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(54) **INDUCTION SEAL DISK**

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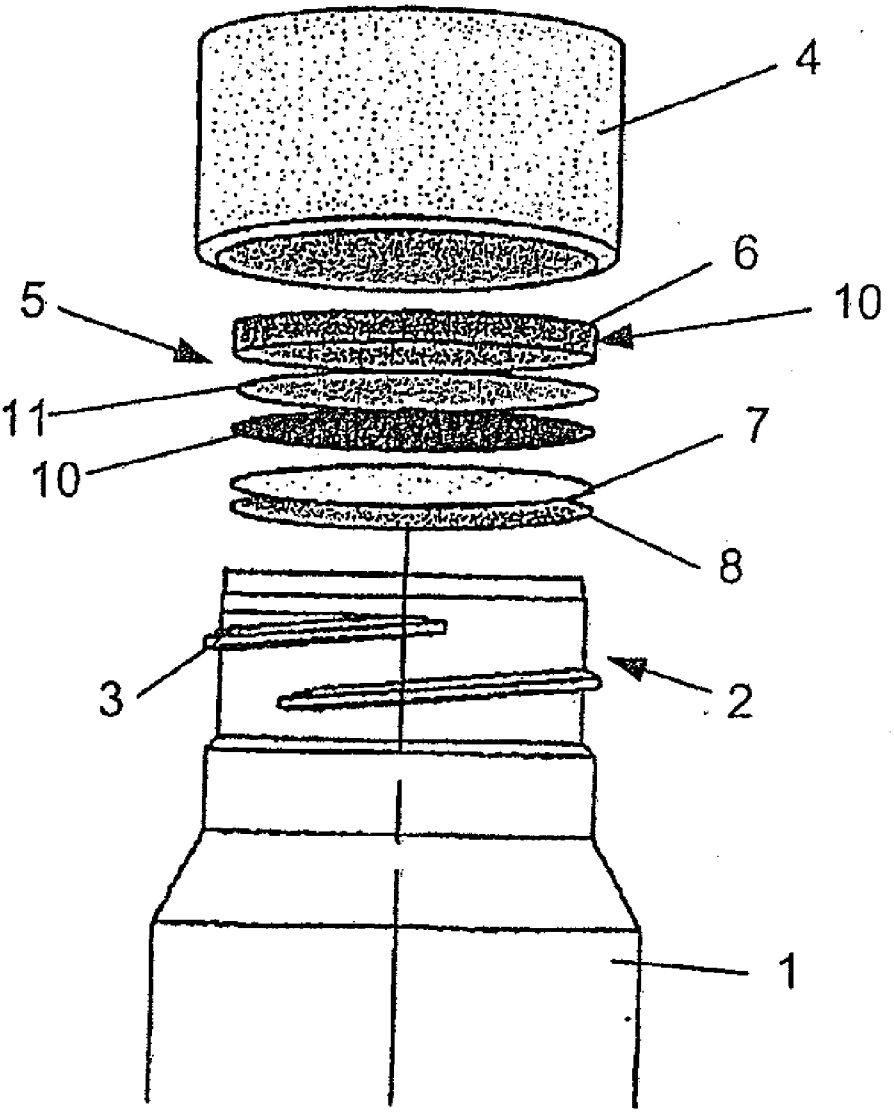
(57) **ABSTRACT**

An induction seal disc for a closure (**4**) of a bottle for storing medicaments comprises an elastic pressure inlay (**9**) and an, in particular, metallic sealing foil (**8**). Between the pressure inlay (**9**) and the sealing foil (**8**) is disposed a film (**10**) having low permeability.



