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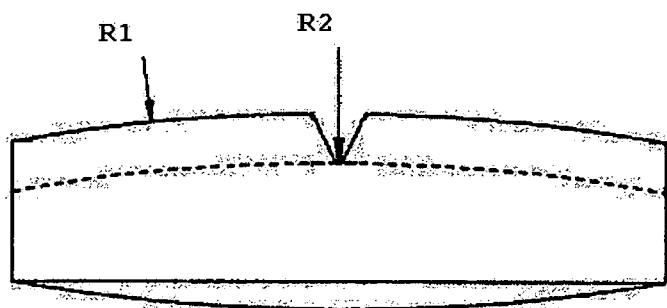
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(54) Title: ACCURATELY DIVISIBLE TABLET



(57) Abstract: The present invention relates to an accurately divisible tablet, a method for its division and a device for accomplishing the method.

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Accurately divisible tablet

5 The present invention relates to an accurately divisible tablet, a method for its division and a device for accomplishing the method.

10 There is a great need to make dosages and in particular tablets available in different dosage strengths to achieve a medication, which precisely complies with the requirements of the individual patient. The dose to be applied is also frequently dependent on the body weight of the patient, on the other hand however also on the severity of the treated illness.

15 Tablets are provided with break scores or cross break scores to meet these needs. These permit breaking the tablet into two or also four approximately equal parts.

20 However, the known state-of-the-art tablets frequently have the disadvantage that the tablet does not break accurately in the break score but into several, differently sized parts. Accurate dosage is then not possible anymore and can result in problems concerning the medication.

25 A well-known tablet shape is called "Snap tab" and exhibits a cross break score. These tablets exhibit a central depression and curve upwards towards the edge. The bottom surface of these tablets has a convex shape. This type of
30 tablet however only enables an acceptable symmetrical division into four parts.

The remit of the present invention is to create a tablet, which permits accurate division into two or four parts.

35

A tablet, as described in the main claim, solves the re-
mit. Favourable further developments are characterised in
the dependent claims.

5 The subject of the present invention is thus a tablet
with a break score, whereby the tablet always exhibits a
curvature on the bottom surface, which essentially has
the shape of a spherical cup and the break score is es-
sentially prismatic, whereby one edge -f the prism is di-
10 rected to the interior of the tablet and this edge exhib-
its a part-circular -,-cross section, characterised by
the fact that the relationship of the curvature radius
(R1) of the tablet to the radius (R2) of the pitch circle
of the break score is between 110 and 580.

15 A particular advantage of the present invention is that
the ratio of the curvature radius (R1) of the bottom sur-
face of the tablet to the radius (R2) of the break score
pitch circle is between 130 and 520.

20 A further particular advantage of the present invention
is that the break score depth is larger, than the height
of the spherical cup of the curvature of the tablet bot-
tom surface.

25 A further particular advantage of the present invention
is that the top and bottom surfaces of the tablet exhibit
a curvature respectively, which essentially has the shape
of a spherical cup.

30 A particular advantage is that the curvature radii of the
top and bottom surfaces are equal.

A special advantage of the present invention is that the
35 break score is a cross break score.

A further feature of the present invention is a method for accurate division the tablets embodying the present invention. The method for dividing tablets embodying the present invention is as such that the tablet to be divided lies on a hard surface in such a manner that the break score points to the viewer and the break score is vertically positioned and that a vertical pressure is then applied along a line, which runs horizontally at a right angle to the break score, to both ends at the respective distance of the half radius of the tablet in the direction of the hard surface, until the tablet breaks.

A particular advantage of the present invention is the method whereby the tablet exhibits a cross break score and the second, horizontal break score shapes the mentioned line.

A further method embodying the present invention is furthermore advantageous, whereby in a further step the tablet halves continue to be divided, by placing the semi-circular tablet half in such a way on a firm hard surface that the break score is vertical and the straight side of the divided tablet is directed upwards and by then applying a vertical pressure in the direction of the hard surface to both pointed ends of the upper edge of the tablet in the respective distance of the half radius of the tablet until the tablet breaks.

A further subject of the present invention is a device to accomplish the method embodying the present invention.

