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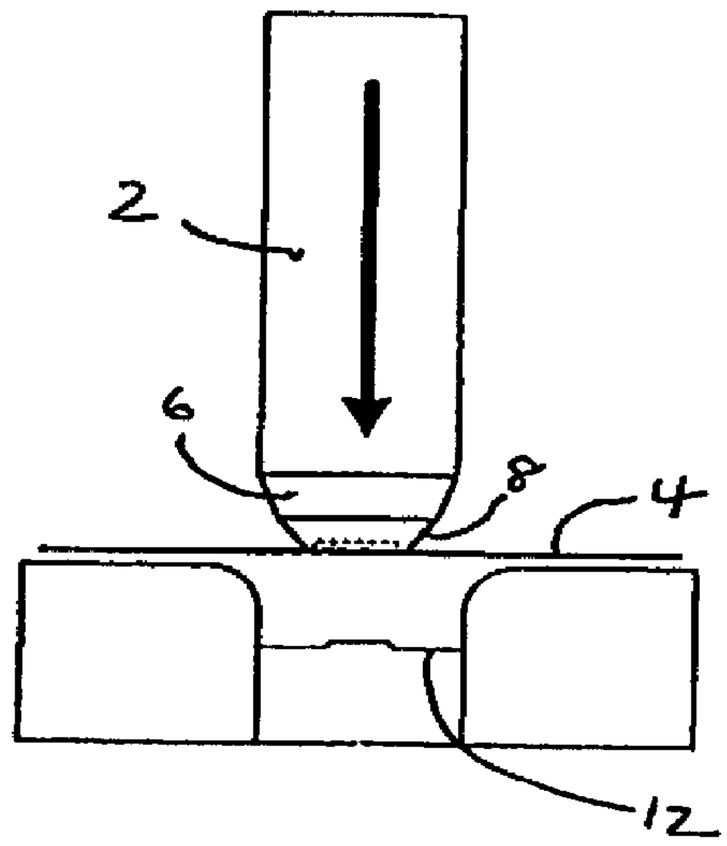
(54) **FORMATION DE REPERES DANS LA BASE D'UN EMBALLAGE-COQUE EN VUE D'UNE MIGRATION VERS UN CORPS QUI Y A ETE COULE**

(54) **THE FORMATION OF INDICIA IN THE BASE OF A BLISTER PACK FOR TRANSFERENCE TO A BODY CAST THEREIN**



(57) La présente invention concerne la réalisation d'au moins un emballage coque dans un film d'emballage-coque (4), lequel procédé consiste en la formation de marques-repères dans la base de l'emballage-coque au cours de la phase finale d'un passage unique de poinçon (2) ou de broche de formation de l'emballage-coque. Pour former à froid l'emballage-coque, on fait avancer la broche (2) selon un axe de progression transversal par rapport au plan du film (4), jusqu'à toucher une platine portant le poinçon (12) de formage des marques-repères. La face d'extrémité de la broche comporte un moule pour marques-repères dont la forme est complémentaire de celle du poinçon (2). Le déplacement de la broche (2) en direction de la platine tire et étire le film (4) principalement en partant du pourtour de l'emballage-coque, ce qui permet de minimiser l'étirement du film (4) au niveau de la base de l'emballage-coque.

(57) In a process for creating one or more blisters in a blister film (4), indicia are formed in the base of the blister in the final stage of a single pass of the blister forming punch (2) or pin. The blister is cold formed by advancing the pin (2) in a direction transversely relative to the plane of the film (4), towards and into engagement with a platen carrying indicia-forming die (12). The end face of the pin is formed with a mould for indicia complementary to the die (2), and movement of the pin (2) towards the platen draws and stretches film (4) predominantly from around the blister, thereby minimizing stretching of the film (4) at the base of the blister.