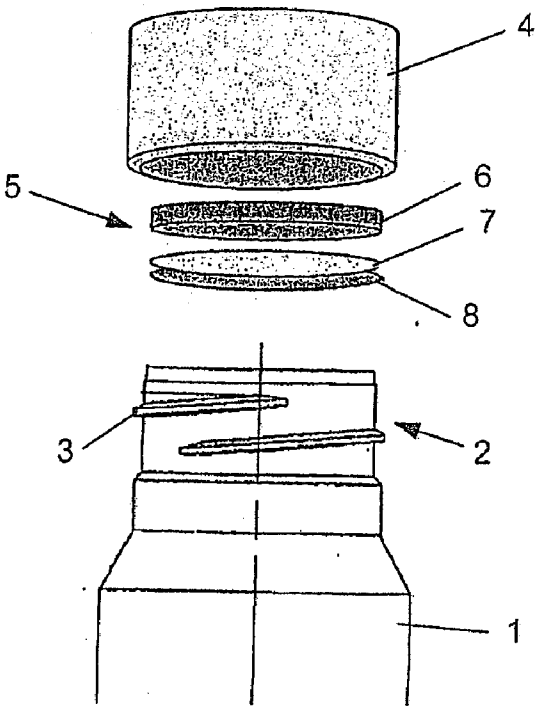


Fig. 1

Prior art

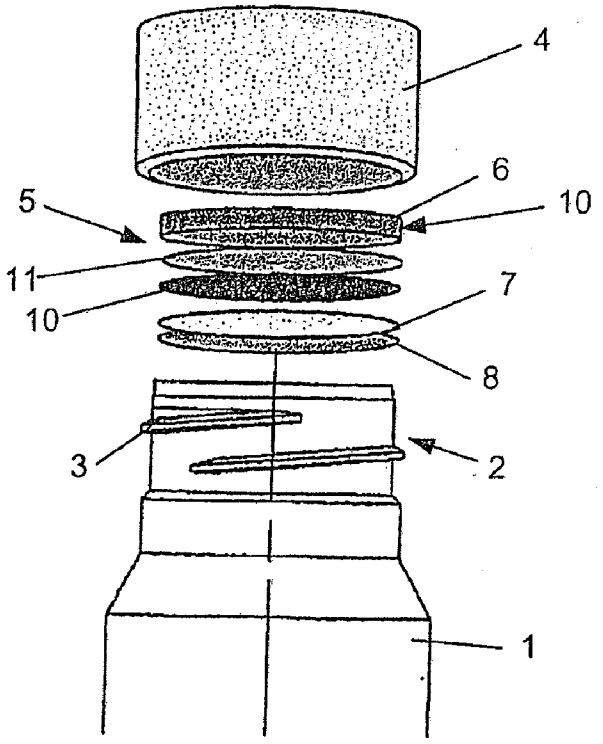


Fig. 2

INDUCTION SEAL DISK

[0001] The invention relates to an induction seal disk for a closure of a bottle for storing medicaments, comprising a cardboard inlay and an essentially metallic sealing foil, a closure having an induction seal disk and a plastic bottle with a corresponding closure.

[0002] In the pharmaceutical industry, pharmaceutical active substance formulations are sold in the form of plain or coated tablets or filled capsules in sealed bottles made of glass or plastics. Between the free end of the neck of the bottle and the closure there is generally provided an induction seal disc which on the one hand serves as proof of origin and on the other hand prevents moisture from getting into the bottle. Induction seal discs are known in a great many variations and are manufactured separately. Before the filled bottle is sealed, an induction seal disc is placed in a corresponding closure which is generally screwed onto the bottle with a certain torque. Then the sealed bottle passes through an induction device in which the actual sealing operation takes place, by the induction of alternating current in a metal foil of the induction seal disc, which is converted into heat which either causes the metal foil to bond directly to a bottle neck made of plastics or causes a corresponding adhesive to melt, thereby securing the foil to the bottle neck. On the side of the foil remote from the bottle neck is provided an elastic pressure inlay which allows the foil or the sealing layer to be pressed on satisfactorily thanks to the clamping pressure of the closure. Often, the pressure inlay is attached to the film by wax or some another adhesive. During sealing, the wax or the adhesive liquefies as a result of being heated and diffuses into the correspondingly configured pressure inlay, or special paper layers are provided that hold the wax or the adhesive.

