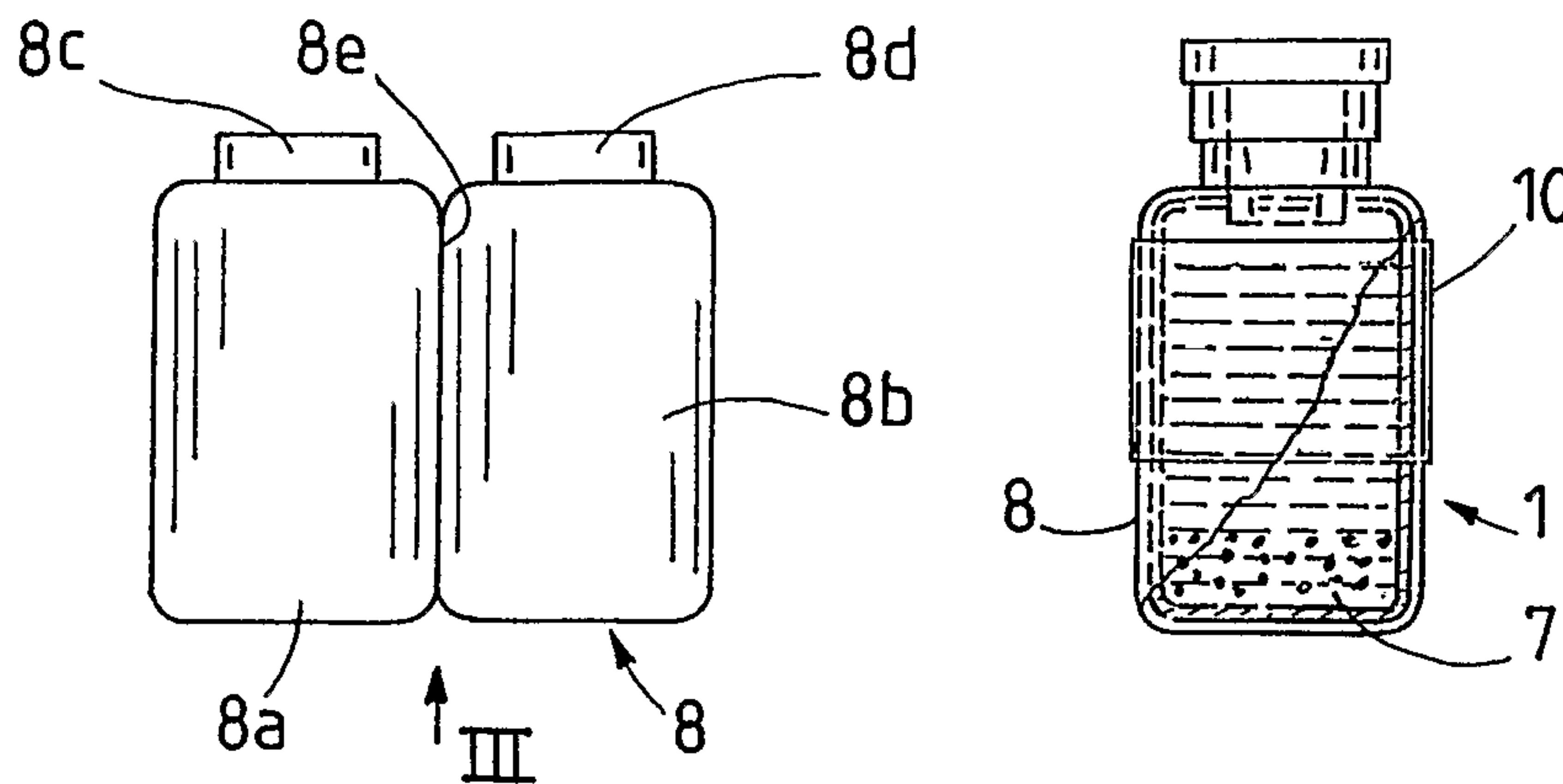




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(54) Titre : CONTENANT PRESENTANT UNE PAROI DE CONTENANT CYLINDRIQUE TRANSPARENTE
 (54) Title: CONTAINER COMPRISING A TRANSPARENT CYLINDRICAL CONTAINER WALL



(57) Abrégé/Abstract:

The invention relates to a container (1) comprising a transparent cylindrical container wall (2) and an envelope (8) covering the entire container wall. Such containers are used in the form of a vial, an ampulla or a syringe, for example, in clinical tests of medicaments or remedies. According to the invention, the envelope is embodied in an opaque manner such that it can be determined whether undissolved particles are still present in the liquid, but the actual colour of the content cannot be determined.