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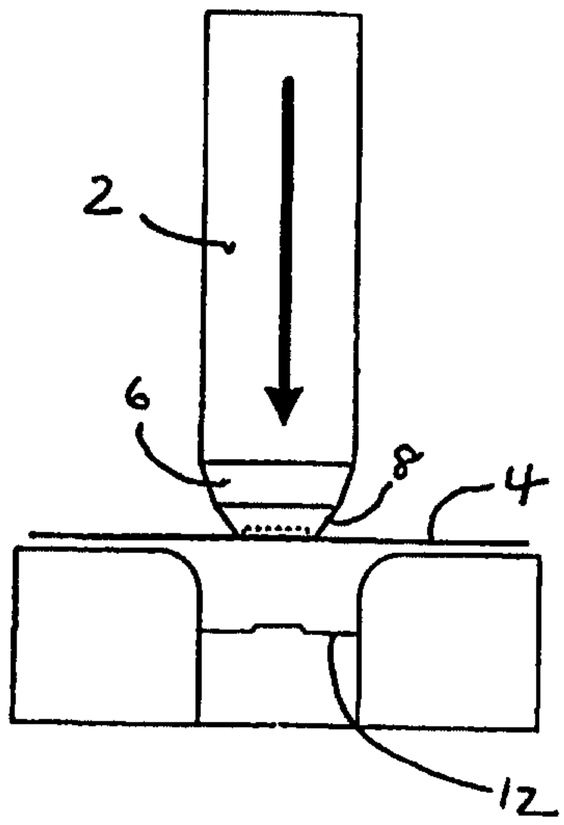
(54) Title: THE FORMATION OF INDICIA IN THE BASE OF A BLISTER PACK FOR TRANSFERENCE TO A BODY CAST THEREIN



(57) Abstract

In a process for creating one or more blisters in a blister film (4), indicia are formed in the base of the blister in the final stage of a single pass of the blister forming punch (2) or pin. The blister is cold formed by advancing the pin (2) in a direction transversely relative to the plane of the film (4), towards and into engagement with a platen carrying indicia–forming die (12). The end face of the pin is formed with a mould for indicia complementary to the die (2), and movement of the pin (2) towards the platen draws and stretches film (4) predominantly from around the blister, thereby minimizing stretching of the film (4) at the base of the blister.

THE FORMATION OF INDICIA IN THE BASE OF A BLISTER PACK FOR TRANSFERENCE TO A BODY CAST THEREIN

This invention relates to the use of a laminated film to form blister packs in the blisters of which bodies are cast. Such blister packs typically comprise polymeric films in which the blisters are heat formed. The present invention is particularly concerned with the use of laminated films in which a metal foil is sandwiched between two polymeric layers.

Blister films are particularly suited for the casting of frangible bodies which comprise some pharmaceuticals. These bodies are commonly made using lyophilisation or freeze-drying processes, but alternative techniques such as those including a solid state dissolution stage are also used. The liquid material of the body is poured into the blister or blisters, and then subjected to various treatments while still in the blisters. The products remain in the blister until they are ready for use and at this stage they are readily extractable.

Polymeric blister films suffer from the disadvantage of being permeable, with the consequence that however well the individual blisters are sealed, there is always a potential storage problem if the contents of the blister must be protected from the surrounding atmosphere. With the above points in mind, laminated blister films have been developed in which a metal foil is sandwiched between polymeric films on either side. Such films are less permeable than all-polymeric films, but some known films can become distorted when subjected to heat treatments, generating irregularity in the cast products and making subsequent handling of the blister pack more difficult. Although some laminated films have been developed which are more stable under heat treatment; see our published European Patent Specification Nos. 0 646 367 and 0 710 101, generally these laminated films are not suitable for the hot-forming of blisters therein. The metal foil core, normally of

aluminium, is much better suited to cold forming.

There is currently a strong demand for products cast in blister films as described above to bear some indelible marking. To meet this demand, a hot formed blister can readily be adapted to bear indicia on its internal surface, which indicia are then reflected in the respective surface of the cast product.