[0003] One of the determining factors for the stability of pharmaceutical active substances is moisture. In view of the increasing development of active substances which are ever more effective but ever more sensitive to moisture, reduction and monitoring of the moisture in packages is essential. The packaging of medicaments involves a substantial use of plastic bottles which are sealed for the delivery chain from a manufacturer or bottling plant to a pharmacy or to the patient by means of the induction seal, thus sealing the plastic bottles particularly effectively from moisture during delivery and storage. Surprisingly, it has been found that it is this particularly high-quality closure method that results in induction-sealed plastic bottles becoming particularly leaky in the region of the opening once the bottle has been opened (so-called in-use permeation). When the bottle is opened, the sealing foil is pierced and there is only a cardboard layer and the plastic closure screwed shut to protect the product from moisture.

[0004] The problem of the invention is to provide an induction seal disc of the kind mentioned hereinbefore which will still provide an effective seal against moisture even after the induction seal has been broken.

[0005] According to the invention the problem is solved by arranging a film of low permeability between the pressure inlay and the sealing foil.

[0006] To reduce the in-use permeation, an additional barrier in the form of the film is introduced into the induction seal disc associated with the closure, this film preferably being firmly adhesively bonded to the pressure inlay. During the induction sealing, the sealing foil is firmly attached to the neck of a bottle and ensures the low permeation rate during the storage of the bottle that has thus been sealed. The sealing foil may be connected to the film by an adhesive or sticky layer which is more particularly releasable by heating, so that after the sealing process it is possible to rotate the film relative to the sealing foil without destroying the sealing foil. After the bottle has been opened, i.e. after the sealing foil has been pierced, the water permeation through the main permeation route, namely through the pressure inlay and the material from which the closure is made, is completely blocked by the additional film inserted. This method of improving the in-use permeation is not restricted to a specific type of bottle or container, and various materials may be used, particularly aluminium composites and/or polymers, for example polypropylene. It is also possible to use the induction seal disc in containers or bottles made of materials other than plastics. Moreover, the induction seal disc can be used with all common types of lid, particularly childproof or senior-friendly closures.

[0007] In one embodiment, the film is adhesively bonded to the pressure inlay in the form of a cardboard inlay and an adhesive layer is applied between the film and the sealing foil. There is therefore a strong bond between the cardboard inlay and the film and a releasable adhesive bond between the film and the sealing foil.

[0008] Expediently, the sealing foil and the film are made of aluminium. Other metallic materials or laminates of metal and/or plastic films are not ruled out, however, and will be selected by the skilled man according to the particular requirements.

[0009] In order to provide a reliable barrier for reducing water permeation, the surface of the cardboard inlay, the film and the sealing foil are advantageously all the same size. The size is matched to the internal diameter of the closure and the contact surface of the container that is to be sealed off, in order to permit a large-area seal.

[0010] The remaining difference between the permeation of the opened and sealed container can be attributed to the lateral permeation through the adhesive layer between the film and the sealing foil. The permeation can be further reduced by the advantageous provision of an adhesive layer between the film and the sealing foil, the area of which is less than the area of the sealing foil, while the adhesive layer does not extend as far as the edge of the sealing foil. The diameter of the adhesive layer applied in a circle between the film and the sealing foil is such that the adhesive layer does not come into contact with the bottle sealing surface (top edge). Thus, after the bottle has been opened, the adhesive layer itself cannot contribute to the lateral permeation between the film and the sealing foil.

[0011] Preferably, the adhesive layer consists of a wax, particularly with low permeability. The wax melts on sealing and thereafter permits non-destructive rotation of the film relative to the sealing foil as the lid is unscrewed and screwed shut. In order to reduce the permeation through the wax layer between the film and the sealing foil, a functional material is used as the wax which not only allows non-destructive opening of the closure, by its lubricating properties, but also has very low permeation and additionally minimises the ingress of water, for example as a result of strong adhesive properties, its low tendency to scoring and clumping and its elastic properties.