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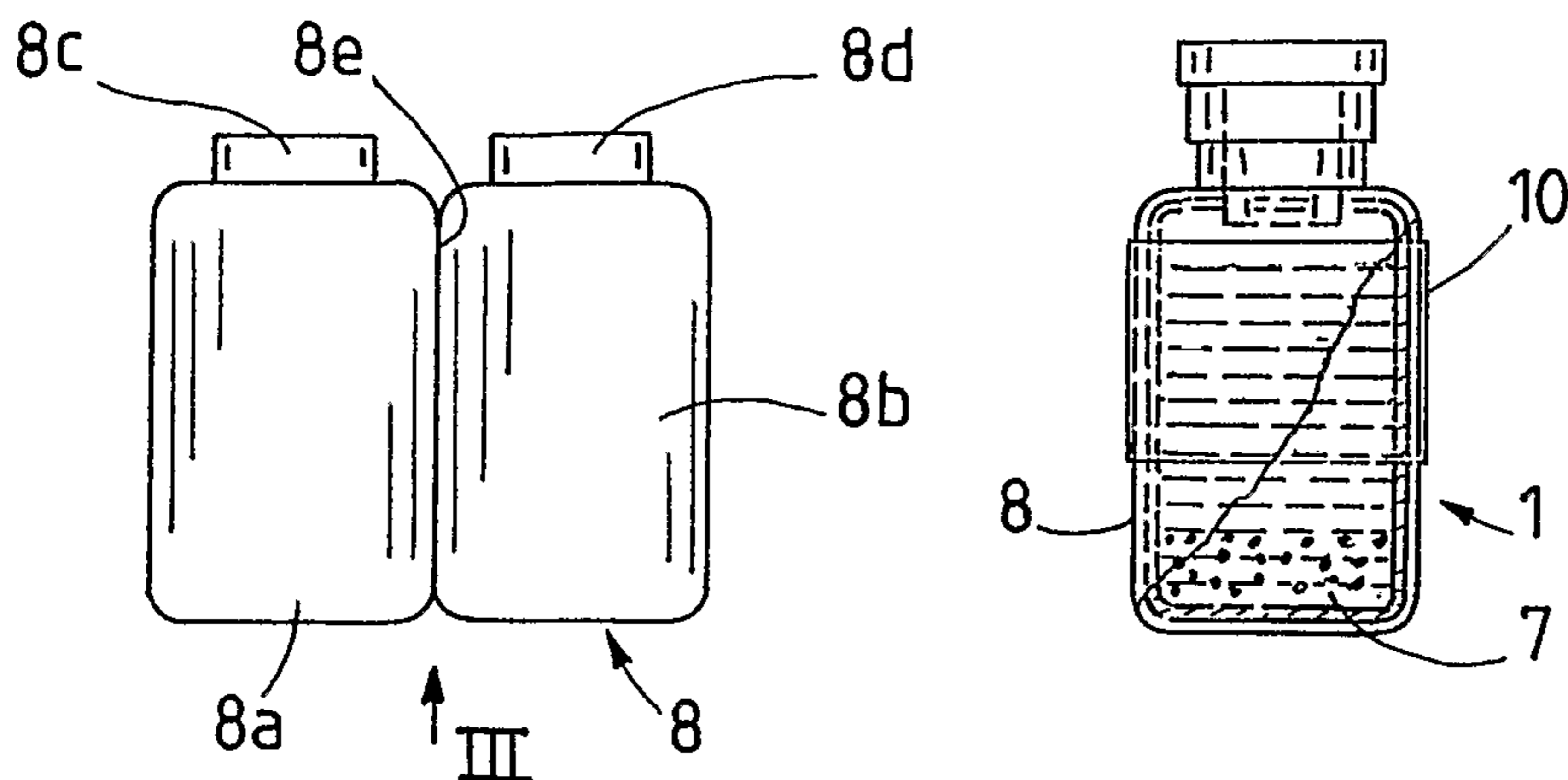
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Zur Erklärung der Zweibuchstaben-Codes und der anderen Ab-
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(54) Title: CONTAINER COMPRISING A TRANSPARENT CYLINDRICAL CONTAINER WALL