A device embodying the present invention for dividing the tablet embodying the present invention is foreseen, consisting of a cylindrical body with first and a second end, whereby its first end exhibits a circular cross section, whereby the exterior cross section is smaller, than

the diameter of the tablet to be divided, and whereby on this end at least two triangular notches are attached, whose points show away from the body and which are symmetrically positioned on the cross section, and whereby the second end of the body basically exhibits a rectangular cross section, whereby one exterior side length is larger than the diameter of the tablet to be divided and the other exterior side length is smaller than the diameter of the tablet to be divided, and whereby a triangular notch is attached centrically on the longitudinal sides respectively, whose point is directed away from the body, whereby the notches are designed in such a manner that these do not reach to the bottom of the break score.

It was surprisingly ascertained that tablets with the geometry embodying the present invention can be accurately and reproducibly broken. This in particular, if the method embodying the present invention is applied. This method results in extremely reproducible results with an only low variation of the masses of the tablet halves and/or tablet quarters.

It is another advantage of the present invention that it is now possible to obtain an individual dose for a pharmaceutical preparation like a tablet, without the need for manufacturing a single dose form with a lower or higher dose. This is especially important if these medicaments are applied to children. According to a guideline of the European Commission it is now necessary to provide lower dose medicaments suitable for the application with children. With the present invention the problem is solved that in general the fragments of tablets obtained with break scores known in the art, show a great deviation in the content of the active ingredient. This fact is especially of importance for children and even adults with low body weights.

The present invention is described in the following figures. These are:

5 Fig. 1 the top view of a tablet with a break score embodying the present invention;

Fig. 2 the cross section of the tablet from figure 1,
whereby the section is at a right angle to the break score;
10

Fig. 3 the top view of a tablet with a cross break score embodying the present invention;

15 Fig. 4 the cross section of the tablet from figure 3, whereby the section runs through a break score;

Fig. 5 the top view and the side view of a further design of the tablet with a break score embodying the present
20 invention;

Fig. 6 the cross section of the tablet from figure 5, whereby the section is at a right angle to the break score;
25

Fig. 7 the functioning of the method embodying the present invention for the division of a tablet with a cross break score embodying the present invention;

30 Fig. 8 the functioning of the method embodying the present invention for the further division of the previously obtained tablet halves embodying the present invention according to Fig. 7;

Fig. 9 the weight distribution for examination of the uniformity of the divided tablets in halves embodying the present invention;

5 Fig. 10 the weight distribution for the examination of the uniformity of the divided tablets in quarters embodying the present invention; and

Fig. 11 a device for accomplishing this method.

10

The geometry of the tablets embodying the present invention is now illustrated with reference to the figures 1 and 2.

15 The tablet is manufactured in a conventional manner by appropriate mixing of active substance(s), carrier, and auxiliary substances. The shape of the tablets embodying the present invention is particularly suitable for active substances, which are only given in low dosages. The tablet represented in figure 1 has a diameter of only approx. 9 mm. This diameter can be adapted however to the requirements of the respective active substance. Diameters from 4 to 15 or 20 mm are still in the scope of the present invention. The tablet thereby exhibits a curvature radius R_1 , which in the represented case is approx. 26 mm. This curvature radius can however vary within a wide range. Radii R_1 between 10 and 50 mm with a tablet diameter within the range of 4 to 20 mm are still in the scope of the present invention. The curvature radius was only limited upwards by the fact, that for breaking the tablet by means of the method embodying the present invention a curvature is required, in order to permit symmetrical breaking of the tablet. The size of the radius R_2 is also of special meaning for the present invention
30 beside the curvature radius R_1 . The radius R_2 of the pitch circle of the break score embodying the present in-
35

vention must possess a certain value, so that the ratio $R1/R2$ embodying the present invention is ensured. The ratio $R1/R2$ lies according to invention within the range of 110 to 580. The range of 130 to 520 is particularly preferential. The radius $R2$ is approx. 0.05 mm in the present case of the figures 1 and 2. It can furthermore be recognised in figure 2 that the break score depth is larger than the height of the spherical cup of the curvature of the lower side of the tablet.

