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2,609,818

AUTOMATIC INJECTING AMPULE

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2 SHEETS—SHEET 1

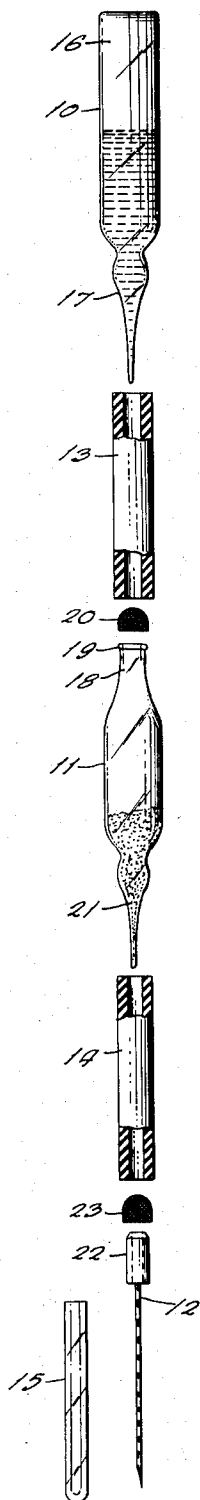


*Fig. 1*

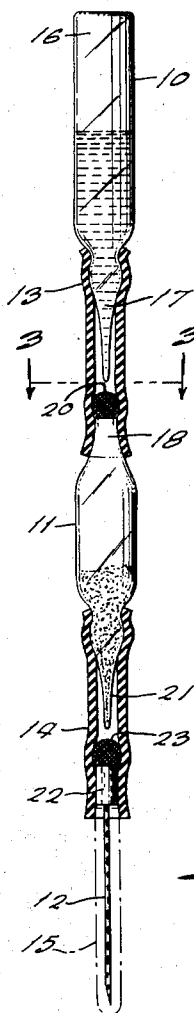


*Fig. 2*

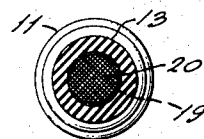


*Fig. 3*

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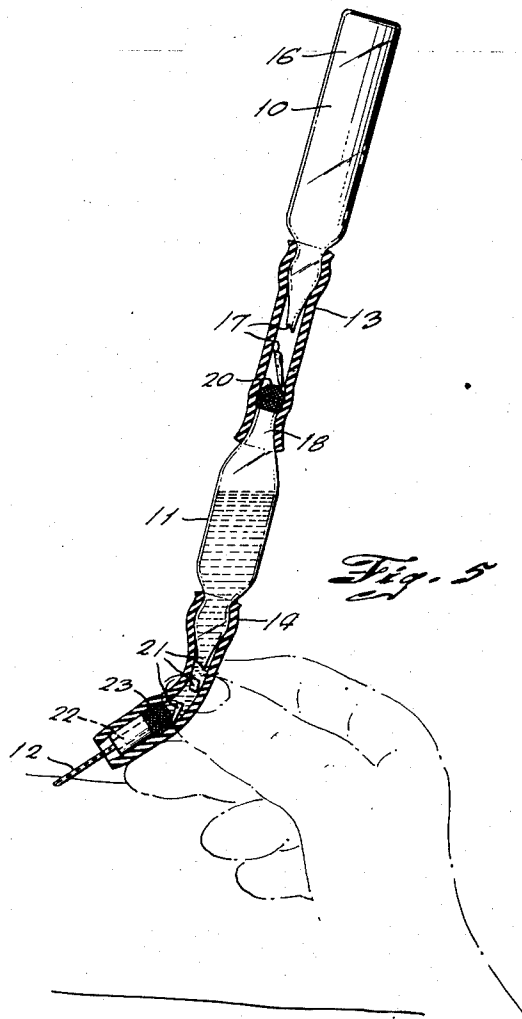
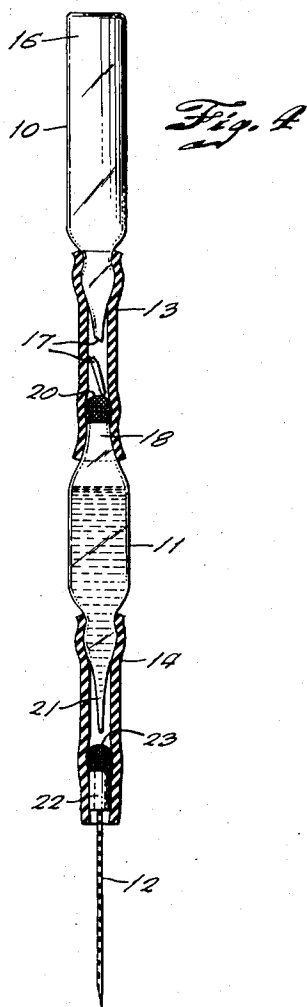
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2 SHEETS—SHEET 2



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## UNITED STATES PATENT OFFICE

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## AUTOMATIC INJECTING AMPULE

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This invention relates to a new and useful improved form of combination ampule in which a solution or suspension is freshly prepared therein just prior to injection thereof and is then automatically expelled into a patient through an associated hypodermic needle by gas pressure within the new combination ampule.