(54) Bezeichnung: BEHÄLTER MIT DURCHSICHTIGER ZYLINDRISCHER BEHÄLTERWANDUNG



(57) Abstract: The invention relates to a container (1) comprising a transparent cylindrical container wall (2) and an envelope (8) covering the entire container wall. Such containers are used in the form of a vial, an ampulla or a syringe, for example, in clinical tests of medicaments or remedies. According to the invention, the envelope is embodied in an opaque manner such that it can be determined whether undissolved particles are still present in the liquid, but the actual colour of the content cannot be determined.

(57) Zusammenfassung: Gegenstand der Erfindung ist ein Behälter (1) mit durchsichtiger zylindrischer Behälterwandung (2) und einer die ganze Behälterwandung bedeckenden Hülle (8). Solche Behälter werden in der Form eines Vials oder einer Ampulle oder einer Spritze zum Beispiel bei klinischen Prüfungen von Arznei- bzw. Heilmitteln eingesetzt. Erfindungsgemäss ist nun die Hülle derart opak ausgebildet, dass sich zwar feststellen lässt, ob in der Flüssigkeit noch ungelöste Teilchen vorhanden sind, nicht aber, welches die wirkliche Farbe des Inhalts ist.

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CONTAINER COMPRISING A TRANSPARENT
CYLINDRICAL CONTAINER WALL

DESCRIPTION

5 In medicine the problem of quality assurance, thus knowledge about effects and side effects of therapeutics, becomes more and more important. That is why these effects are established and verified in clinical trials by means of statistical tests.

In such trials a large number of subjects receive orally, parenterally or topically the to-be-tested medicine over a period of time set in advance and according to a special protocol, and
10 the reactions of the subjects and the effects of the medicines are registered and statistically evaluated.

Statistically significant evaluations of clinical trials require now that in a series of tests, various preparations and/or their formulations and/or concentrations are used, for example, in a predetermined order and that these, independent of their original packaging, their
15 colour, their original labelling or the like have a uniform appearance so that their characteristics cannot be distinguished neither by the subjects nor other persons involved in carrying out the tests.

Besides the generally known, blisterlike push-out packagings containing pills or dragées
20 which are used, among other things, for the above-mentioned purpose, there are still other galenic forms of administration, for example, as liquid which are presented to the subjects in syringes and ampoules as well as lyophilisates, thus freeze-dried substances which are kept in vials and then are dissolved again for the application in a liquid delivered by means of a syringe in order that they can be administered orally or by injection. Also such forms of
25 administration are used increasingly for the clinical trial where in these applications the to-be-tested medicines as well as the control and comparison preparations required likewise for the statistical evaluation are each contained in a sealed container thus, for example, a vial, an ampoule or syringe.

The object of the invention is now to propose for the use of liquid or freeze-dried galenic administration, a novel container which takes into account the anonymity requirements/blinding in such tests.

5 The subject-matter of the invention is thus a container according to claim 1 usable for this purpose which can be designed as vial, ampoule or disposable syringe as well as a set of several such containers according to claim 9.

Advantageous embodiments of the invention are subject-matter of the claims dependent upon claim 1.

10 Transparent containers with a jacket more or less covering the container wall are in themselves known: Thus, for example, FR 2 731 210 A shows an obviously commercial beverage bottle with a glued on jacket which has insulating as well as aesthetic functions and moreover makes the bottle, on the one hand, somewhat more damage resistant and, on the other hand, holds together the fragments in case of damage. This previously known jacket is translucent, however, obviously not so that with it the colour of the bottle contents
15 can be made unrecognizable since particularly for beverage bottles it is not unimportant to be able to establish the colour of the contents.

