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The invention relates to a dropper tip comprising a circularly cylindrical body whose top portion has a narrow central channel flaring slightly all the way to a calibrated outlet orifice. The outside surface (116) of the top portion (106) of the tip is terminated by a hemispherical portion (112) that is directly connected to the side surface (107) of the central channel (107) at a small diameter (D) circular outlet orifice (109), said hemispherical portion enabling a drop to be formed which is essentially constant in size for a given liquid regardless of the tilt angle of the flask when the drop is delivered. The invention is particularly applicable to droppers for delivering eye drops.

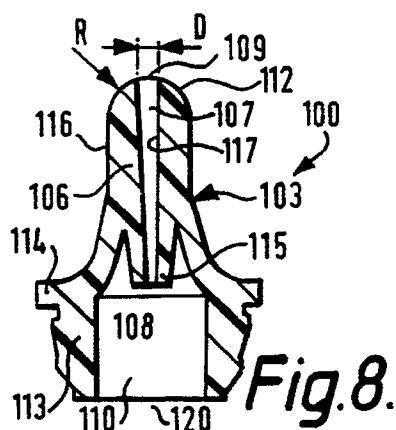


Fig. 8.

A DROPPER TIP FOR DISPENSING A LIQUID, IN PARTICULAR EYE DROPS

The invention relates to instilling a liquid, in particular eye drops, and it relates more particularly to dropper tips for use in instilling.

Old-fashioned droppers comprising a glass tube and actuated by a flexible sleeve thrust against the tube are being replaced more and more, in particular for ophthalmological solutions, by tips constituting the top, drop-dispensing ends of associated flasks, with the tips being fixed to the flasks by gluing, welding, or snap-fastening, as the case may be.

The technological background is illustrated by the following documents: U.S. patent numbers 4,138,040, 3,897,670, 3,788,528 and 3,572,558; European patent specification numbers 275754, 070777 and 093 493; and German patent application numbers 3,318,039, 2,446,564, 2,949,262, 2,722,178, 2,605,704, 2,554,038, 2,531,690 and 2,006,108.

In general, a conventional dropper tip is constituted by a circularly symmetrical body fixed by its bottom end to the associated flask and having a narrow central channel through its top portion which flares out slightly to a calibrated outlet orifice level with an annular lip.

The narrow central channel appears to be essential for ensuring that the outlet flow rate is small enough and for forming a drop. This should make it possible to drop a desired quantity of liquid independently of the pressure exerted by the user on the body of the flask.

For a long time, manufacturers have been seeking a way of controlling drop size, when the flask is held vertically.

To do this, numerous tests have been performed in order to determine the most favourable dimensions both for the central channel and for the annular lip surrounding the calibrated outlet orifice.

The liquid running along the central channel of the tip wets the side wall of said channel by surface tension, thereby initiating drop formation on the tip.

In order to control the size and/or weight of the drop, attempts have been made firstly to find the optimum diameter for the calibrated orifice (given that the smaller the diameter of said orifice the smaller the quantity of liquid leaving via the orifice), and secondly to find the optimum outside diameter of the annular lip surrounding the calibrated orifice, or alternatively the optimum surface area extending perpendicularly to the axis of the central channel (given that the annular lip is required to hold the drop by means of surface tension).

This approach is particularly well illustrated in U.S. patent number 4,584,823.

According to the teaching of that document, a small diameter calibrated orifice is used in conjunction with a small diameter (or small area) annular lip, and the resulting drop is small in size. In order to obtain drops which are larger in size, it is necessary to increase both the diameter of the calibrated orifice and the diameter of the annular lip.

The reference dimensions given in that document correspond to an annular lip whose width is about 1/6-th of the diameter of the outlet orifice.

It can already be seen that manufacturers encounter difficult problems when small-sized drops are to be dispensed.

The Applicant has performed numerous tests in order to provide a dropper tip that delivers drops of 20 μ l or 30 μ l depending on the type of ophthalmic solution used, and it has been observed that drop size varies not only, as was already known with the viscosity and the surface tension of the liquid in question, but also, and very largely, with the tilt angle of the flask when delivering a drop.