The figures 3 and 4 show a further tablet embodying the present invention. The break score is a cross break score in this design example. The tablet represented in figure 3 has a diameter of approx. 9 mm. This diameter can be adapted however to the requirements of the respective active substance. The radii $R1$ and $R2$ are represented again in figure 4, by which the geometry of the tablet embodying the present invention is obtained on account of their ratio to each other. The curvature radius is approx. 26 mm in the present case. The curvature radius can also vary within a wide range in this case. The radius $R2$ of the pitch circle of the break score is 0.12 mm here. It can be recognised in figure 4 that the break score depth in this case is smaller than the score of the spherical cup of the curvature of the bottom surface side of the tablet. This is also in the context of the present invention. At least the bottom surface of the tablet embodying the present invention, thus the surface opposite to the break score, must exhibit a curvature, to be able to accomplish the method embodying the present invention to devide the tablets. It is hereby crucial that the curvature, whose size is determined by the radius $R1$, is sufficient so that sufficient force can be applied to the tablet ends in order to break the tablet.

The figures 5 and 6 represent a further design example of the tablet embodying the present invention with a break score. The tablet surfaces are not evenly shaped as spherical cups in this case, but exhibit stronger curvatures at the outer periphery of the tablet as well as in the proximity of the break score. Such shaped tablets are also suitable for the symmetrical division according to the method of division embodying the present invention. A tablet with a diameter of approx. 9 mm is represented again in the present case. The radius R2 of the pitch circle of the break score is approx. 0.2 mm here. The curvature radius R1 has a value of approx. 26 mm. The stronger curvatures at the edges within the range of the periphery have a radius of approx. 2.5 mm. Figure 2 also represents that the break score depth is larger than the height of the spherical cup of the curvature of the lower side of the tablet. The curvature radii of the top and bottom surface are also equal according to the figure. The curvature radii of the top and bottom surface were also equal in the previously represented figures 2 and 4. This is however not required for embodying the present invention, since as previously mentioned, only the bottom surface, i.e. the opposite surface of the break score surface must exhibit a curvature, so that the break method embodying the present invention can be accomplished.

The method embodying the present invention for the division of the tablets is represented in the figures 7 and 8. The left field in figure 7 demonstrates how a tablet with a cross break score is placed onto an even, hard surface and points to the viewer. Pressure is now applied by means of the represented fingers to the ends of the tablet along now the horizontally positioned break score. It is now recognisable in the right field of figure 7 how the vertically positioned break score expands and then, not represented, finally breaks. This results in two tab-

let halves with a cross score. If the tablet however only has one break score, then the break score must be arranged in such a manner that the break score appears vertically when seen from the viewer, thus runs parallel to the fingers. The pressure for dividing the tablet is then applied along a line, which runs horizontally at a right angle to the break score at both ends at the respective approx. half radius distance of the tablet. Pressure is applied with the fingertips, as represented here, in the direction of the firm hard surface until the tablet breaks.

A further partial step concerning the division of a tablet embodying the present invention is now represented in figure 8. The tablet part which is obtained according to figure 7, namely one half, is now likewise placed onto on the firm hard surface, whereby the break score once again points towards the viewer and is vertically positioned. Pressure is again applied to the tablet half in the direction of the hard surface along the upper edge of the tablet at a distance of approximately the half radius of the tablet until this tablet breaks. The left field of figure 8 shows the positioning of the tablet half to be divided on a firm hard surface. The right field shows, how the break score of the tablet expands during application of pressure in the direction of the hard surface and the tablet finally, not represented here, breaks. Thus, four very even large tablet quarters are obtained from a tablet with a cross break score.

The tablet weights of the tablet halves and tablet quarters are represented in the figures 9 and 10, which are obtained when breaking the tablet represented in the figures 3 and/or 4. According to the requirements of the European Pharmacopoeia, no more than two individuals may deviate in their mass by more than 7.5 % from the average