Also US 3 965 920 shows a beverage bottle with a stuck on, in some cases multi-layered jacket consisting of synthetic material which serves the purpose of protecting the bottle against breakage and, in case of breakage, to hold together the fragments. In contrast to this,
20 US 5 261 546 shows now a glass bottle for pharmaceutical liquids. However, in significant distinction to the container according to the present invention, this has a jacket with an opening serving especially for the exact control of the contents.

In the following an exemplified embodiment of the invention is elucidated further with the aid of the drawing. In the drawing

25 Fig. 1 shows a container, drawn partly in section, partly in view, containing a liquid,

Fig. 2 shows a view of a jacket made of synthetic material in the opened-up state, that is, before it is put on the container,

Fig. 3 shows a view in the direction of arrow III of Fig. 2,

Fig. 4 shows a view of the container with put-on synthetic jacket in which case some parts are cut away, and

Fig. 5 shows a set of five identical containers according to Fig. 4 in which case each
5 container can have different contents.

The cylindrical container shown in Figs. 1, 4 and 5, and designated as a whole by 1, called vial in the following, has a transparent, for example, clear glass or synthetic material wall 2 with a bottom 3 and a stopper 5 lodged firmly, detachably or undetachably in the bottleneck 4, with accompanying cap 6. The cap 6 is in this case designed and dimensioned in such a
10 way that in the secured state it protrudes over the edge of the filling opening, here, in the present example, over the bottleneck 4. The vial 1 contains a liquid or freeze-dried, thus solid or liquid galenic formulation 7 in which case the latter, during the dissolution in a liquid, still can contain soluble particles 9.

According to the invention, the vial now, as is apparent from Fig. 4, has a jacket 8 covering
15 the entire container wall. This jacket consists preferably of coloured, thermally formable synthetic material, thus, for example, a PVC or a polyethylene. Important and essential is that the colour of this jacket is selected in such a way that two containers which are filled with different contents take on the same appearance in which case, however, the intensity of this colour may only be so strong that the transparency through the container wall only is
20 reduced to the extent that it still can be established whether undissolved particles are present in the liquid.

Such jackets are suitably made with the deep drawing process in such a way that first, by means of a single or multiple tool, several synthetic material jackets, one which is shown in Figs. 2 and 3, are produced in a PVC film. Afterwards, these are punched out of the film so
25 that each jacket comprises two identical half shells 8a and 8b, connected hinged to one another along a generatrix 8e, of which the inside surfaces correspond exactly to the form of the vial 1, which thus each also have a neck part 8c and 8d respectively as well as a bottom part.

After this jacket 8, comprising two half shells, have been put around the vial according to Fig. 1, its two parts are covered and kept together by placing a safety sealing tape 10 enclosing them. As safety sealing tape one uses suitably a synthetic material tape, coated on one side with adhesive, with scored separating lines which serve to destroy the tape when removed so that a reattachment becomes impossible. This sealing tape can be colourless or coloured. Suitably its surface not provided with the adhesive, thus the exterior surface, is structured in such a way that it can be printed on or written on. If the surface available for the accommodation of multilingual information is too small, a paper or synthetic material tape, enclosing the container once or repeatedly, can also be used of which one end is attached to the container by means of an adhesive and of which the other end is provided, if necessary, with a repeatedly usable adhesive.

It is, of course, also possible to attach the jacket undetachably to the container by means of an adhesive.

Fig. 5 shows now a set of five identically looking vials 11-15 according to Fig. 4. Each of these five vials has, however, different contents in which case in some there are still undissolved particles. The translucency of the five jackets now is such that the presence of still undissolved particles but not a difference in colour of the contents of the various vials can be detected.

Although in the above exemplified embodiment the container is described as a vial, the container also can be of a different design, for example, ampoule or injection syringe.