[0012] An alternative embodiment encompasses the omission of the adhesive layer between the film and the sealing

foil. Preferably, the sealing foil or the closure is of such dimensions that the sealing foil is held in the closure in the unsealed state. The sealing foil used is a sufficiently stable foil which can be prevented from dropping out of the closure during the packaging process by the fact that the internal diameter of the closure at the seating of the induction seal disc is somewhat greater than the internal diameter of the closure that is left free by the thread. The sealing foil introduced into the closure cannot thereafter fall out during the packaging process before the sealing operation. In order to ensure the correct positioning of the film and sealing foil it is possible to make the film and sealing foil of different configurations that are optically perceptible, for example by the application of structures, prints and/or colours. Thus, an optical check can be carried out to determine whether the film and the sealing foil are present in the closure during the packaging process.

[0013] According to a further feature, the film and/or the sealing foil are coated, particularly with a lacquer or a plastic, for example polyolefin, polyethylene, polypropylene, ethylenevinyl alcohol, ethylenevinyl acetate, or a barrier film, for example cycloolefin copolymer, highly crystalline polyvinylidene chloride, polychlorotrifluoroethylene. The coating may serve to prevent metallic abrasion during the repeated opening and closing of the closure and thus protect the product in the container or bottle. In addition, a coating can be selected, both for its material or combinations of material and its thickness, such that the direct application of the film and the sealing foil to one another is ensured and any unevenness is cancelled out and in this way the lateral permeation is further reduced. Coatings used may be, for example, lacquers, simple polymers, for example polyolefins such as high or low density polyethylenes (HDPE or LDPE), polypropylene (PP), or barrier films such as for example cycloolefin copolymer (COC), highly crystalline polyvinylidene chloride (PVDC) or polychlorotrifluoroethylene (PCTFE=Aclar®). In other variants, barrier properties against water may be combined, for example, with barrier properties against gases, e.g. oxygen. For this purpose, suitable barrier plastics such as highly crystalline polyvinylidene chloride (PVDC) or ethylenevinyl alcohol (EVOH) may be used as coatings, particularly for coating the film. Moreover, the coating may be used in controlled manner as a flavour protection, by the controlled use of suitable barrier plastics such as e.g. PVDC (for water protection and at the same time for flavour protection) or ethylenevinyl acetate (EVA, predominantly for flavour protection). For simultaneously achieving a barrier effect against various substances, e.g. water and gases and flavours, etc., foil composites having the corresponding barrier properties may be used. Foil composites may also be used to improve the mechanical stability of the film and/or the sealing foil. For the purpose of improving lateral permeation the film may also be wholly or partly coated and/or physically modified, e.g. by blasting or vapour deposition. For this purpose the layers or coatings may also be surface-treated or physically modified. In another variant the film may be replaced by an aluminium barrier foil or by a foil composite. This may itself be coated, pre-treated or physically modified.

[0014] To improve the in-use permeation properties further, the coating preferably comprises a sorbent which is suitable in particular for absorbing water, gases and/or flavours. It may be, for example, silica gel, a molecular sieve, clay or gypsum.

[0015] The problem is also solved with a closure for a bottle for storing medicaments with an induction seal disc having the properties described hereinbefore.

[0016] To safeguard repeated and reliable opening and closing, the closure is expediently configured as a screw closure. With the screw closure it is relatively simple to obtain the contact pressure required for a reliable seal.

[0017] The problem is further solved with a plastic bottle having a closure as shown above.

[0018] A plastic bottle of this kind can be produced inexpensively in particular by the blow-moulding method and also by coextrusion of a plurality of material layers. It is particularly advantageous if the plastic bottle consists of a polyurethane elastomer, a cellular polyurethane elastomer, a thermoplastic material, particularly high or low density polypropylene or polyethylene, or a laminate.

