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(56) Documents cited

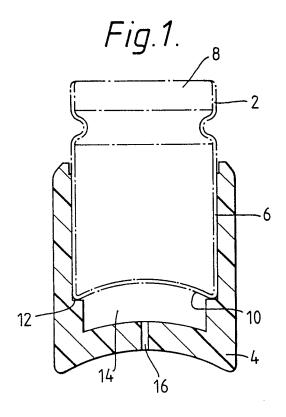
GB 1468953 A GB 1389324 A GB 1471253 A

GB 1132709 A GB 1004363 A

(58) Field of search UK CL (Edition K) F1R RAA RCC INT CL5 B65D

(54) Aerosol vial

(57) An aerosol vial has secured to its outer surface means to increase at least one external dimension thereof by at least 1mm. Thus a shroud 4 allows the outer dimensions of a 5ml vial 2 to be modified to be identical with the outer dimensions of a 10ml vial thereby allowing the modified vial to be handled by the same automatic machinery and/or adaptors as 10ml



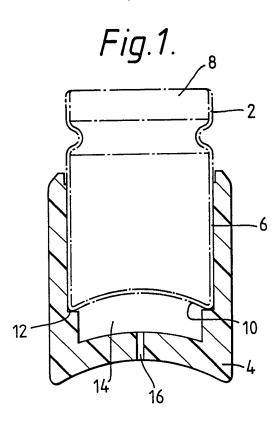
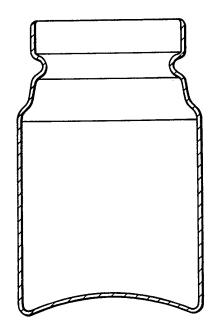


Fig. 2.



AEROSOL VIAL

This invention relates to aerosol vials and in particular to means for modifying the external dimensions of aerosol vials.

Since the metered dose pressurised inhaler was introduced in the mid-1950's, inhalation has become the most widely used route for delivering bronchodilators, offering a rapid onset of action and a low instance of systemic side effects. More recently, inhalation from a pressurised inhaler has been a route selected for the administration of other drugs, e.g., ergotamine, which are not primarily concerned with the treatment of a bronchial malady.

The metered dose inhaler is dependent upon the propulsive force of a propellant system used in its manufacture. The propellant generally comprises a mixture of liquified chlorofluorocarbons (CFC's) which are selected to provide the desired vapour pressure and stability of the formulation. Propellants 11, 12 and 114 are the most widely used propellants in aerosol formulations for inhalation administration. Recently, non-CFC propellant systems have been proposed in view of the adverse effect of CFC's on the ozone layer. The drugs are formulated in the propellant system as a solution or dispersion, generally in the presence of a surfactant.

The drug/propellant formulation is contained in an aerosol vial equipped with a metered dose valve. The aerosol vial is inserted within an adaptor which comprises a housing having a mouthpiece or nasal port through which the patient inhales the drug during actuation of the valve. The adaptor may be of the "press and breathe" type which requires the patient to actuate the valve during inhalation or of the "inhalation—actuated" type which actuates the valve as the patient inhales.

Inhalation activatable dispensers for use with aerosol containers are described in British Patent Specification Nos. 1269554, 1335378, 1392192 and 2061116 and United States Patent Nos. 3,456,644, 3,456,645, 3,456,646, 3,565,070, 3,598,294, 3,814,297, 3,605,738, 3,732,864, 3,636,949, 3,789,843 and 3,187,748 and German Patent No. 3040641.

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European Patent No. 147028 discloses an inhalation activatable dispenser for use with an aerosol container in which a latch mechanism releasing vane is pivotally mounted in an air passage between an aerosol outlet valve and a mouthpiece, which latch mechanism cannot be released if force to activate the dispenser is not applied before a patient inhales.

This inhalation device has been received favourably by patients and doctors since it not only overcomes the hand-lung co-ordination problem but it does so at a very low triggering flow-rate (approximately 30 litres/minute) essentially silently, and with a very compact design barely larger than a standard inhaler.

With the introduction of longer acting bronchodilator drugs there is a trend towards fewer doses per inhaler. For such products it is important to use a small vial to minimise both the dead space within the vial and the internal surface area since some formulations have a tendency for the drug to deposit on the internal surface of the vial.

There are inherent disadvantages in using small aerosol vials, including:

- 1. Insufficient labelling area for including the necessary information.
- 2. Handleability, and
- 3. Compatibility with current adaptors, both press and breathe and inhalation-actuated.

The present invention has been made with the above points in mind.

According to the present invention there is provided an aerosol vial having secured to its outer surface means to increase at least one external dimension thereof by at least 1mm, generally by at least 2mm.

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The invention provides a simple, effective means of modifying the external dimensions of an aerosol vial. Generally, the means comprises a plastics shroud which covers the base and extends at least partially, e.g. one quarter, preferably at least half, more preferably substantially completely up the sidewall of the vial. The thickness of the base and walls of the shroud may be selected to attain the desired width and height of the aerosol vial. The selection criteria may be for a variety of purposes e.g. providing a particular surface area for labelling, providing a desired height or width for handling by automatic machinery or providing the required dimensions for inserting into an inhalation-actuated or press and breathe adaptor.

