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(71) Applicant: **Radial Italica 3000, S.L.**
08301 Mataro (ES)

(72) Inventors:
• **Massaguer i Agulló, Miquel**
Mataro (ES)
• **Gutiérrez Xivillé, Mario**
Mataro (ES)

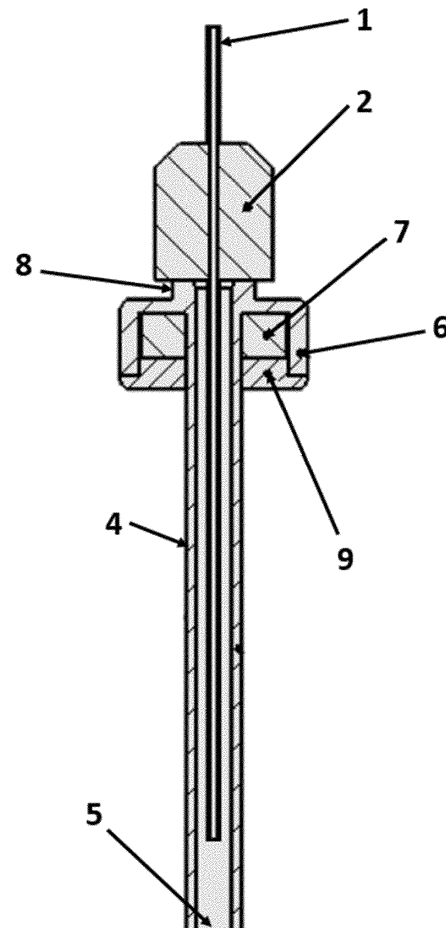
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(74) Representative: **Isern Patentes y Marcas S.L.**
Avda. Diagonal, 463 Bis, 2º
08036 Barcelona (ES)

(54) **FILLING NEEDLE PROTECTION SYSTEM**

(57) The present invention relates to a filling needle protection system configured to be installed on a filling needle characterised in that it comprises at least: a centring device of the filling needle, configured to mount the filling needle on the fork of the filling machine; and a needle protector, comprising: a protective tube with an open end; a housing located at the end opposite the open end of the protective tube, which houses a magnet therein, configured to carry out a removable joint between the protective tube and the centring device of the filling needle; and an extension element, located adjacent to the housing of the magnet, configured to enable the needle protector to be mounted on the filling needle when the filling needle is mounted on the fork of the filling machine.

Figure 1



Description

TECHNICAL FIELD

[0001] The present invention falls within the pharmaceutical product production sector, more specifically to the field of pharmaceutical product production by means of filling vials using needles or nozzles, and more specifically to the field of sanitising and sterilising the needles or nozzles used for filling vials of pharmaceutical products.

BACKGROUND OF THE INVENTION

[0002] Currently, systems for filling vials or ampoules are widely known, used by the pharmaceutical industries for the storage and distribution of medicines, which must comply with certain aseptic processes, characterised by the assurance of sterility, that is, with the prevention of microbiological contamination during production.

[0003] These systems comprise a nozzle or needle, connected by pipes to a reactor, in which the pharmaceutical product is stored, dispensing it into the vials or ampoules by means of the aforementioned nozzles or needles, which are aligned and introduced inside the same, enabling the correct filling.

[0004] However, these systems must be properly sterilised, in order to comply with current regulations regarding sanitation and sterilisation of medicines distributed to pharmaceutical companies.

[0005] Commonly, sterilisation is carried out by means of an autoclave, which is nothing more than a pressure vessel, with air-tight closure, carrying out sterilisation with steam, such that pharmaceutical materials and instruments are sanitised.

[0006] However, after these elements are sterilised, and until they are installed in the machine for use thereof, they remain unprotected against subsequent contamination.

[0007] That is why it is necessary to find a needle protection system that enables handling once they have been sterilized in the autoclave, limiting the risk of contamination.

[0008] In this sense, document CN210915250U belongs to the state of the art, in which a filling unit for moving vehicles is described, with a liquid filling operation platform, where the moving vehicle comprises a body, with a pump, a rolling assembly and a positioning assembly for the rolling assembly, arranged in the lower portion of the body; and a drug injection assembly, comprising a needle support and a lifting mechanism arranged on the platform of the pump unit.

[0009] According to this document, the support of the needle comprises a support connection part and a needle mounting seat, which extends outside the platform of the pump unit, as well as a cleaning sleeve for the needles of the filling machine, with an opening and a sealing platform that act as a centring collar.

[0010] Document CN203625000 also belongs to the state of the art, in which a cleaning and sterilisation method for filling needles is described, wherein an internal filling needle, with a sleeve, which is inserted into an external filling needle, which comprises an access port.

[0011] Likewise, it describes an outer filling cavity, which is formed between the inner wall of the outer filling needle and the outer wall of the inner filling needle. In this way, when the liquid is introduced into the inner filling needle, the inert gas can be filled into the outer filling cavity through the access port, and the filling of the inert gas can be carried out at the same time.

[0012] In this way, cleaning and sterilisation can be carried out when a cleaning and sterilisation source is introduced into the inner filling needle and the outer filling chamber, since the outer needle comprises an open end in the lower portion.