Due to the fact that many medicinal and therapeutic solutions or suspensions, particularly aqueous suspensions intended for intramuscular injection, are more effective and reliable when freshly prepared or are subject to a certain amount of deterioration due to aging, it is extremely desirable to prepare a fresh solution or suspension from the ingredients or component parts thereof just prior to injection and under completely sterile conditions. At present there is no convenient or satisfactory device for accomplishing this result. While it is possible to mix the ingredients in a container and then draw them into a hypodermic syringe by retracting the plunger of such syringe, this is not a particularly desirable procedure and hence it is customary to provide the injectable solution or suspension in an already prepared condition either in a disposable or partially disposable syringe or in a container provided with a closure through which the needle of the hypodermic syringe can be plunged to withdraw a desired amount of the preparation, such container ordinarily having therein a multiple dose so that several such measured amounts can be withdrawn as required. It is also known to prepare cartridges of such injectables which are sold under the trademark name Carpules.

One of the objects of the present invention is to provide a simple and relatively inexpensive disposable combined ampule and syringe, hereinafter termed an automatic injecting ampule, in which the ingredients or components of the medicinal or therapeutic solution or suspension are separately maintained under sterile conditions with means for admixing them just prior to injection and then ejecting the freshly made solution or suspension through an operatively associated hypodermic needle.

Another object of the invention resides in an automatic injecting ampule comprising a pair of aligned glass receptacles or containers, one of which contains a solvent or a liquid medium under gas pressure and the other of which contains a solid powdered or crystalline material which is to be dissolved or suspended in the liquid medium.

A further object of the invention resides in

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the provision of an automatic injecting ampule which includes a container for a liquid ingredient or component, a container for a solid ingredient or component and a hypodermic needle arranged and maintained in alignment with the said containers, said containers and hypodermic needle being normally out of communication with one another but being adapted to be placed in communication at will.

A still further object of the invention resides in an automatic injecting ampule which includes a sealed ampule containing sterile water and gas under pressure, an ampule-like receptacle containing a penicillin or other therapeutic salt or substance which is adapted to be admixed with the water in the ampule to produce an aqueous suspension of penicillin or the like, a hypodermic needle maintained in operative position and in alignment with the said ampule and ampule-like receptacle by means of flexible rubber tubing, both the ampule and the ampule-like receptacle terminating in reduced frangible extensions, and a screening or filtering element intermediate the ampule and the ampule-like receptacle and intermediate the ampule-like receptacle and the hypodermic needle to prevent undesired particles, e. g., of glass, from being ejected into or through the hypodermic needle.

Other and further objects and advantages will be understood and appreciated by those skilled in this art or will be apparent or pointed out hereinafter.

In the accompanying drawing, wherein like numerals designate corresponding parts through the various views:

Figure 1 is an exploded view illustrating the several parts of an automatic injecting ampule responding to the present invention;

Figure 2 is an assembled view of the several parts shown in Figure 1, but with the flexible tubing shown in section to illustrate the operative positions of the parts when ready for use;

Figure 3 is a transverse sectional view on a somewhat enlarged scale taken along the line 3-3 of Figure 2;

Figure 4 represents the condition of the parts when the pressurized ampule has been ruptured and showing that the liquid within the ampule has been forced by the gas under pressure within the ampule-like receptacle; and

Figure 5 is a view showing the condition of the parts after the ampule-like receptacle has been ruptured subsequent to the insertion of the hypodermic needle into a patient.

By reference to the drawings, it will be ob-

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served that my new automatic injecting ampule includes a standard or conventional ampule 10, an ampule-like receptacle 11 and a hypodermic needle 12, together with lengths of flexible tubing 13 and 14 and a needle protective cap or guard 15. Ampule 10 is of any suitable or usual construction and is ordinarily composed of a cylindrical body portion 16 with a reduced frangible extension 17 at one end thereof terminating in a sealed tip. In accordance with known practices, this ampule has sealed within it a sterile liquid which may be any suitable solvent or suspending medium but which in the instant case is pure sterile water. The reduced frangible extension 17 is inserted within one end of the length of flexible tubing 13, as best shown in Figure 2, and this tubing is preferably of flexible rubber of either a natural or synthetic composition.