Generally the aerosol vial will have a volume of less than 15ml, usually not more than 10ml, preferably about 5ml. A particularly preferred shroud is selected such that a 5ml vial will be provided with substantially identical height and width dimensions as a 10ml vial thereby allowing the same automatic machinery and/or the same adaptors to be used for both the 5ml and 10ml vials.

The invention will now be illustrated by the following drawings in which:

Figure 1 is a cross-section through an aerosol vial in accordance with the invention and

Figure 2 is a cross-section through a conventional aerosol vial having comparable dimensions to that of Figure 1.

Figure 1 shows a 5m vial (2) inserted in a plastics shroud (4) dimensioned such that the combination has comparable external dimensions to a 10ml vial as shown in Figure 2.

The vial (2) has substantially cylindrical sidewalls (6), a neck (8) and base (10). The shroud (4) is substantially cylindrical having an internal diameter such that the sidewalls (6) of the vial are a force fit within the shroud. The interior of the shroud (4) has a ledge (12) on which the base (10) of the vial rests. There is a dead space (14) between the base (10) of the vial and end of the shroud. The shroud has an aperture (16) to allow air trapped in the shroud to exit as the vial is inserted. The aperture (16) is not essential and other arrangements may be made to allow displacement of air e.g. a channel extending down the inner surface of the shroud. The vial and/or inside of the shroud may be coated with adhesive prior to assembly to secure the shroud to the vial.

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The vial is generally of aluminium and the shroud of plastics material, such as, high density polyethylene.

It will be appreciated the shroud may take a variety of different configurations depending upon the exterior dimensions required. For example, the shroud need not have a base if the height of the vial may remain the same. The shroud may comprise a plurality of longitudinal and/or circumferential ribs on the sidewall of the vial to increase the effective external diameter of the vial whilst retaining the ability to read data on the vial.

CLAIMS

- 1. An aerosol vial having secured to its outer surface means to increase at least one external dimension thereof by at least 1mm.
- 2. An aerosol vial as claimed in Claim 1 said means increases at least one external dimension by at least 2mm.
- 3. An aerosol vial as claimed in Claim 1 or Claim 2 in which said means comprises a plastics shroud.
 - 4. An aerosol vial as claimed in Claim 3 in which the shroud covers the base of the vial and extends at least one quarter of the way up the sidewall of the vial.
- 5. An aerosol vial as claimed in Claim 4 in which the shroud extends at least half way up the sidewall.
 - 6. An aerosol vial as claimed in Claim 4 in which the shroud extends substantially completely up the sidewall.
 - 7. An aerosol vial as claimed in any one of Claims 3 to 6 in which the shroud extends the width of the vial by at least 2mm and the height of the vial by at least 5mm.
 - 8. An aerosol vial as claimed in any one of Claims 3 to 7 in which the shroud is adhered to the vial.
 - 9. An aerosol vial as claimed in any preceding Claim in which the vial is substantially cylindrical.
 - 10. An aerosol vial as claimed in any preceding Claim in which the vial has a volume of less than 15ml.
 - 11. An aerosol vial as claimed in any preceding Claim in which the vial has a volume of not more than 10ml.
- 30 12. An aerosol vial as claimed in any preceding Claim in which the vial has a volume of about 5ml.
 - 13. An aerosol vial as claimed in Claim 1 substantially as herein described with reference to the accompanying drawings.

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14. A pressurised aerosol for administration of medicament to the respiratory system of a patient comprising an aerosol vial as claimed in any preceding Claim equipped with a metered dose dispensing valve and containing a composition comprising drug and aerosol propellant.

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Patents Act 1977 Framiner's report to the Comptroller under Section 17 (The Search Report)

Application number

GB 9212174.8

Relevant Technical fields			Search Examiner
(i) UK Cl (Edition	K)	F1R (RAA, RCC)	D DODD
(ii) Int CI (Edition	5)	B65D	
Databases (see ove			Date of Search
(i) UK Patent Office)		10 SEPTEMBER 1992
(ii)			

Documents considered relevant following a search in respect of claims

1-14

Category (see over)	Identity of docum	Relevant to claim(s)	
х	GB 1471253	(DANA) - note figure 2	1 at least
x	GB 1468953	(ALTER) - whole document	1 at least
x	GB 1389324	(GORMAN) - note page 3 lines 22-26	1 at least
X	GB 1132709	(FISONS) - whole document	1 at least
Х	GB 1004363	(MESHBERG) - note page 2 lines 35-58	1 at least
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Category	Identity of document and relevant passages	Relevant to claim(s)
Categories o	f documents	
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- X: Document indicating lack of novelty or of inventive step.
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- A: Document indicating technological background and/or state of the art.
- P: Document published on or after the declared priority date but before the filing date of the present application.
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