[0019] The plastics used for the plastic bottle may consist of polyvinylchloride (PVC), cyclo-olefin-copolymer (COC), polychlorotrifluoroethylene (PCFE), polyethylene (PE), polypropylene (PP), polyethylene terephthalate (PET), polycarbonate (PC), polyester (UP), polyacrylate, polyamide (PA) or another plastic or a multi-layer composite plastic, consisting for example of a combination of polychlorotrifluoroethylene (PCTFE), which is known particularly by the brand name Aclar® registered as a trade mark by Honeywell International, Inc., with polyvinylchloride (PVC) or polyvinyl chloride (PVC) with polyvinylidene chloride (PVdC).

[0020] Preferably, a sealing surface is formed on the free end of the bottle neck. The sealing surface is configured so as to provide a relatively large and flat abutment surface for the sealing foil and/or the film.

[0021] According to a further feature, the plastic bottle is filled with a pharmaceutical active substance formulation in the form of plain or coated tablets or filled capsules.

[0022] It will be understood that the features mentioned above and about to be explained hereinafter may be used not only in the particular combination specified but also in other combinations. The scope of the invention is defined only by the claims.

[0023] The invention is hereinafter explained in more detail by means of an embodiment by way of example, with reference to the associated drawings, wherein:

[0024] FIG. **1** shows a plastic bottle with a closure and an induction seal disc according to the prior art and

[0025] FIG. **2** shows a plastic bottle with a closure and an induction seal disc according to the invention.

[0026] The plastic bottle **1** according to the prior art is made from a high density polyethylene (HDPE) and has a capacity of about 150 ml. A thread **3** for a closure **4** is formed on the neck **2** of the bottle. An induction seal disc **5** is placed in the closure **4** and consists of a cardboard inlay **6** on which a sealing foil **8** made of aluminium is attached by means of a wax **7**.

[0027] After being filled, the plastic bottle **1** is sealed with the closure **4** with an induction seal disc **5** contained therein, by the application of a certain torque, in order to press the cardboard inlay **6** with the sealing foil **8** adhesively bonded thereto onto the free end of the neck **2** of the bottle with the corresponding contact pressure. Then the sealed plastic bottle **1** passes through an electromagnetic field of a certain power that is irradiated in close above the closure **4**, as a result of which an electric current is induced in the electrically conductive sealing foil **8**, which dissipates as a result of the electrical resistance of aluminium, i.e. is converted directly into heat. The heat produced melts the contact surface at the free end of the bottle neck **2** and bonds the bottle neck **2** to the sealing foil **8**. After leaving a sealing machine, the heated area

cools down and the sealing foil **8** is welded to the plastic bottle **1**. During heating, in the sealing operation, as well as the plastic the wax **7** between the cardboard inlay **6** and the sealing foil **8** also melts, after which the cardboard inlay **6** is detached from the sealing foil **8**. This induction sealing process has already been used successfully for years in the packaging of pharmaceutical products. HDPE bottles sealed by this method have low permeation rates of about 0.85 mg of water per day, for example, in the sealed state, in the case of a 150 ml HDPE bottle, based on 100% [relative humidity] difference in humidity (inside/outside) and at 25° C. When the plastic bottle **1** is opened, the sealing foil **8** is pierced. Then the cardboard inlay **6** pressed against the free end of the bottle neck **2** to form a seal and the tightly screwed closure **4** protect the product in the plastic bottle **1** from moisture and the permeation rate is about 7.3 mg of water per day under the conditions stated above.

[0028] In the plastic bottle **1** according to the invention shown in FIG. **2** the induction seal disc **5** has been improved by the provision of a low-permeability film **10** between a pressure inlay **9**, which may also be made of an elastic plastics, for example, and the sealing foil **8**, the film **10** made of aluminium being firmly adhered to the pressure inlay **9** configured as a cardboard inlay **6** using an adhesive **11**. The sealing foil **8** which is also made of aluminium is attached to the film **10** with wax. The cardboard inlay **6**, the film **10** and the sealing foil **9** are all the same size.