CLAIMS

1. Container (1) with transparent, cylindrical container wall and a jacket (8) covering the entire container wall, containing a liquid or freeze-dried galenic formulation (7) characterized in that the jacket (8) is of an opaque design so that it can be determined whether in the container there are solid particles or a liquid or a liquid with still undissolved particles (9) but not what the actual colour of the contents is.
2. Container according to claim 1, characterized in that the jacket (8) consists of coloured material.
3. Container according to one of the claims 1 or 2, characterized in that the jacket (8) comprises a thermally formable synthetic material.
4. Container according to one of the claims 1 to 3, characterized in that the jacket (8) comprises a preformed synthetic material jacket lying fully against the container wall.
5. Container according to claim 4, characterized in that the synthetic material jacket comprises two half shells (8a, 8b) connected hingedly to one another.
6. Container according to claim 5, characterized in that the two half shells are kept together by a safety sealing tape (10) enclosing the half shells.
7. Container according to claim 6, characterized in that the safety sealing tape can be written on or that on the safety sealing tape a printed or writeable label can be placed.
8. Container according to claim 5, characterized in that the half shells (8a, 8b) are attached undetachably to the container wall (2).
9. Set of several containers (11-15) according to one of the claims 1 to 8 in which case not all containers have the same contents, characterized in that all containers are provided with an identical jacket (8) so that all containers only can be distinguished from one another by lettering or numbering.