Flask tilt thus appears to be a parameter whose influence is very important when it is desired to deliver drops that are small in size.

Tests have been performed on solutions having different viscosities and surface tensions, using a flask initially held vertically, and then tilted (at 45° and at 10° relative to the horizontal): these tests have shown that drop size dispersion is indeed highly influenced by the tilt of the flask.

Conventional dropper tips clearly do not overcome this problem which appears not to have been recognised in the past.

Various attempts were performed with a cylindrical tip having a 1.2 mm calibrated outlet orifice and a 0.3 mm wide annular lip, and with a tip having a conical end (with a half angle at the apex of about 50°) connected to a 0.5 mm annular lip, and also with a tip having a curved end having a large radius of curvature (about 6 times the diameter of the calibrated orifice). However, none of these tests gave rise to satisfactory results.

An object of the invention is to provide a dropper tip enabling the above problems to be solved in satisfactory manner, making it possible to form a drop of substantially constant size for a given liquid even

if the flask is tilted when the drop is formed.

Another object of the invention is to provide a dropper tip making it possible to obtain drops of essentially constant size for all conventional types of ophthalmic solution, with the size differing for different solutions but remaining essentially constant for any particular solution.

5 Another object of the invention is to design a dropper tip whose shape is compatible with manufacture by moulding.

More particularly, the present invention provides a flask dropper tip for delivering drops of a liquid, in particular eye drops, said tip comprising a circularly cylindrical body whose top portion has a narrow central channel which flares slightly up to a calibrated outlet orifice, the top being characterised by the fact that the
10 outside surface of the top portion is terminated by a hemispherical portion that is directly connected to the side surface of the central channel around a small diameter circular outlet orifice, said hemispherical portion enabling a drop of substantially constant size to be produced for a given liquid, regardless of the tilt angle of the flask at the moment the drop is dispensed.

In a particularly advantageous embodiment, the radius of the hemispherical portion is selected as a
15 function of the desired drop size, and lies in the range 2 mm to 5 mm; in particular, the radius of the hemispherical portion preferably lies between 3mm and 4mm.

It is also advantageous for the diameter of the outlet orifice to lie in the range 0.8 mm to 1.4 mm; in particular, the diameter of the outlet orifice preferably lies in the range 1.0 mm to 1.3 mm.

Advantageously, the bottom of the hemispherical portion is connected to a same-radius cylindrical
20 surface, or to a surface which is slightly frustoconical.

In a particular variant, the side surface of the central channel to which the hemispherical portion is connected is itself cylindrical in the vicinity of the outlet orifice; more precisely, the side surface of the central channel is frustoconical, having a small diameter of about 0.2 mm and a large diameter equal to the diameter of the outlet orifice, with the cylindrical portion of said surface being less than 1 mm high, and
25 preferably about 0.5 mm high.

Finally, it is preferable for the dropper tip to be made of plastic material and preferably of low density polyethylene; in a variant, the dropper tip may be made of glass or metal, in which case it is preferably made of aluminium.

Other characteristics and advantages of the invention appear more clearly in the light of the following
30 description of a particular embodiment described with reference to the accompanying drawing, in which:

Figure 1 shows a flask surmounted by a prior art dropper tip, and Figure 2 is a section on II-II for clearly distinguishing the dropping end of the tip with its annular lip surrounding its calibrated outlet orifice;

Figure 3 and the associated axial section of Figure 4 taken on line IV-IV show a different prior art dropper tip made independently from the flask to which it is subsequently fixed, and having a conical end
35 connected to its annular lip;

Figure 5 and the associated axial section of Figure 6 taken on line VI-VI show yet another prior art dropper tip having a curved end with a large radius of curvature;

Figure 7 and the associated axial section of Figure 8 taken on VIII-VIII show a dropper tip in accordance with the invention, having a top terminated by a hemispherical portion (radius R) connected to the side
40 surface of the central channel at a circular outlet orifice of small diameter (D);

Figure 9 is a fragmentary half section on a larger scale through the dropper tip of the invention and serving to clarify the geometry of the top end of said tip; and

Figure 10 is another fragmentary half section on an enlarged scale showing a variant in which the central channel has a frustoconical surface extending all the way to its connection with the hemispherical
45 portion (unlike Figure 9 where the central channel terminates at its top end with a short cylindrical portion).

