

A SUPPORT STRUCTURE FOR A MEDICAMENT

The present invention relates to a support structure for a medicament in the form of, for example, a blister pack for a drug or an injection moulded drug dosing element as used in an inhalation device. A typical blister pack for a medicament is described in WO 01/45777 and a typical drug dosing element is described in US 5,590,645.

With powdered medicaments there is a demand for a package/support structure which is able to keep the powder free from the ingress of moisture both during storage and when the powdered medicament has been loaded into a delivery device. Similarly, if the drug is in tablet or capsule form there is also a demand to keep the tablets/capsules, which are typically held in a blister pack, free from the ingress of moisture. The main weakness in a support structure which has a lid sealed to a base, having one or more cavities for holding the medicament, is in the region where the lid is sealed to the base. If the support structure is in the form of a blister pack, the lid and base are often both made from a material having an aluminium layer which makes these elements moisture impermeable. Accordingly, the only region where moisture can penetrate the blister pack is through the lid sealing region which is typically a heat seal. If the base of the blister pack is made from a plastic material then there will also be moisture ingress through the base material to the medicament. If the support structure is in the form of an injection moulded dosing element, the injection moulded base will be made from a moisture permeable material whereas the lid will typically have an aluminium layer making it moisture impermeable. In this case, there will also be moisture ingress through both the heat seal between the lid and base and through the base material.

The problem of moisture ingress has been overcome to a certain degree in prior art inhalation device components by using aluminium containing foil materials for both the lid and base and spacing adjacent cavities by approximately 3mm. With such a construction, moisture within an empty cavity does not then compromise an adjacent cavity which still contains a dose of medicament. The only weakness resides in the heat seal between lid and base. A disadvantage with this construction is that there is a limit to the number of doses which can be arranged on the blister pack/dosing element due to the spacing requirement.

Other prior art solutions include providing a desiccant source which is connected to or placed within a cavity containing the medicament. However, this solution is reactive only, in that moisture is removed after having penetrated a cavity rather than preventing moisture from entering the cavity in the first place. Similarly, an alternative solution has been to use a desiccant box inside an aluminium bag which holds a plurality of medicament doses, e.g., tablets, but this form of moisture protection is destroyed when the bag is opened for the first time so that there is no in-use stability. For further examples of prior art solutions, reference should be made to WO 03/61742 and US 6,132,394.

In view of the problems discussed above, the present invention seeks to provide moisture protection for the medicament and to maximise the number of doses arranged on the support structure.

According to the present invention, there is provided a support structure for a medicament comprising a base with at least one cavity for the medicament and a lid for sealing the medicament within the cavity characterised in that each moisture permeable region of the structure is protected against the ingress of moisture by locating a moisture absorbing sink between that region and the ambient air outside the structure.

Preferably, the sink reduces the relative humidity (RH) of the air passing through it to substantially the relative humidity (RH) of the air within the cavity so that there is minimal diffusion of moisture from the sink to the cavity.

Preferably, each moisture permeable region comprises an inner moisture permeable barrier located adjacent to the cavity and an outer moisture permeable barrier, the moisture absorbing sink being located between the inner and outer barriers.

Preferably, the base and the lid are moisture impermeable and the moisture permeable region of the structure is located where the lid is sealed to the base.

Preferably, the moisture absorbing sink between the lid and the base is spaced from the periphery of the cavity thereby forming an inner moisture permeable region and an outer moisture permeable region, the sink breaking the moisture ingress path so that there is minimal diffusion of moisture through the inner moisture permeable region to the cavity.

Preferably, the moisture absorbing sink comprises a channel in the base surrounding the cavity which contains dry air.

Preferably, there is provided a plurality of cavities each having a channel filled with dry air.

5 Preferably, each channel is connected to a single desiccant source which dries the air in all the channels.

Preferably, the moisture absorbing sink comprises a polymer ring surrounding the cavity and located between the lid and the base.