In our International Patent Application filed today with priority from British Application Nos. 9717491.6 and 9718382.6, we have addressed the difficulties of creating indicia on the base of a blister formed with a laminated foil of the kind to which this invention relates simultaneously with the formation of the blister itself. In that Application, the problem is met by creating the indicia in the second stage of the two stage process in the first of which the blister itself is formed. According to the present invention, these two stages are accomplished in the single pass of the blister forming punch or pin by effectively controlling the manner in which the laminated film is stretched to form the blister. According to the invention, the blister is cold formed by advancing a pin in a direction transversely relative to the plane of the film towards and into engagement with a platen bearing an indicia-forming dye thereon. The end face of the pin is formed with a mould for the indicia complementary to the dye, and the movement of the pin towards the platen draws and stretches film predominantly from around the blister, thereby minimising stretching of the film at the base of the blister. As a consequence, the film at the base of the blister requires less recovery time before it is again stretched to form the indicia, which can thus be accomplished at the end of the single pass of the punch or pin.

In order to ensure that during the initial movement of the pin the film is stretched from around the blister rather than from the base thereof, a slightly greater frictional contact between the periphery of the end face of the pin and

the laminated film can be created. To some extent, this is accomplished by the formation of the mould in the pin end face, if around the mould the end face is substantially flat. However, the effect can be enhanced by forming the end face of the pin around the mould slightly concave whereby a peripheral edge is created which provides some additional grip.

The profile of the pin itself will of course also significantly influence the manner in which the film is stretched as the pin advances towards the platen. We have found that two or more contiguous frusto-conical sections are suitable, with the apex angle of the frusto-conical cone adjacent the end face being substantially 60°, and the apex angle of the frusto-conical section contiguous thereto being around 30°.

Another means by which the desired differential stretching of the film as the blister is formed can be achieved is by using a different material for the end face of the pin from that used for the flanks. Preferred materials for the punch or pin in methods of the invention are stainless steel or polytetrofluethylene (PTFE). When this variant is adopted, the punch or pin is formed in stainless steel which also forms the end face, with the flanks of the pin being coated with PTFE.

An embodiment of the invention will now be described by way of example and with reference to the accompanying drawings in which Figures 1 to 4 show the progressive stages in the formation of a blister in a laminated film of the kind to which the invention relates.

In Figure 1, a punch or pin 2 is shown over a laminated film 4 of the kind described in our published European Patent Specification Nos. 0647367 and 0710101, which film 4 comprises a metal foil with a polymeric layer on either side thereof. Towards the lower end of the pin 2 as shown, there are two contiguous frusto-conical flanks 6 and 8 leaning towards an end face 10 in which is formed the mould for indicia to be created in the base of the eventual

blister.

The film 4 is clamped in known manner, and as shown in Figure 2 the pin 2 advances thereagainst towards a platen 12 bearing an indicia forming dye thereon. During the initial stage shown in Figure 2 the stretching is relatively uniform, but the periphery of the end face 10 is of course making contact with the film 4 under progressively greater pressure. Thus, as the punch advances to its final position shown in Figure 3, the stretching at the base of the blister being formed is minimised, with film being stretched from the areas around the blister. As a consequence, indicia may be formed in the base of the blister as the blister is itself created, during the final movement of the punctual pin against the platen 12. This is typically within the last millimetre of movement of the punch or pin, normally within the last 0.3 to 0.5 millimetres thereof. Typical indicia will normally have a depth within these ranges.

Figure 4 shows the punch or pin 2 being withdrawn, and illustrates the resilient response of the laminated film which arises from the platen 12. It will be noted that the platen 12 and the surrounding base 16 which define the recess in which the blister is created do not themselves form a mould against which the laminated film is urged. The punch or pin 2 determines the entire shape of the blister itself, only the indicia are formed positively from both sides.

It should be understood that the invention applies to the application of indicia to be reflected in the respective surface of the cast product in the broadest sense of the term. Thus, any form of marking is included, and particularly marking having a purely functional purpose such as the creation of break lines. Break lines are commonly used on tablets for oral administration where there is an occasional need for only a portion of a tablet to be taken at a particular time. The invention thus has particular value in the formation in a face of a product cast in a blister pack of indicia or marking which takes the form of

or includes a break line. In this respect it will be appreciated that a break line can be effectively formed by a sequence of depressions or grooves; it does not have to be a continuous groove in all circumstances. What is important is that a line of weakness is formed which enables the cast product to be easily broken into two or more pieces as defined by the break line or lines.