Figure 1 shows a complete prior art packaging assembly 1. The assembly comprises a flask 2 surmounted by a dropper tip 3 (which forms an integral portion with the body of the flask, i.e. the assembly is made by a single moulding operation). The bottom of the tip is provided with an outside thread 5 for receiving a closure cap 4 (shown in dot-dashed lines).

50 Figure 2 shows the shape of a top portion 6 of the dropper tip 3 more clearly.

The inside of this top portion has a narrow central channel 7 whose axis 20 coincides with the axis of the packaging assembly. The bottom of the central channel 7 has a very small diameter orifice 8 providing communication with the space 10 inside the flask, and above all providing the required flow rate restriction that prevents liquid from being expelled in the form of a jet when the user squeezes the flask. Above the
55 restriction 8 there is a slightly flaring frustoconical surface 17 going all the way up to a calibrated outlet orifice 9. On the outside, the side surface 16 of the top portion tapers via a portion 12 until it meets an annular lip 11 extending perpendicularly to the axis 20 such that the outside surface 16 and the inside surface 17 run respectively to the outside periphery and to the inside periphery of said annular lip.

As explained above, the prior technique teaches selecting the diameter of the outlet orifice 9 and the area of the annular lip 11 as a function of the size and/or weight required for the drop of liquid that may be formed on the dropper tip 3 and dispensed therefrom.

However, it appears that the size of the drop varies, in fact, not only with the viscosity and the surface tension of the liquid in question, but also, and to a very large extent, with the tilt angle of the flask at the moment the drop is delivered.

The prior art is also illustrated by variant 3' shown in Figures 3 and 4 in which corresponding items are given corresponding references plus the "prime" symbol.

In this variant, the dropper tip 3' is made in the form of a separate body whose bottom portion 13' (in the form of a plug surmounted by a lip 14') is fixed to the flask. This variant also includes a frustoconical projection 15' embodying the bottom portion of the central channel 7'.

The most significant difference compared with the preceding embodiment lies in the presence of an end 12 which is conical in shape (having a half angle at the apex of about 50°) which meets the annular lip 11' which in this case is slightly conical.

Tests performed on a dropper tip of this type have not given rise to satisfactory results.

Another prior variant is shown in Figures 5 and 6 in which item are given corresponding reference numerals plus the "double-prime" symbol.

The only significant difference over the variant shown in Figures 3 and 4 lies in the outside geometry of the top portion 6" of the dropper tip 3". The outside surface 16" is curved with a large radius of curvature, and in this case about six times the diameter of the outlet orifice 9".

Here again, the tests that have been performed have not enabled satisfactory results to be obtained.

As explained above, the Applicant has also performed tests using a cylindrical tip (not shown) having a 1.2 mm calibrated outlet orifice and a 0.3 mm wide annular lip, but here again the results were not very satisfactory.

In order to obtain a better understanding of the degree of dispersion in drop volume that can be obtained using the above dropper tips, and in particular as a function of flask tilt, Table I below summarizes the results of various tests performed using three tips of the above type, with each test being formed with different ophthalmic solutions so as to cover the range of viscosities and surface tensions normally encountered. This table shows the resulting drop volume (in μl) together with the standard deviation (each test being performed twenty times), for three different flask tilt angles (flask vertical; flask tilted at 45° to the horizontal; and flask tilted at 10° to the horizontal).

In this table, tips 1 and 2 correspond substantially to the prior art variant shown in Figures 5 and 6 (but with different dimensions), and tip 3 corresponds to the above-mentioned cylindrical tip having a 1.2 mm calibrated outlet orifice and an 0.3 mm wide annular lip.