Fig.1

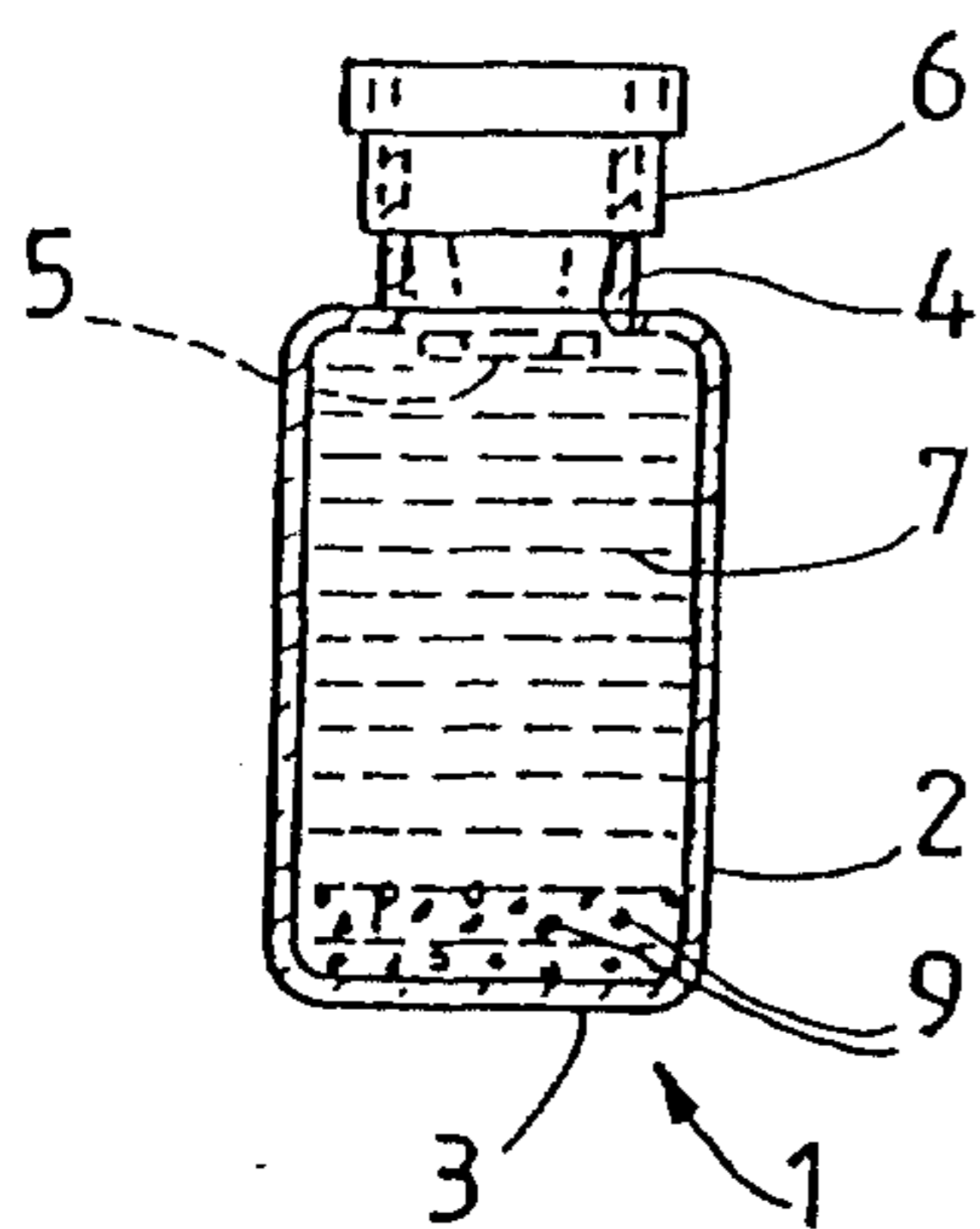


Fig.2