10 Preferably, there is further provided a plurality of cavities each having a polymer ring.

Preferably, the base and the lid have an aluminium layer for moisture impermeability, the lid being heat sealed to the base.

15 Preferably, the lid is moisture impermeable and the base material is moisture permeable, the moisture permeable regions being located where the lid is sealed to the base and within the base material of the cavity walls.

Preferably, a first moisture absorbing sink is located between the lid and the base and is spaced from the periphery of the cavity and a second moisture absorbing sink is located within the base material of the cavity walls thereby forming inner moisture permeable barriers and outer moisture permeable barriers, the sink
20 breaking the moisture ingress path so that there is minimal diffusion of moisture through the inner moisture permeable barriers to the cavity.

Preferably, the moisture absorbing sink comprises a channel containing dry air surrounding the cavity opening where the lid is sealed to the base and passing through the cavity walls.

25 Preferably, there is further provided a plurality of cavities each having a channel containing dry air.

Preferably, each channel is connected to a single desiccant source which dries the air in all the channels.

30 Preferably, the base is injection moulded and the lid has an aluminium layer for moisture impermeability, the lid being heat sealed to the base.

Preferably, the base comprises cooperating stackable elements, each element having a plurality of cavities, the cavities within one of the elements sitting between

the cavities within another element when stacked, a moisture absorbing sink being formed by the spacing between the cooperating elements.

Preferred embodiments of the present invention will now be described in detail, by way of example only, with reference to the accompanying drawings, of
5 which:

Figure 1 is a graphic representation of the relative humidity gradient across a barrier for a drug with conventional moisture protection;

Figure 2 is a graphic representation of the relative humidity gradient across a barrier arrangement with moisture protection according to the present invention;

10 Figure 3 is a section through one blister in a blister pack with moisture protection according to a preferred embodiment of the present invention;

Figures 4A, 4B and 4C depict preferred embodiments of blister packs with multiple cavities having moisture protection;

Figure 5 is a plan view of a section of a dosing element for an inhalation
15 device having moisture protection according to a preferred embodiment of the present invention;

Figure 6 is a sectional view in direction X-X through the dosing element in Figure 5;

Figure 7 depicts a further preferred embodiment of a dosing element having
20 moisture protection;

Figure 8 depicts the underside of annular ring 111b in Figure 7; and,

Figure 9 is an enlarged view of part of the annular ring in Figure 8.

Reference should now be made to Figure 1 which depicts the relative humidity (RH) gradient across a barrier which is moisture permeable. The barrier could be, for
25 example, the material from which the base of the support structure is made or the heat seal between the lid and base of the support structure. The moisture ingress through the barrier arises because the relative humidity in the ambient air outside the support structure is typically 70% whereas the relative humidity of the air and powdered drug within a cavity is typically 20%. The moisture ingress arises both
30 from the ambient air and from neighbouring cavities which have already been emptied. The powdered drug is protected only by a single barrier and moisture is continually transported through the barrier by gradient driven diffusion. The transport

of moisture continues until the relative humidity inside a cavity reaches the ambient level. Moisture protection can only be improved by increasing the barrier thickness or modifying the properties of the barrier material.

In the present invention, it is proposed to locate a moisture absorbing sink
5 between each moisture permeable region of the support structure and the ambient air. This can be achieved, for example, by breaking the single barrier into an outer barrier and an inner barrier with the sink located between the two barriers. Figure 2 depicts a preferred arrangement where the sink effectively breaks the moisture ingress path. The relative humidity gradient across the outer barrier is high giving
10 moisture diffusion as in Figure 1. However, when the moisture passes into the sink which has high moisture absorption qualities, any moisture diffusion through the inner barrier will be low. For example, if dry air is present in the sink, the relative humidity of the air in the sink could fall to 20% (which is a similar level to that within the cavity) with the result that the relative humidity gradient would be very low across the inner
15 barrier and the moisture ingress path could be broken.