CLAIMS

1. A method of forming a laminated film comprising a metal foil and a polymeric layer on either side of the foil with at least one blister the base of which bears projecting indicia for moulding into a body cast therein, which method comprises cold-forming the blister by advancing a pin in a direction transversely relative to the plane of the film towards and into engagement with a platen bearing an indicia-forming dye thereon, the end face of the pin being formed with a mould for the indicia complementary to the dye, wherein the movement of the pin towards the platen draws and stretches film from around the blister and minimises stretching of the film at the base of the blister.

2. A method according to Claim 1 wherein the end face of the pin is formed in a different material from that forming the flanks thereof.

3. A method according to Claim 1 or Claim 2 wherein the flank or flanks of the pin are shaped to progressively engage the film from the end face.

4. A method according to Claim 3 wherein the pin is formed with at least two contiguous frusto-conical sections adjacent the pin end face.

5. A method according to any preceding Claim wherein the end face of the pin around the mould is substantially flat.

6. A method according to any of Claims 1 to 4 wherein the end face of the pin around the mould is concave and forms a peripheral edge.

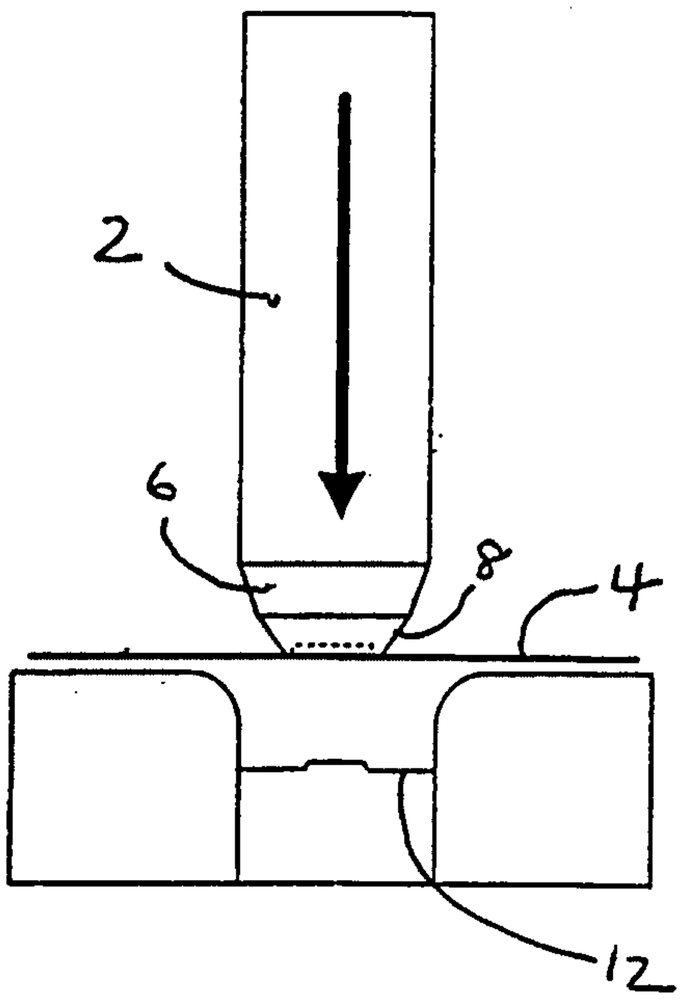


Fig 1

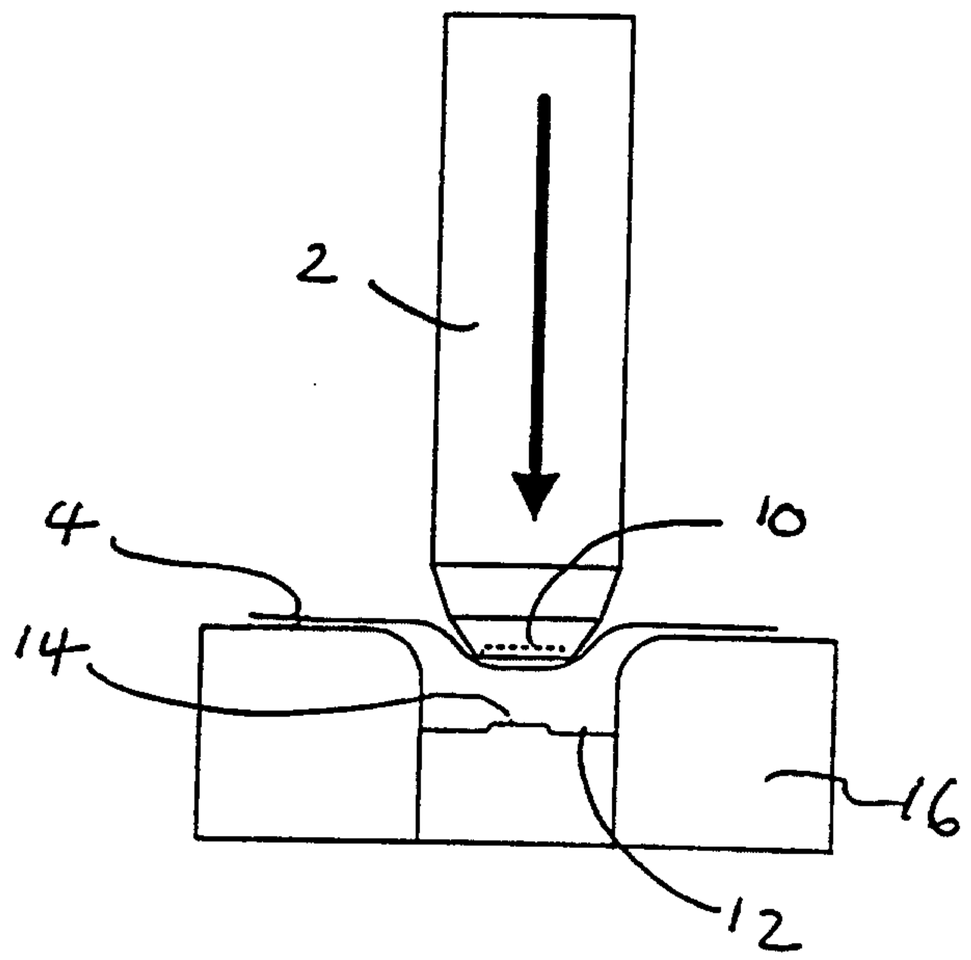


Fig 2

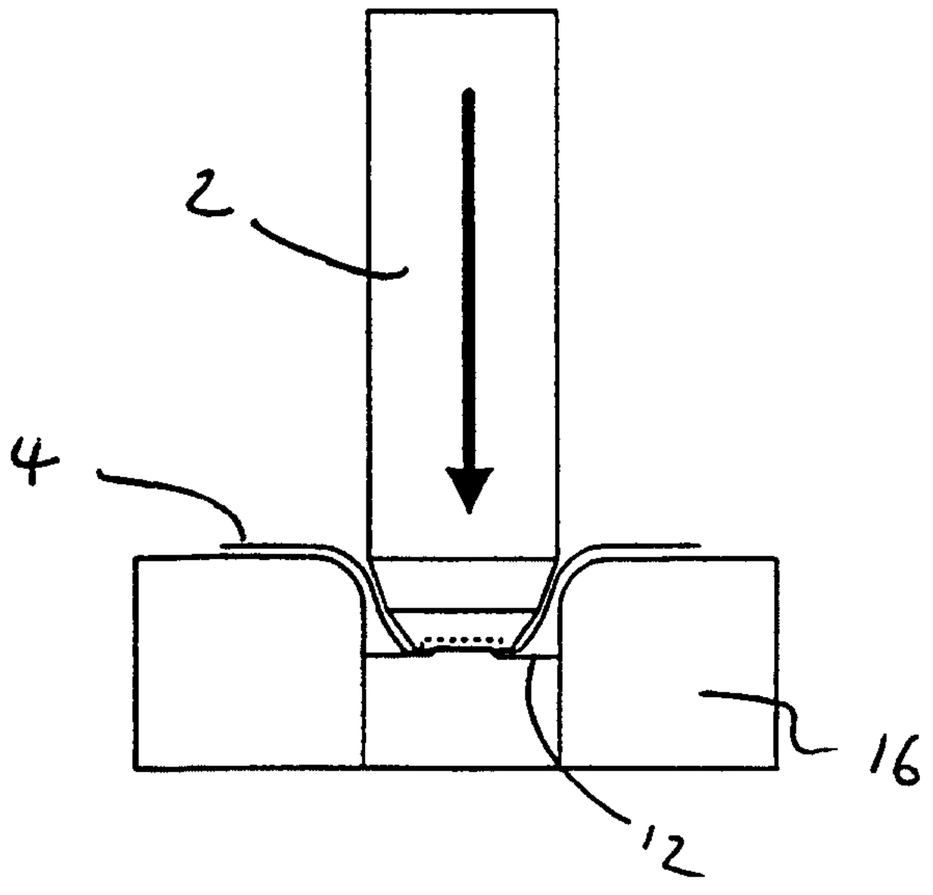


Fig 3

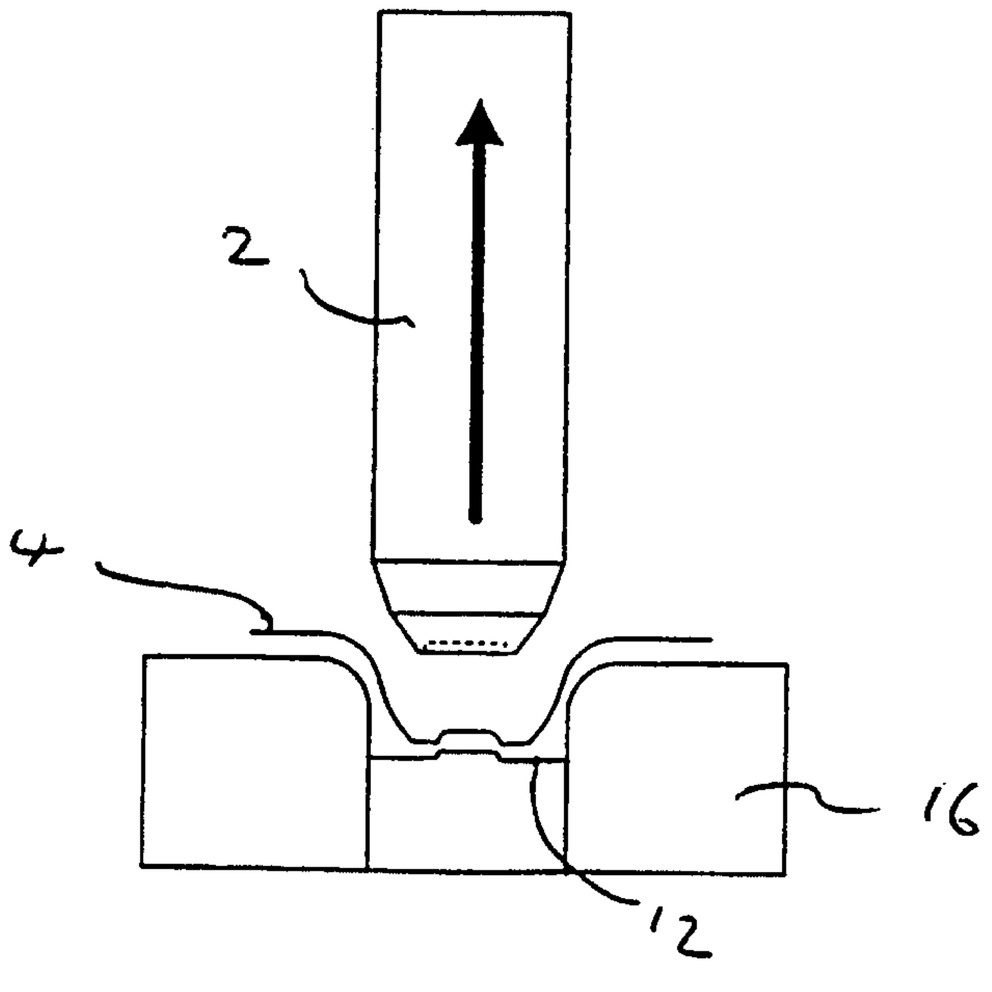


Fig 4