Into the other end of the length of flexible tubing 13 is inserted the open somewhat reduced end 18 of the ampule-like receptacle 11. This portion 18 preferably terminates in a rounded lip or bead 19 which aids in holding the receptacle within the flexible rubber tubing and which further serves as a means for positioning the circumferential edge of the filtering or screening element 20, which may be made of any suitable material, such as a pre-shaped hemisphere of stainless steel fine mesh screening, but which in the present instance is preferably composed of a textile material such as cotton or nylon of fine weave having extremely small interstices between the warp and weft threads or filaments. When a hemispherical screen is employed, it can be readily placed over the bead 19 prior to inserting the same within the tubing 13 and when a fabric is employed, such as is preferred, a small disk of such fabric is placed over the open end of the receptacle 11 and tucked under the bead 19 prior to inserting the end of the receptacle 11 into the flexible tubing. When the indicated members are within the length of tubing 13 they are in the relative positions clearly shown in Figure 2 and the terminus of the reduced frangible extension 17 of the ampule 10 is directed toward and located close to the filtering or screening element 20 and the open end 18 of the receptacle 11.

The ampule-like receptacle 11 has its central portion of cylindrical shape and its end opposite the open end 18 is constructed and sealed in ampule-fashion as shown and as indicated by the numeral 21 and is substantially the same as the portion 17 of the ampule 10. Receptacle 11 contains the solid ingredient or component which is to be dissolved or suspended in the solvent or liquid in the ampule 10 and while this may be of any suitable or desired medicinal, chemical or antibiotic substance, it is in the present instance a finely powdered penicillin salt such as potassium or sodium penicillin. The amount of such penicillin salt is such that with the sterile water in ampule 10 a predetermined dosage having a desired volume and potency will be formed just prior to injection. The reduced frangible extension 21 of receptacle 11 is inserted in one end of the flexible tubing 14 which is the same as tubing 13. Hypodermic needle 12 is any suitable, known or conventional hypodermic needle including a hollow hub 22 and a needle proper which terminates in a beveled point. Needle 12 and hub 22 provide a continuous passageway therethrough, as is well known.

A filtering or screening element 23 is placed over the end of the needle hub 22 which is inserted in the other end of the length of flexible

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tubing 14 as clearly shown in Figure 2. Screening element 23 is preferably a hemisphere of fine mesh stainless steel or other metallic woven screening, which is pre-shaped into hemispherical form so that it can be readily slipped over the end of hub 22 and will remain in proper position while the hub is being inserted into the flexible tubing 14. As is the case with frangible extension 17 and screening element 20, frangible extension 21 and screen element 23 are also in proximity within the flexible tubing 14 with the sealed terminus of the frangible extension 21 directed toward the passageway within the needle hub 22. The combination is completed by the tubular guard or cap member 15 which fits over hypodermic needle 12, as shown, to protect the needle against damage and to maintain the same in a sterile condition until the contents of the ampule are to be injected. The open end of the guard or cap 15 is inserted into and held within the lower end of the length of flexible tubing 14 (see Figure 2).

It is understood, of course, that all the component parts of my automatic injecting ampule have been sterilized and are in a sterile condition as assembled and marketed and that sterilization just prior to use is thus rendered unnecessary. The individual component parts of the ampule as a whole lend themselves conveniently thereto and consequently my new automatic injecting ampule is free from contamination at all times subsequent to the sterilization of the individual and/or assembled parts until injection has been completed. Due to the fact that the ampule 10 contains an inert and innocuous gas under substantial pressure, which is preferably nitrogen under a pressure of the order of about two atmospheres, namely about thirty pounds per square inch, the flexible tubing is so selected and of such nature that it will readily withstand such pressures and is sufficiently impervious to prevent the escape of significant amounts of gas therethrough during use. However, it will be understood that the actual injecting time is so short, i. e. a matter of only a few seconds, that these requirements for the flexible tubing are in no way disadvantageous. The material of the tubing must, however, be sterilizable, without embrittlement, cracking or other forms of deterioration. I have found that so-called gum rubber is entirely suitable.