Figure 3 depicts a first preferred embodiment of the present invention where the support structure is in the form of a blister pack 1 having a base 2 with at least one cavity 3 holding a medicament and a lid 4 which is sealed to the base 2 by way of heat seals 5 and 6. Between the outer seal 5 and the inner seal 6 is a moisture
20 absorbing sink in the form of a channel 7 which surrounds the cavity 3. The channel 7 could contain dry air to remove moisture in the region of the lid 4. The moisture ingress path M for this support structure will only be through the heat seals 5 and 6 as the blister pack base 2 and lid 4 would typically be manufactured from a moisture impermeable material having an aluminium component. The moisture ingress path M
25 would result in a relative humidity gradient similar to that depicted in Figure 2. The outer barrier would be heat seal 5 and the inner barrier would be heat seal 6. The dry air in channel 7 would be dried by way of a desiccant. If the dry air reduces the relative humidity in the channel 7 to approximately 20% then there will only be minimal moisture diffusion through the heat seal 6 to the cavity 3 assuming that the
30 relative humidity within cavity 3 is also approximately 20%.

Reference should now be made to Figures 4A, 4B and 4C which depict three configurations for a blister pack having a plurality of cavities 3. In Figure 4A each

cavity 3 is surrounded by a dry air channel 7. The channels 7 are all connected to a desiccant 8 which ensures that air within the channels is continually dried to the required level. The channels and desiccant reservoir would typically be cold formed in the same manufacturing process step as the cavities. Figure 4B depicts a further
5 modification using a rectangular channel configuration. Figure 4C depicts a preferred configuration when the moisture absorbing sink for each cavity 3 is a moisture absorbing material, e.g., a polymer in the form of a nylon ring 9. In this case, there is no need for a desiccant and each cavity 3 has a dedicated nylon ring which sits between the base 2 and lid 4 of the support structure.

10 In Figure 5, the support structure for the medicament is in the form of an annular drug dosing element 101. This type of dosing element typically sits within an inhalation device which is able to index the drug cavities 103a, 103b and 103c past a mechanism which ruptures the lid 104 and allows the user to draw the drug from each cavity. Figure 5 shows a segment of the annular dosing element 101
15 containing three adjacent cavities 103a, 103b, 103c. One of the cavities 103a is empty whereas the other two cavities 103b and 103c still contain the powdered drug. Figure 6 is a sectional view taken in direction X-X through the dosing element in Figure 5.

The base 102 of the dosing element 101 would typically be injection moulded
20 and hence would be moisture permeable. With this arrangement, moisture protection is needed both where the lid 104 is heat sealed to the base 102 and within the base material. There are channels 107 running between adjacent cavities and beneath each cavity through the base 102.

The channels 107 all connect to a desiccant 108 which dries the air in the
25 channels to reduce the relative humidity to that within the cavities.

For cavity 103b, the outer heat seal 105 runs around the outer and inner peripheries of the annular dosing disc. There is also an outer moisture barrier 109 in the base 102. The channel 107 creates the inner barriers in the form of the inner heat seal 106 and the inner moisture barrier 110 in the base 102.

30 When the cavity 103a has been emptied, the inner heat seal 106 for that cavity becomes the outer heat seal 105 for cavity 103b thereby ensuring that the empty cavity 103b is not a source for moisture ingress.

Figure 7 depicts a preferred construction for the dosing element 101 which comprises two cooperating annular rings 111a and 111b which sit one above the other within a containing tray 112. The spacing between the annular rings 111a and 111b forms channels 107.

5 This arrangement allows each cavity to be spaced from an adjacent cavity by as little as 1mm. In this way, 60 cavities can be arranged on a dosing disc 101 with a diameter of 72mm. A desiccant 108 (not shown) to dry the air in the channels 107 between components 111a, 111b and 112 sits on the underside of annular ring 111b (see Figures 8 and 9) in a groove 113. A lid 104 would be heat sealed to the
10 arrangement shown in Figure 7.

The annular ring 111a has a plurality of cavities 114 and the annular ring 111b has a plurality of cavities 115.