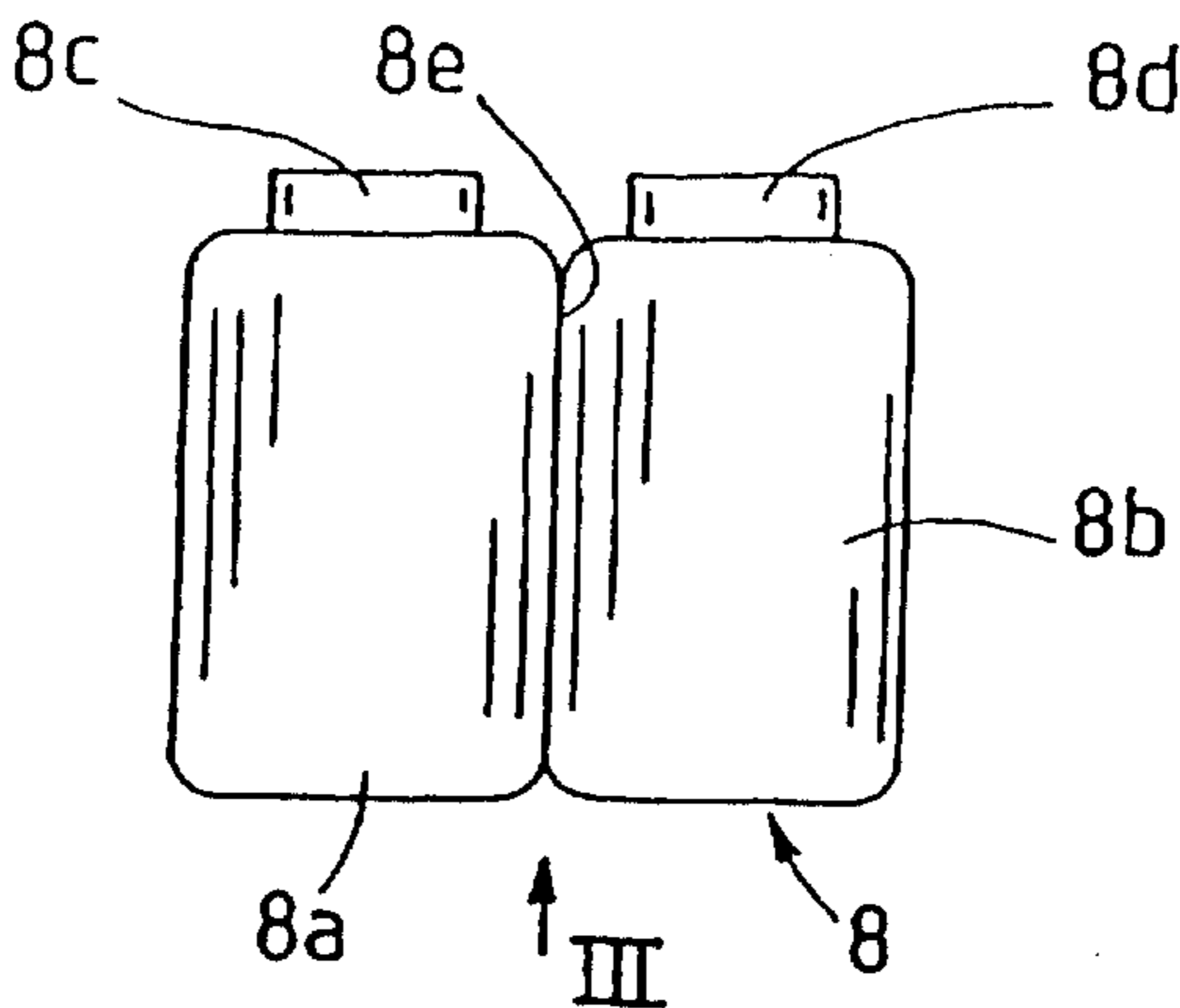


Fig. 4

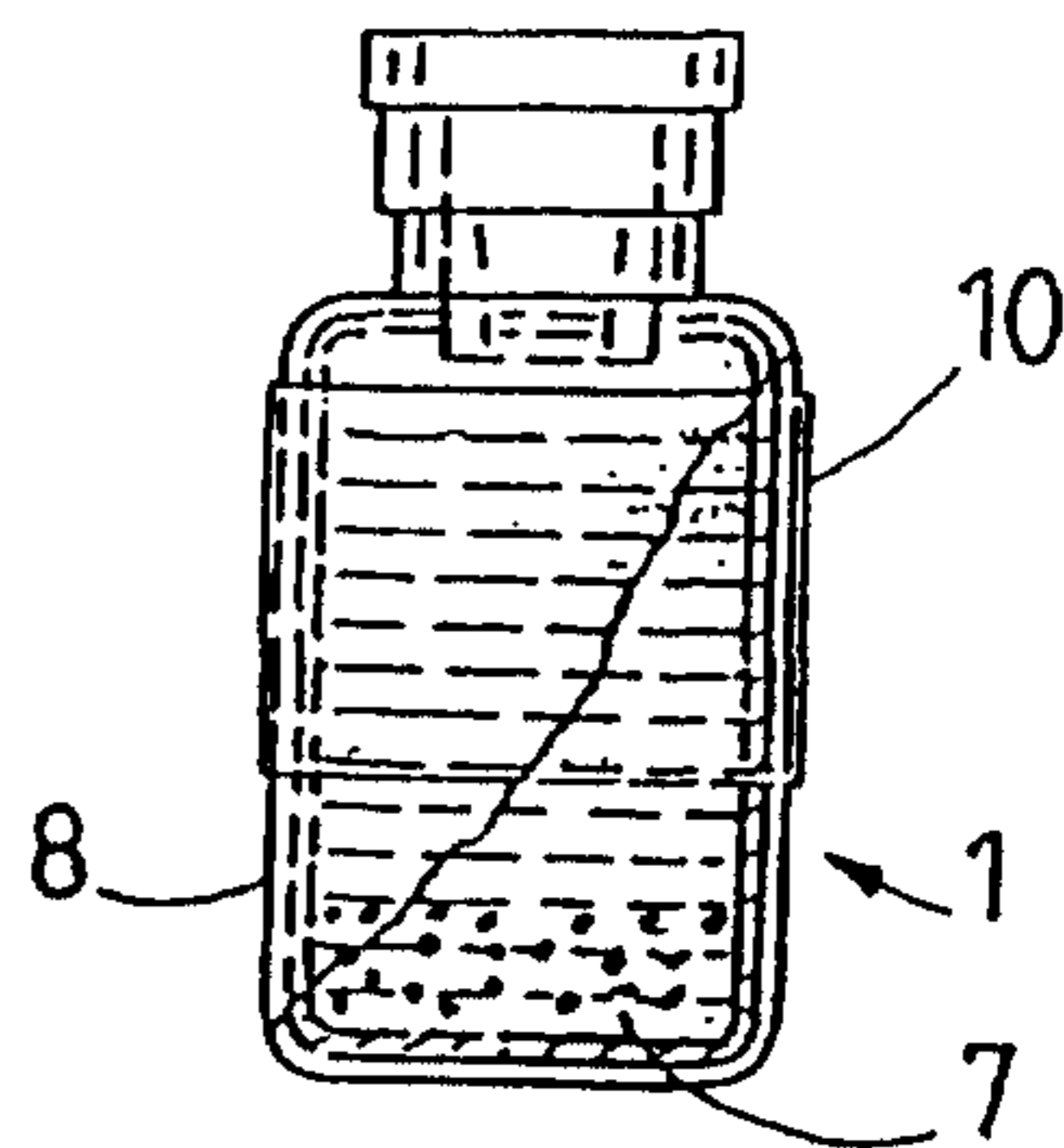