It is believed that the operation of my new automatic injecting ampule will be understood from the construction thereof taken in conjunction with Figures 4 and 5 in particular, but this is effected in the following manner: After having sterilized, as by alcohol, the site at which the injection is to be made, the needle cap or guard 15 is removed and the hypodermic needle is immediately inserted into the patient at the prepared site. Holding the new ampule pencil-fashion, the frangible extension 17 of ampule 10 is ruptured by bending slightly the flexible tubing 13, whereupon the gas under pressure in the ampule 10 immediately forces the liquid contents of the ampule through the screening element 20 through the open end 18 of the container 11 into said container. If desired at this point, slight agitation can be carried out by manually jiggling the receptacle 11 but ordinarily such is not required, due to the gas pressure which effects immediate and complete solution or suspension, depending upon the specific character of the liquid and the solid components.

Having thus prepared a fresh solution or sus-

pension, the frangible extension 21 of the receptacle 11 is now ruptured by bending slightly the flexible tubing 14, whereupon the prepared solution or suspension passes, under the urging of the gas pressure, through the screening element 23 and through the hub 22 and needle 12 into the tissues of the patient. Due to the gas pressure within the system, the freshly prepared solution or suspension is substantially completely forced into the patient's tissues within a short period of time.

It should be noted, however, that in connection with all intramuscular injections, it is highly desirable and often required to make sure that the needle has not pierced a blood vessel, i. e. a vein or artery. Thus, it is important that aspiration take place before the frangible extension 21 is ruptured in order to determine whether the injectable preparation will go into the tissues and not into a blood vessel. This is carried out by exerting lateral compression with the fingers upon that portion of the flexible tubing 14 which is between the screening element 23 and the terminus of frangible extension 21 and then releasing such pressure, and repeating the same one or two times if necessary. If the end of the hypodermic needle is within a blood vessel, this will cause a small amount of blood to be sucked up through the needle and hub so that it will appear in the lower end of the flexible tubing 14 and can be readily noted by its characteristic appearance and coloration. If no such coloration appears, then frangible extension 21 can be ruptured and the injection made. Should, however, the needle be in a blood vessel, it is withdrawn and inserted into a new site, which is again tested by aspiration in the same manner. After the injection has been completed, the needle is withdrawn and the entire device may then be discarded or disposed of. It is understood, of course, that if desired the needle and hub can be reclaimed by cleaning and sterilizing the same, although ordinarily this need not be done due to the relatively inexpensive nature thereof.

It is to be understood that the foregoing is presented as illustrative or exemplary and not as limitative or restrictive and that within the terms of the appended claims various additions, omissions, modifications and substitutions may be made without departing from the spirit or principle of the invention. In particular, I may utilize any desired liquid and solid constituents which are to be injected in solution or suspension form and I may substitute, for nitrogen, any other acceptable gas such as H<sub>2</sub> or CO<sub>2</sub> which is inert and innocuous with respect to the ingredients involved and the patient's welfare.

What I claim is:

1. An automatic injecting ampule comprising a pair of aligned cylindrical chambers each of which has a reduced sealed frangible extension and one of which contains a liquid sealed therein under pressure, a hypodermic needle adjacent and in alignment with one of said chambers but normally out of communication therewith and flexible tubing for maintaining said chambers and said hypodermic needle in alignment and in operative relationship.

2. An automatic injecting ampule comprising a sealed ampule having a reduced frangible extension, an ampule-like receptacle having an open end adjacent the terminus of the frangible extension of the said ampule and an opposite end provided with a reduced frangible sealed ex-

tension similar to that on said ampule, a hypodermic needle having a hollow hub adjacent the terminus of the reduced frangible extension of said ampule-like receptacle, and a cap normally covering and protecting said hypodermic needle, said ampule and ampule-like receptacle and the said hypodermic needle being maintained in alignment and in operative association by means of flexible tubing connecting and holding the same.

3. An automatic injecting ampule in accordance with claim 2 in which communication is adapted to be effected between said ampule and said ampule-like receptacle and between said ampule-like receptacle and said hypodermic needle by the rupturing of said frangible extensions.

4. An automatic injecting ampule in accordance with claim 2 in which said ampule and said ampule-like receptacle are composed of glass and in which a filtering element is provided between said ampule and said ampule-like receptacle and between said ampule-like receptacle and said hypodermic needle to screen out glass and other solid particles.

5. An automatic injecting ampule in accordance with claim 4 in which said first filtering element is a fine woven textile material in the form of a disk of such material over the open end of said ampule-like receptacle.

6. An automatic injecting ampule in accordance with claim 4 in which said second filtering element is a pre-shaped hemisphere of fine metallic screening disposed over the upper end of said needle hub.

7. An automatic injecting ampule in accordance with claim 2 in which said ampule and said ampule-like receptacle contain substances which are to be admixed just prior to their passage to said hypodermic needle.