With this arrangement, it is not necessary to injection mould the annular rings such that there are separate channels as in Figure 5. It is sufficient to injection mould
15 the drug cavities 114 and 115 in the annular rings and sit the annular rings one above the other within the containing tray 112. The groove 113 for the desiccant is located on the underside of annular ring 111b as viewed in Figure 7. The spacing between the annular rings 111a and 111b is sufficient for humidity transport. Tooling is considerably simpler and there is no need to form the narrow channels depicted in
20 Figure 5. Spacing between the annular rings can be increased, for example, by increasing the roughness of the walls or applying a lattice pattern to the walls.

CLAIMS:

1. A support structure for a medicament comprising a base with at least one cavity for the medicament and a lid for sealing the medicament within the cavity, each
5 moisture permeable region of the structure being protected against the ingress of moisture by locating a moisture absorbing sink between that region and the ambient air outside the structure, characterised in that each moisture permeable region comprises an inner moisture permeable barrier located adjacent to the cavity and an outer moisture permeable barrier, the moisture absorbing sink being located between
10 the inner and outer barriers thereby reducing the relative humidity (RH) of the air passing through it to substantially the relative humidity (RH) of the air within the cavity so that there is minimal diffusion of moisture from the sink to the cavity.
2. A support structure as claimed in Claim 1, wherein the base and the lid are
15 moisture impermeable and the moisture permeable region of the structure is located where the lid is sealed to the base.
3. A support structure as claimed in Claim 2, wherein the moisture absorbing sink between the lid and the base is spaced from the periphery of the cavity thereby
20 forming an inner moisture permeable region and an outer moisture permeable region, the sink breaking the moisture ingress path so that there is minimal diffusion of moisture through the inner moisture permeable region to the cavity.
4. A support structure as claimed in any of Claims 1 to 3, wherein the moisture
25 absorbing sink comprises a channel in the base surrounding the cavity which contains dry air.
5. A support structure as claimed in Claim 4, comprising a plurality of cavities each having a channel filled with dry air.
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6. A support structure as claimed in Claim 5, wherein each channel is connected to a single desiccant source which dries the air in all the channels.

7. A support structure as claimed in any of Claims 1 to 3, wherein the moisture absorbing sink comprises a polymer ring surrounding the cavity and located between the lid and the base.

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8. A support structure as claimed in Claim 7, comprising a plurality of cavities each having a polymer ring.

9. A support structure as claimed in any of Claims 2 to 8, wherein both the base and the lid have an aluminium layer for moisture impermeability, the lid being heat sealed to the base.

10. A support structure as claimed in Claim 1, wherein the lid is moisture impermeable and the base material is moisture permeable, the moisture permeable regions being located where the lid is sealed to the base and within the base material of the cavity walls.

11. A support structure as claimed in Claim 10, wherein a first moisture absorbing sink is located between the lid and the base and is spaced from the periphery of the cavity and a second moisture absorbing sink is located within the base material of the cavity walls thereby forming inner moisture permeable barriers and outer moisture permeable barriers, the sink breaking the moisture ingress path so that there is minimal diffusion of moisture through the inner moisture permeable barriers to the cavity.

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12. A support structure as claimed in Claim 10 or Claim 11, wherein the moisture absorbing sink comprises a channel containing dry air surrounding the cavity opening where the lid is sealed to the base and passing through the cavity walls.

13. A support structure as claimed in Claim 12, comprising a plurality of cavities each having a channel containing dry air.

14. A support structure as claimed in Claim 13, wherein each channel is connected to a single desiccant source which dries the air in all the channels.

15. A support structure as claimed in any of Claims 10 to 14, wherein the base is injection moulded and the lid has an aluminium layer for moisture impermeability, the lid being heat sealed to the base.

16 A support structure as claimed in Claim 10, wherein the base comprises cooperating stackable elements, each element having a plurality of cavities, the cavities within one of the elements sitting between the cavities within another element when stacked, a moisture absorbing sink being formed by the spacing between the cooperating elements.

17. A support structure for a medicament substantially as herein described with reference to the accompanying drawings.