TABLE I
Drop Size $\pm$ Standard Deviation (μ l)

Tip	Test Solution	Flask Vertical	Flask at 45°	Flask at 10°
10	W	28.3 $\pm$ 1.0	29.2 $\pm$ 3.5	31.5 $\pm$ 2.7
	0.25% T	18.9 $\pm$ 1.9	25.2 $\pm$ 2.0	28.3 $\pm$ 1.4
	Tip 1 0.3% N	27.5 $\pm$ 1.5	28.9 $\pm$ 1.6	31.9 $\pm$ 2.1
	0.6% GV	30.3 $\pm$ 3.6	42.0 $\pm$ 8.0	45.4 $\pm$ 3.9
	0.4% GV	27.3 $\pm$ 3.3	37.0 $\pm$ 7.0	41.3 $\pm$ 4.5
20	W	42.7 $\pm$ 1.4	37.7 $\pm$ 1.2	32.2 $\pm$ 2.1
	0.25% T	30.1 $\pm$ 1.4	29.5 $\pm$ 1.1	30.3 $\pm$ 1.5
	Tip 2 0.3% N	43.7 $\pm$ 1.5	36.4 $\pm$ 1.9	31.0 $\pm$ 2.5
	0.6% GT	43.9 $\pm$ 2.4	44.6 $\pm$ 4.5	48.9 $\pm$ 5.3
30	W	26.0 $\pm$ 0.6	22.0 $\pm$ 0.6	24.7 $\pm$ 3.0
	0.25% T	14.8 $\pm$ 1.3	14.9 $\pm$ 0.8	17.3 $\pm$ 1.0
	Tip 3 0.3% N	22.8 $\pm$ 1.5	22.7 $\pm$ 2.6	24.2 $\pm$ 3.3
	0.6% GT	24.6 $\pm$ 1.8	22.5 $\pm$ 2.7	31.7 $\pm$ 3.6

Where W = deionized water, T = Timoptic (Registered Trademark), N = Noroxine (Registered Trademark), and GV = Gelrite (Registered Trademark) vehicle, GT = Gelrite(Registered Trademark)/Timolol, and the percentages are W/V.

Figures 7 to 9 show a dropper tip 100 in accordance with the invention. This tip shares a number of features with the above-described variants of Figures 3 to 6 such that corresponding items are given the same references plus one hundred.

In accordance with an essential aspect of the invention, the outside surface 116 of the top portion 106 is terminated by a hemispherical portion 112 of radius R directly connected to the side wall 117 of the central channel 107 around a circular outlet orifice 109 of smaller diameter D, with said hemispherical portion enabling a drop of substantially constant size to be formed for a given liquid, regardless of the tilt of the flask when the drop is formed.

In general, the radius R of the hemispherical portion 112 determines the size of the drop which can be formed and dropped from the dropper tip 100. The diameter D of the outlet orifice 109 is naturally chosen to be small enough to avoid interfering with the spherical effect, whereby the drop formed adheres to the spherical surface all around the calibrated outlet orifice and can slide over said surface when the flask is tilted during dropping, thereby guaranteeing in an entirely original manner that the size of the drop remains constant for a given liquid.

In practice, the radius R of the hemispherical portion 112 is selected to be between 2 mm and 5 mm, while the diameter D of the calibrated outlet orifice 109 lies between 0.8 mm and 1.4 mm.

In the particular case of ophthalmic solutions, given the viscosities and surface tensions normally encountered, the radius R preferably lies in the range 3 mm to 4 mm, and the diameter D preferably lies in the range 1 mm to 1.3 mm.

Table II below shows the results of various tests performed using dropper tips in accordance with the invention under conditions analogous to the tests performed with prior art tips as summarized in above Table I.

TABLE II
Drop Size $\pm$ Standard Deviation (μ l)

