected within the framework of the package production (currently only labelling possible) as well as alternatively during further processing.

What sizes are the dosing tubes available in?

- The dosing tube is available in the sizes 10, 20, 30, 50 and 100 ml. Packaging in intermediate sizes can be effected by using the next largest package, e.g. 15 ml – packages using the 20 ml dosing tube.

What does the dosing tube cost in comparison with current primary packaging?

- The dosing tube does not cost more than a dropper bottle – on the contrary, it offers savings possibilities. In comparison with the sum of the required components otherwise required (bottle, dropper and cap), it is up to 10% less expensive depending on the size and design.
- To be taken into consideration in this case is the fact that the dosing tube is supplied as pre-fabricated package. The dropper is already inserted, the screw cap is already on, the tamper-evidence and child-resistant features are basically installed. These value added procedures which are embodied into the dosing tube owing to these features have not been taken into account for the above-mentioned comparison in costs not to mention the other benefits derived from the dosing tube!

Are the materials utilised physiologically safe?

- Yes, all components in the dosing tube are made out of 100% physiologically biocompatible plastics. The biocompatibility declaration from the material producer generally considered to be necessary is available on request.

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