8. An automatic injecting ampule in accordance with claim 2 in which said ampule contains a sterile liquid under gas pressure and said ampule-like receptacle contains a medicament or the like which is to be admixed with said liquid.

9. An automatic injecting ampule in accordance with claim 8 in which said sterile liquid is water under pressure of an inert innocuous gas and wherein said medicament or the like is powdered penicillin.

10. An automatic injecting ampule in accordance with claim 9 in which the inert innocuous gas is nitrogen under a pressure of approximately two atmospheres.

11. In an automatic injecting ampule of the character described, a sealed ampule containing sterile water and an inert, innocuous gas under pressure, an open-ended ampule-like receptacle containing a powdered therapeutic preparation, a filtering element over the open end of said ampule-like receptacle and a length of flexible, gas-imperious tubing connecting said ampule and ampule-like receptacle and maintaining the same in aligned, operative relationship, said ampule when broken discharging its contents of sterile water into said ampule-like receptacle under the action of said gas under pressure, whereby a freshly prepared injectable preparation is obtained which is still under pressure.

12. A combination ampule in which an injectable preparation is adapted to be made up under gas pressure which is subsequently utilized to eject such preparation from the combination ampule when injection is to be made through an associable hypodermic needle comprising an am-

pule having a vehicle sealed therein under gas pressure, an ampule-like receptacle containing an active ingredient to be admixed with said vehicle and having an opening through which said vehicle and gas are adapted to be transferred upon rupture of said ampule and gas-tight flexible tubular means for holding said ampule and ampule-like receptacle in aligned gas-tight position with the ampule tip adjacent the opening of the ampule-like receptacle.

13. A combination ampule in which an injectable preparation is adapted to be made up under gas pressure which is subsequently utilized to eject such preparation from the combination ampule when injection is to be made through an associable hypodermic needle comprising an ampule having a vehicle sealed therein under gas pressure, an ampule-like receptacle containing an active ingredient to be admixed with said vehicle and having an opening through which said vehicle and gas are adapted to be transferred upon rupture of said ampule and gas-tight flexible tubular means for holding said ampule and one end of the ampule-like receptacle in aligned gas-tight position with the ampule tip adjacent the opening of the ampule-like receptacle, a hypodermic needle having its hub adjacent the other end of said ampule-like receptacle and gas-tight flexible tubular means for holding said ampule-like receptacle and said hypodermic needle in aligned, gas-tight operative association.

14. An automatic injecting ampule comprising a sealed ampule having a reduced frangible extension, an ampule-like receptacle having an open end adjacent the terminus of the frangible extension of the said ampule and an opposite end provided with a reduced frangible sealed extension similar to that on said ampule, a hypodermic needle having a hollow hub adjacent the terminus of the reduced frangible extension of said ampule-like receptacle, said ampule and ampule-like receptacle and the said hypodermic needle being maintained in alignment and in operative association by means of flexible tubing connecting and holding the same.

15. An automatic injecting device comprising a sealed ampule having an injectable liquid and a gas under pressure therein, an ampule-like receptacle containing an injectable powdered therapeutic agent therein and one end of which is open and in a position to receive the liquid and gas from the ampule upon rupture of the latter and the other end of which is reduced and sealed, a hypodermic needle disposed adjacent the sealed end of the ampule-like receptacle to receive the admixed gas, liquid and powder therefrom upon

rupture of the reduced sealed end thereof and tubular means of flexible, substantially impervious material holding said ampule, ampule-like receptacle and hypodermic needle in alignment in the above relative positions while enabling rupturing when injection is to be made.

16. An automatic injecting device in accordance with claim 15 in which the tubular means is constituted of a pair of lengths of rubber tubing forming closed passageways from said ampule to said ampule-like receptacle and from said ampule-like receptacle to said hypodermic needle.

17. An automatic injecting ampule which comprises a plurality of substances which are adapted to be admixed just prior to their injection, each such substance being disposed in a separate receptacle and normally out of contact with the substance in the other receptacle, and an associated hypodermic needle disposed contiguous to one such receptacle in a position to receive the admixed substances, said receptacles being arranged in tandem alignment and each being provided with a frangible extension adapted to be ruptured to effect communication of one receptacle with the other when the substances are to be admixed, one such substance being a liquid which is sealed in its receptacle together with an inert, innocuous gas under pressure, and flexible tube means impervious to the contents of the receptacles for maintaining said receptacles in such relative positions and said hypodermic needle in tandem alignment with said receptacles.

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