Fig.3

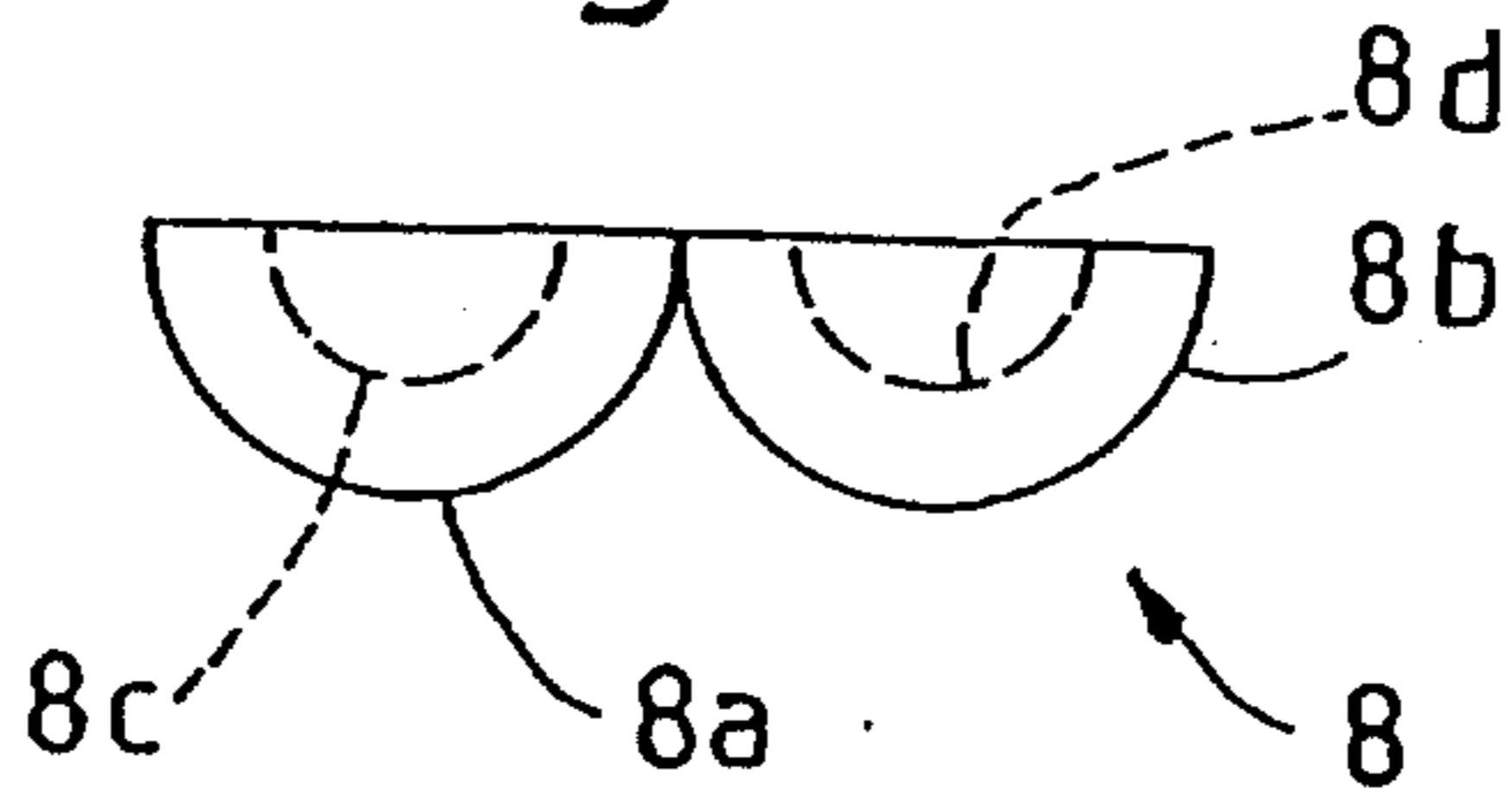


Fig.5