Tip	Test Solution	Flask Vertical	Flask at 45°	Flask at 10°
Tip I	W	23 $\pm$ 1.0	28 $\pm$ 2.2	26 $\pm$ 2.2
R = 3.0	0.3% N	23 $\pm$ 2.2	29 $\pm$ 2.1	28 $\pm$ 2.1
D = 1.3	0.25% T	23 $\pm$ 1.3	24 $\pm$ 1.1	27 $\pm$ 1.6
	TGV	36 $\pm$ 3.2	36 $\pm$ 2.1	38 $\pm$ 2.5
Tip J	W	23 $\pm$ 2.4	31 $\pm$ 2.8	30 $\pm$ 2.5
R = 3.2	0.3% N	24 $\pm$ 3.4	31 $\pm$ 1.5	29 $\pm$ 1.7
D = 1.3	0.25% T	25 $\pm$ 1.2	26 $\pm$ 1.0	28 $\pm$ 1.5
	TGV	41 $\pm$ 3.1	42 $\pm$ 4.2	42 $\pm$ 2.4
Tip K	W	25 $\pm$ 3.7	32 $\pm$ 1.6	28 $\pm$ 1.9
R = 4.0	0.3% N	29 $\pm$ 6.0	33 $\pm$ 1.7	30 $\pm$ 2.0
D = 1.3	0.25% T	27 $\pm$ 3.1	27 $\pm$ 2.8	29 $\pm$ 2.9
	GTV	39 $\pm$ 4.3	40 $\pm$ 3.2	40 $\pm$ 2.7
Tip L	W	27 $\pm$ 1.8	19 $\pm$ 1.0	27 $\pm$ 1.9
R = 3.0	0.3% N	27 $\pm$ 1.8	27 $\pm$ 1.6	26 $\pm$ 1.6
D = 1.0	0.25% T	23 $\pm$ 0.6	22 $\pm$ 1.3	23 $\pm$ 1.1
	TGV	36 $\pm$ 1.5	36 $\pm$ 1.6	35 $\pm$ 1.4
	CGV	23 $\pm$ 0.9	23 $\pm$ 0.7	23 $\pm$ 1.1

Where W = deionized water, N = Noroxine, T = Timoptic,
TGV = Timolol Gelrite vehicle, and CGV = CAI Gelrite

vehicle which is very viscous, and where the percentages are W/V.

In Table II above, the parameters R and D for the four tips are tested, referenced tip I, tip J, tip K and tip L, were as follows:

tip I: $R = 3.0 \text{ mm}$, $D = 1.3 \text{ mm}$;
 tip J: $R = 3.7 \text{ mm}$, $D = 1.3 \text{ mm}$;
 tip K: $R = 4.0 \text{ mm}$, $D = 1.3 \text{ mm}$;
 tip L: $R = 3.0 \text{ mm}$, $D = 1.0 \text{ mm}$.

A comparison of Tables I and II clearly shows the highly significant effect of the hemispherical outside shape.

This provides a dropper tip which is highly satisfactory since drop size is essentially constant for a given liquid, in particular an eye wash, regardless of the tilt of the flask at the moment the drop is formed.

In addition, the bottom of the hemispherical portion 112 may run into a same-radius cylindrical surface 116, or more advantageously into a slightly frustoconical surface 116 as shown in Figure 9 where the half angle at the apex a of the conical portion is equal to about 1.5° , thereby facilitating manufacture of the tip by moulding.

The shape of the central channel may be adapted to particular applications.

In Figure 9, the frustoconical side surface 11 of the central channel 107 is terminated in the vicinity of the outlet orifice 109 in the form of a small cylindrical top portion 118. By way of example, for the above-mentioned values of the parameters R and D , the cylindrical portion 118 could be less than 1 mm high and preferably about 0.5 mm high (with the diameter of the portion 118 naturally being equal to the diameter D of the calibrated outlet orifice 109).

The variant shown in Figure 10 differs from the preceding variant solely in the shape of its central channel. The side surface 117' of the central channel 107 extends frustoconically all the way to the calibrated outlet orifice 109.

In both cases, there is a frustoconical side surface 117 or 117' having a small diameter d of about 0.2 mm at orifice 108, and a large diameter equal to the diameter D , at the calibrated outlet orifice 109.

The dropper tip of the invention is preferably made by moulding plastic material: several plastics are suitable, but it is preferable to use polyethylene or low density polyethylene.

However, it would also be possible to make such a tip out of glass or out of metal (e.g. aluminium).

The invention is not limited to the embodiment described above but, on the contrary, covers any variant which uses equivalent means to reproduce the essential characteristics of the claims.