value and none of the individuals may deviate by more than 15 % from the mass when breaking single dose preparations (tablets), which have an average mass of 80 to 250 mg. The same applies according to the European Pharmacopoeia for tablet quarters, i.e. that for a single dose with a medium mass of 80 mg or less not more than two individuals may deviate from the average mass by more than 10 %, and none of the individuals may deviate by more than 20 %. The respective individual tablet values 1 to 20 are now represented in figure 9 and 1 to 10 in figure 10 on the x-axis in the figures 9 and 10. The mass of the respective tablet half and/or tablet quarter is specified in mg on the y-axis. The respective individuals are characterised with the ♦-T and the broken and dash-dotted lines in the figures 9 and 10 represent the respective limit values for the tablet mass. It can be recognised from figure 9 that altogether only one tablet half lies in the range above the 7.5 % limit. It is also noticeable, that the remaining tablet masses are located within a very close corridor and that there is an extremely even mass distribution of the respective tablet halves, which are obtained after the partition method, embodied the present invention. The corresponding situation can be recognised in figure 10 for the tablet quarters. Only one individual is located outside of the 10 % interval in this case, that here also an extremely even distribution of the masses of the now present tablet quarters is obtained by application of the method embodying the present invention for the division of tablets.

Figure 11 displays a device for the accomplishment of the method, consisting of a cylindrical body with first and a second end, whereby its first end exhibits a circular cross section, whereby the outer cross section is smaller, than the diameter of the tablet to be divided, and whereby on this end at least two triangular notches are

attached, whose points show away from the body and which are symmetrically located on the cross section, and whereby the second end of the body exhibits a practically rectangular cross section, whereby the outer side length is larger than the diameter of the tablet to be divided and the other outer side length is smaller than the diameter of the tablet to be divided, and whereby centrally on the longitudinal sides a triangular notch is attached in each case, whose point shows away from the body, whereby the notches are shaped in such a manner that these do not reach to the bottom of the break score.

The device embodying the present invention is especially suitable for accomplishing the method embodying the present invention for dividing the tablets embodying the present invention. It is therefore no longer necessary to accomplish division by means of fingertips. Enabling a hygienically unobjectionable division permits nursing staff, relatives or third parties to accomplish the division. An extremely reproducible division is furthermore possible with the help of this device, so that the low mass variation of the tablet parts required by the European Pharmacopoeia can be easily fulfilled.

Claims

1. Tablet with break score, whereby the tablet always
5 exhibits a curvature on the bottom surface, which essentially has the shape of a spherical cup and the break score is essentially prismatic, whereby one edge of the prism points towards the inside of the tablet and this edge exhibits a part-circular cross
10 section, thereby characterised, that the ratio of the curvature radius (r_i) of the tablet to the radius (R_2) of the pitch circle of the break score is between 110 and 580.
- 15 2. Tablet according to claim 1, thereby characterised, that the ratio of the curvature radius (r_i) of the bottom surface of the tablet to the radius (R_2) of the pitch circle of the break score is between 130 and 520.
- 20 3. Tablet according to one of the preceding claims, thereby characterised, that the depth of the break score is larger than the height of the spherical cup of the curvature of the bottom surface of the tablet.
- 25 4. Tablet according to one of the said claims, thereby characterised, that the top and bottom surfaces of the tablet each exhibit a curvature, which essentially has the shape of a spherical cup.
- 30 5. Tablet according to claim 4, thereby characterised, that the curvature radii the top and bottom surfaces are equally large.

6. Tablet according to one of the said claims, thereby characterised, that the break score is a cross break score.

5 7. Method for dividing tablets according to one of the said claims, whereby one places the tablet to be divided on a firm hard surface in such a way that the break score points to the viewer and the break score is vertically positioned and then a vertical pressure
10 is applied in the direction of the hard surface, at both ends in the respective distance of half radius of the tablet along a line, which runs horizontally at a right angle to the break score, until the tablet breaks.

15 8. Method according to claim 7, thereby characterised that the tablet exhibits a cross break score and the second, horizontal break score forms the said line.

20 9. Method according to claim 7 or 8, whereby the tablet halves previously obtained are divided in a further step, by placing the semicircular tablet half on a firm hard surface in such a way that the break score is vertically positioned and the straight surface of
25 the divided tablet points upward and then a vertical pressure is applied in the direction of the hard surface, at both pointed ends of the upper edge of the tablet in the respective distance of the half radius of the tablet until the tablet breaks.