[0029] To reduce the lateral permeation through the layer of wax **7** between the film **10** and the sealing foil **8**, a functional material is used as the wax **7** itself, which safeguards the non-destructive opening of the closure **4** by its lubricating properties and also has a low permeability. To reduce the lateral permeation through the wax **7** still further, the diameter of the circular layer of wax **7** provided between the film **10** and the sealing foil **8** is small enough so that the wax **7** cannot come into contact with the sealing surface at the free end of the bottle neck **2**. Once the plastic bottle **1** has been opened, the wax **7** itself cannot contribute to the lateral permeation between the films **10** and the sealing foil **8**.

[0030] During the sealing, the sealing foil **8** is firmly welded to the bottle neck **2** and, as previously, safeguards the low permeation rate of the sealed plastic bottle **1** during storage. The wax **7** between the film **10** and the sealing foil **8** melts during sealing, as a result of the prevailing heat, and enables the film **10** to be rotated non-destructively relative to the sealing foil **8** during the opening and closing of the closure **4**. Thus the film **10** and sealing foil **8** remain intact and retain their barrier properties. Once the plastic bottle **1** has been opened and the sealing foil **8** pierced accordingly, the water permeation through the main permeation route, namely via the cardboard inlay **6** and the material from which the closure **4** is produced, is completely blocked by the additional film **10**.

[0031] The in-use permeation rate of originally about 7.3 mg/d is reduced to about 2.35 mg/d in the plastic bottle **1** according to the invention, under the conditions explained hereinbefore.

1. Induction seal disc for a closure (**4**) of a bottle for storing medicaments, comprising an elastic pressure inlay (**9**) and a metallic sealing foil (**8**), characterised in that between the pressure inlay (**9**) and the sealing foil (**8**) is arranged a low permeability film (**10**).

2. Induction seal disc according to claim **1**, characterised in that the film (**10**) is adhesively bonded to the pressure inlay (**9**) embodied as a cardboard inlay (**6**) and an adhesive layer is applied between the film (**10**) and the sealing foil (**8**).

3. Induction seal disc according to claim **1**, characterised in that the sealing foil (**8**) and the film (**10**) are made of aluminium.

4. Induction seal disc according to claim **1**, characterised in that the surface of the cardboard inlay (**6**), the film (**10**) and the sealing foil (**8**) are all the same size.

5. Induction seal disc according to claim **1**, characterised in that between the film (**10**) and the sealing foil (**8**) is provided an adhesive layer, the area of which is less than the area of the sealing foil (**8**), wherein the adhesive layer does not extend to the edge of the sealing foil (**8**).

6. Induction seal disc according to claim **1**, characterised in that the adhesive layer consists of a wax (**7**) with a low permeability.

7. Induction seal disc according to claim **1**, characterised in that the sealing foil (**8**) or the closure (**4**) is of such dimensions that the sealing foil (**8**) is held in the closure (**4**), in the unsealed state.

8. Induction seal disc according to claim **1**, characterised in that the film (**10**) and/or the sealing foil (**8**) is or are coated with a lacquer or a plastic selected from polyolefin, polyethylene, polypropylene, ethylenevinyl alcohol, ethylenevinyl acetate, or a barrier foil selected from cycloolefin copolymer, highly crystalline polyvinylidene chloride, polychlorotrifluoroethylene.

9. Induction seal disc according to claim **8**, characterised in that the coating comprises a sorbent which is suitable in particular for absorbing water, gases and/or flavours.

10. Closure for a bottle for storing medicaments, having an induction seal disc (**5**) according to claim **1**.

11. Closure according to claim **10**, characterised in that the closure (**4**) is embodied as a screw closure.

12. Plastic bottle having a closure (**4**) according to claim **10**.

13. Plastic bottle according to claim **11**, characterised in that a sealing surface is formed at the free end of the bottle neck (**2**).

14. Plastic bottle according to claim **11**, characterised in that the plastic bottle (**1**) is filled with a pharmaceutical active substance formulation in the form of plain or coated tablets or filled capsules.

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