Claims

1. A dropper tip for a flask for delivering drops of a liquid, in particular eye drops, said tip comprising a circularly cylindrical body whose top portion has a narrow central channel which flares slightly up to a calibrated outlet orifice, the tip being characterised by the fact that the outside surface (116) of the top portion (106) is terminated by a hemispherical portion (112) that is directly connected to the side surface (117) of the central channel (107) around a small diameter (D) circular outlet orifice (109), said hemispherical portion enabling a drop of substantially constant size to be produced for a given liquid, regardless of the tilt angle of the flask at the moment the drop is dispensed.
2. A dropper tip according to Claim 1, characterised by the fact that the radius (R) of the hemispherical portion (112) is selected as a function of the desired drop size, and lies in the range 2 mm to 5 mm.
3. A dropper tip according to Claim 2, characterised by the fact that the radius (R) of the hemispherical portion (112) preferably lies between 3 mm and 4 mm.
4. A dropper tip according to any one of Claims 1 to 3, characterised by the fact that the diameter (D) of the outlet orifice (109) lies in the range 0.8 mm to 1.4 mm.
5. A dropper tip according to Claim 4, characterised by the fact that the diameter (D) of the outlet orifice (109) preferably lies in the range 1.0 mm to 1.3 mm.
6. A dropper tip according to any one of Claims 1 to 5, characterised by the fact that the bottom of the hemispherical portion (112) is connected to a same-radius cylindrical surface (116).