30 10. Device for dividing tablets according to the method after one of the claims 7 to 9, consisting of a cylindrical body with first and a second end, whereby its first end exhibits a circular cross section,
35 whereby the outer cross section is smaller than the diameter of the tablet to be divided, and whereby at

this end at least two triangular notches are attached, whose points show away from the body and which are symmetrically located on the cross section, and whereby the second end of the body exhibits a
5 practically rectangular cross section, whereby the outer side length is larger than the diameter of the tablet to be divided and the other outer side length is smaller than the diameter of the tablet to be divided, and whereby a triangular notch is attached
10 centrically on the longitudinal sides in each case, whose point shows away from the body, whereby the notches are shaped in such a way that these do not reach to the bottom of the break score.

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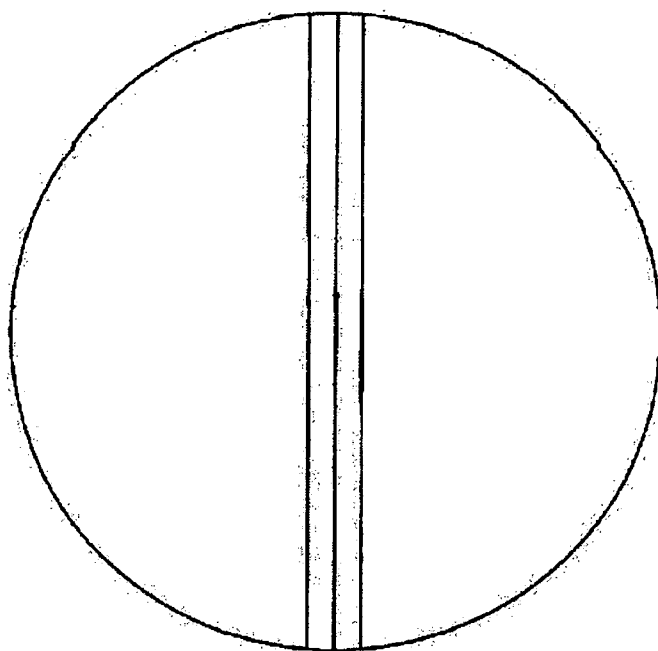


Fig. 1

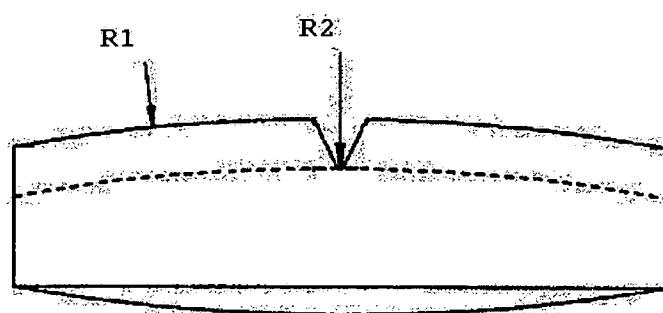


Fig. 2

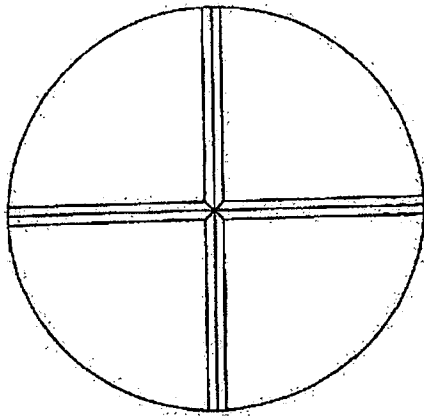


Fig. 3

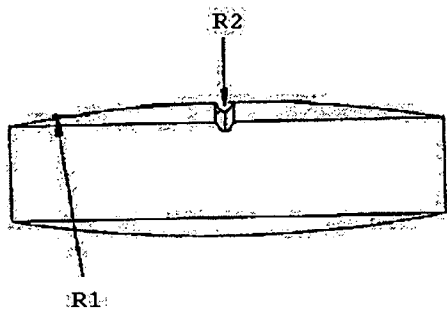


Fig. 4

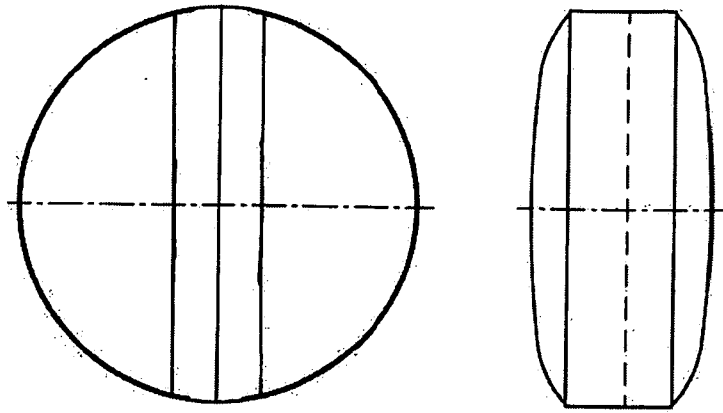
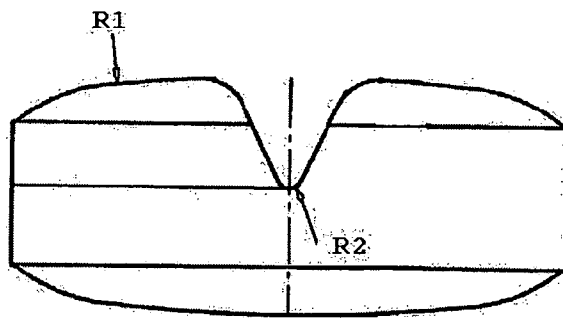