7. A dropper tip according to any one of Claims 1 to 5, characterised by the fact that the bottom of the hemispherical portion (112) is connected to a slightly frustoconical surface (116).
- 5 8. A dropper tip according to any one of Claims 1 to 7, characterised by the fact that the side surface (117, 118) of the central channel (107) to which the hemispherical portion (112) is connected is itself cylindrical (118) in the vicinity of the outlet orifice (109).
9. A dropper tip according to Claim 8, characterised by the fact that the top cylindrical portion (118) of the side surface (107) of the central channel (117) is less than 1 mm high, and preferably about 0.5 mm high.
- 10 10. A dropper tip according to any one of Claims 1 to 9, characterised by the fact that the side surface (117, 117') of the central channel (107, 107') is frustoconical, having a small diameter (d) of about 0.2 mm and a large diameter equal to the diameter (D) of the outlet orifice (109).
- 15 11. A dropper tip according to any one of Claims 1 to 10, characterised by the fact that it is made of plastic material, and preferably low density polyethylene.
12. A dropper tip according to any one of Claims 1 to 10, characterised by the fact that it is made of glass or metal, and preferably of aluminium.
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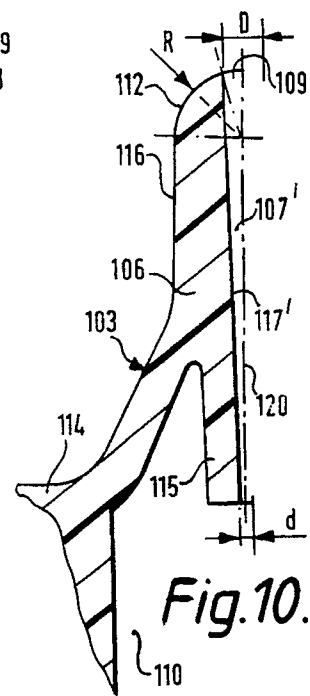
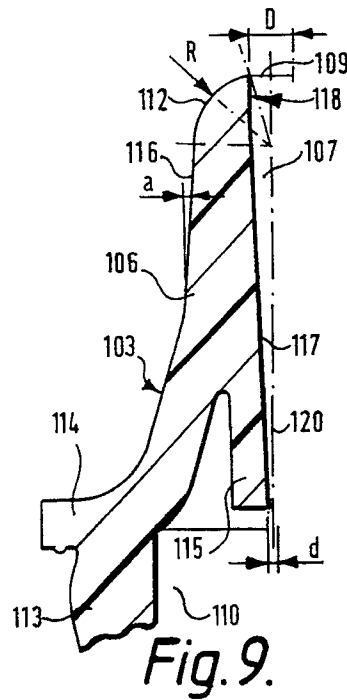
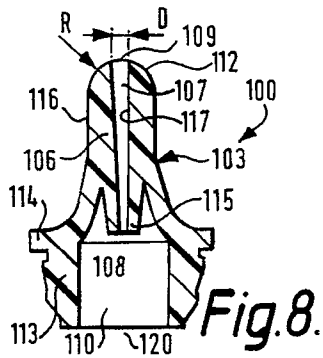
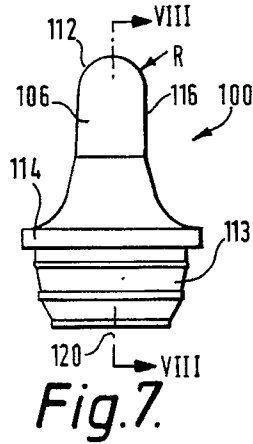
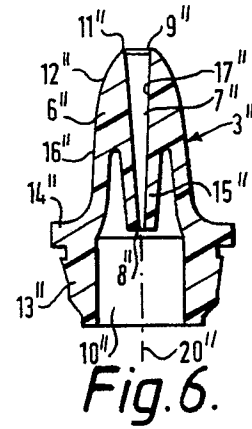
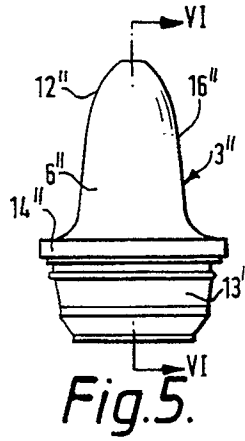
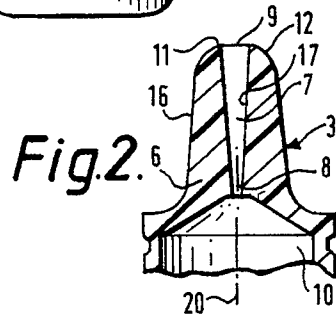
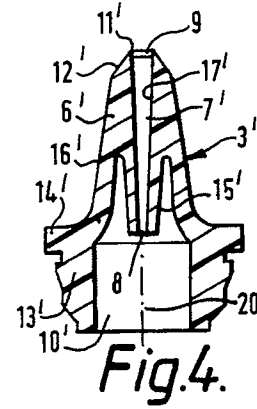
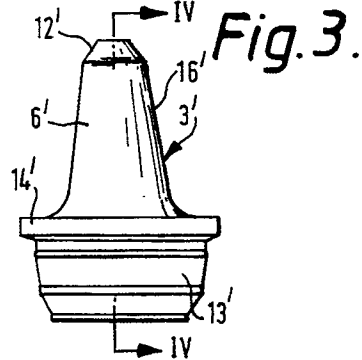
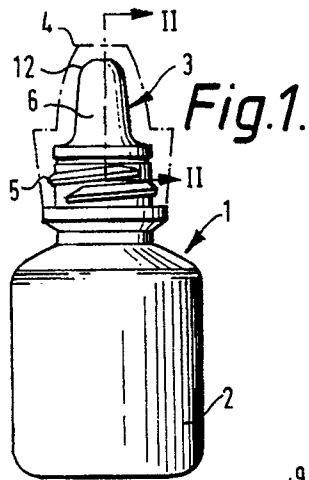
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European
Patent Office

EUROPEAN SEARCH REPORT

Application Number

EP 90 31 3135

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.5)
A,D	DE-A-3 405 648 (NAGEL) * Page 5, line 18 - page 7, line 4; figure 3 * - - -	1	B 65 D 47/18
A	DE-A-2 355 057 (PFIZER GmbH) * Page 2, line 6 - page 3, line 10; figure * - - -	1	
A	CH-A-2 314 73 (MOREL) * Figure * - - - - -	1	
			TECHNICAL FIELDS SEARCHED (Int. Cl.5)
			B 65 D B 01 L A 61 F
The present search report has been drawn up for all claims			
Place of search The Hague		Date of completion of search 25 January 91	Examiner MARTINEZ NAVARRO A
CATEGORY OF CITED DOCUMENTS X: particularly relevant if taken alone Y: particularly relevant if combined with another document of the same category A: technological background O: non-written disclosure P: intermediate document T: theory or principle underlying the invention E: earlier patent document, but published on, or after the filing date D: document cited in the application L: document cited for other reasons ----- &: member of the same patent family, corresponding document			