Fig. 5



5 **Fig. 6**

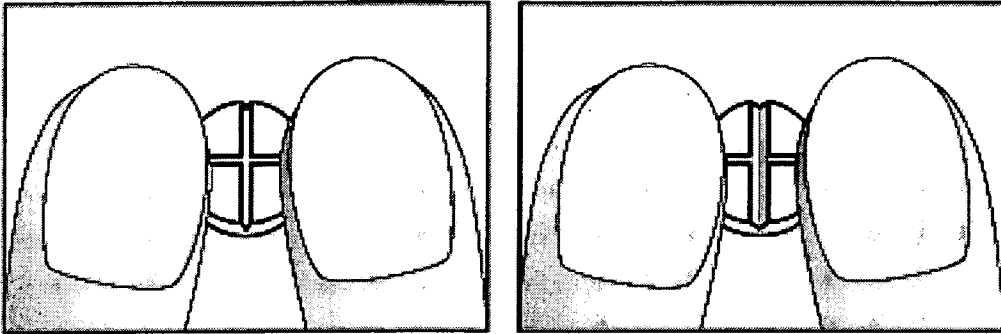


Fig. 7

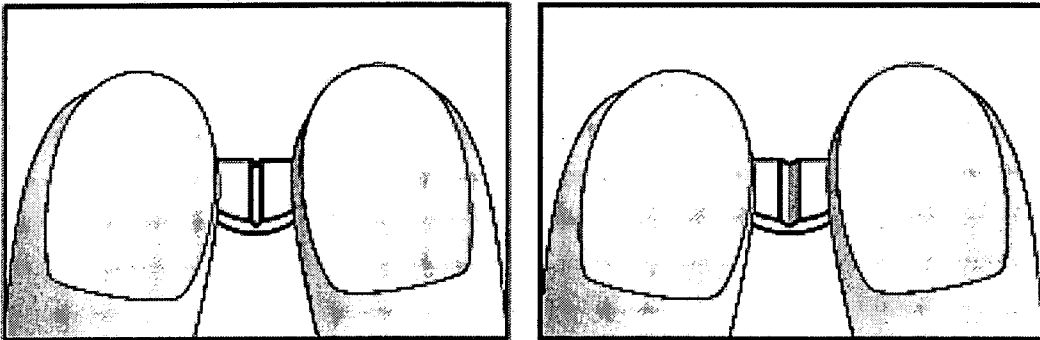
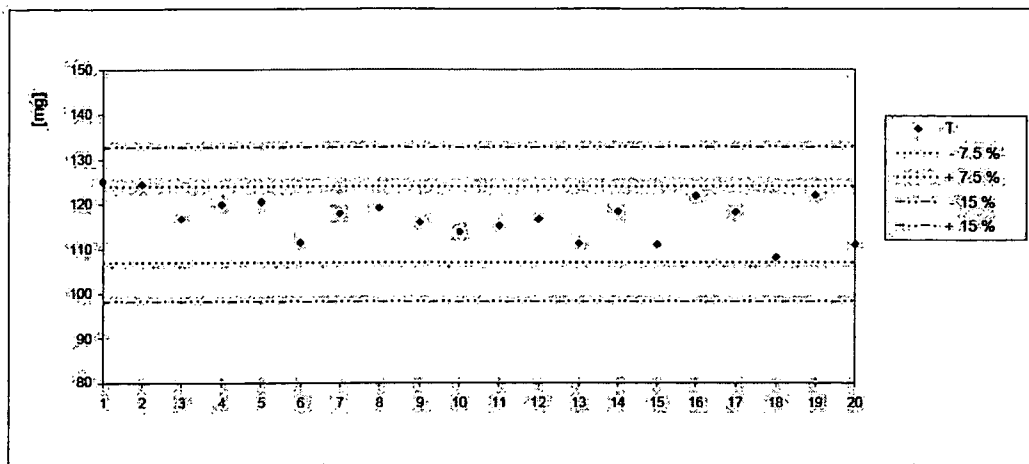
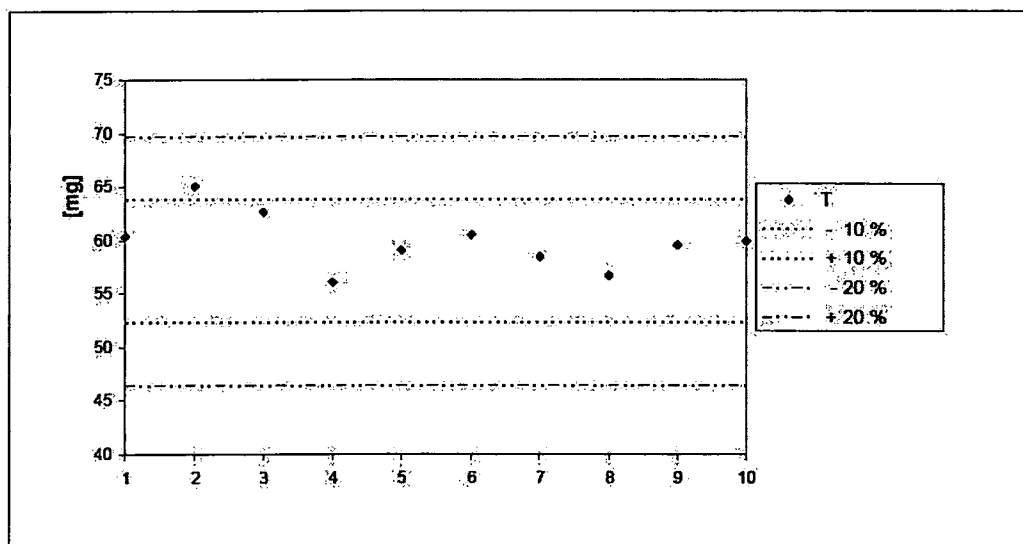


Fig. 8

**Fig. 9****Fig. 10**

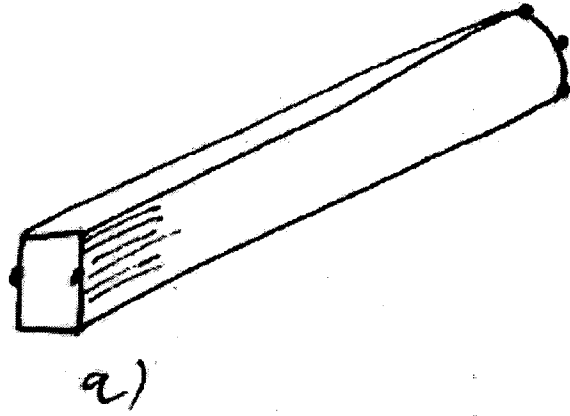


Fig. 11

INTERNATIONAL SEARCH REPORT

International application No
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A. CLASSIFICATION OF SUBJECT MATTER
INV. A61J3/10 A61J7/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61J A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EP0-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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A	US 4 422 553 A (HOEKS HAROLD L [US] ET AL) 27 December 1983 (1983-12-27) figure 1	10

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

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Date of the actual completion of the international search

19 July 2007

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

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