[0013] However, none of the cited documents, nor the known art closest to that of the present invention, disclose a method that enables a quick fastening and/or release system between the protective tube and the needle centring device, comprising a sufficient clamping force to enable the sterilisation of the needles in an autoclave or the like, but which enables the protective tube to be removed to use the needle in the subsequent filling of the vials.

DESCRIPTION OF THE INVENTION

[0014] The filling needle protection system that the invention proposes is thus configured as a notable novelty within its field of application, since according to its implementation and in an exhaustive manner, the indicated objectives are satisfactorily achieved, with the characterising details that make it possible and that differentiate them conveniently included in the final claims that accompany this description.

[0015] Specifically, the present invention proposes a filling needle protection system that allows its use during the sterilisation phase of the needles, by means of the use of an autoclave or the like, its handling for assembly in the vial filling machine, and the subsequent removal of said protection system, for the use of the needle in vial filling methods.

[0016] To achieve this, the filling needle protection system comprises at least one filling needle, a centring device for the needle, and a protector of the same.

[0017] The centring device of the needle is used to mount it on a fork of the filling machine that is part of the vial filling process, and is made of stainless steel, such as for example Duplex 2205, with which it is intended to avoid corrosion that may occur during sterilisation of the assembly by means of autoclave.

[0018] Furthermore, the protector of the needle comprises at least one protective tube, a housing that is used to house a magnet, and a centring element.

[0019] The protective tube is made of stainless steel, preferably of the 300 series, and specifically AISI 316L; and comprises an open end, such that the accumulation

of moisture due to condensation that occurs during the sterilisation process by means of autoclaving is prevented.

[0020] This element is configured to cover, at least partially, the outside of the filling needle, achieving its protection in the mounting method of the same in the fork of the filling machine, once it has been sterilised by using the autoclave.

[0021] Furthermore, the housing for the magnet is arranged at the end opposite the open end of the protective tube, and houses a magnet that is used to make the removable connection of the protective tube with respect to the centring device of the needle. The magnet is made of a material resistant to high temperatures, and comprises a force of attraction sufficient to achieve the aforementioned objective.

[0022] Both the magnet and its housing are covered by a sealing element, which prevents the entry of moisture during the sterilisation process by means of autoclave, such that the durability thereof is not affected.

[0023] Lastly, the centring element is arranged adjacent or substantially adjacent to the housing of the magnet, and are configured to maintain the mounting of the protector of the needle when the needle is mounted on the fork of the filling machine.

[0024] According to what was previously said, there is a protection system for the filling needles, which is used to protect the same during all the steps prior to their use in the vial filling process, maintaining a removable joint sufficient to achieve the aforementioned objective.

[0025] That is, it can be kept installed during the sterilisation method in the autoclave, since it comprises an open end that prevents the accumulation of humidity due to condensation; and it can also be kept installed during the handling and mounting method of the needle on the fork of the filling machine.

[0026] Lastly, the protection system can be easily removed, allowing the use of the needle in the production steps of filling the vials.

[0027] The filling needle protection system, and the assembly of elements described, represent an innovation of structural and constitutive features unknown until now, reasons that, together with its practical utility, provide it with sufficient grounds to obtain the privilege of exclusivity that is requested.

BRIEF DESCRIPTION OF THE DRAWINGS

[0028] To complement the description that is being made and in order to help make the features of the invention more readily understandable, a set of drawings is attached as an integral part of said description wherein, for illustrative and non-limiting purposes, the following has been represented:

Figure 1 shows a cross-sectional view of the invention

Figure 2 shows an external perspective view of the

invention

Figure 3 shows the complete mounting in the filling machine

Figure 4 shows a detail view of the invention in the filling machine

List of references and figures:

[0029]

1. Filling needle
2. Centring device
3. Filling machine
4. Protective tube
5. Open end
6. Housing
7. Magnet
8. Coupling element
9. Sealing element

PREFERRED EMBODIMENT OF THE INVENTION

[0030] The following detailed description of the preferred embodiments, refers to the accompanying drawings which form part of this specification, and which show by way of illustration specific preferred embodiments in which the invention may be carried out. These embodiments are described in sufficient detail to enable those skilled in the art to carry out the invention, and it is understood that other embodiments may be used and logical structural, mechanical, electrical, and/or chemical changes may be made without departing from the scope of the invention. To avoid unnecessary details in order for those skilled in the art to carry out the detailed description, it must therefore not be taken in a limiting sense.

[0031] The present invention proposes a filling needle protection system, configured to be installed on a filling needle 1, which is mounted in a filling machine 3; and that comprises at least one centring device 2 of the filling needle 1, which is used to assemble the filling needle 1 in the filling machine 3.

[0032] It also comprises a protector of the filling needle 1, which in turn comprises a protective tube 4 with an open end 5; a housing 6, located at the end opposite the open end 5 of the protective tube 4, which house a magnet 7 therein; and an extension element 8, located adjacent or substantially adjacent to the housing 6.

[0033] Wherein the magnet 7 is configured to carry out the removable joint between the protective tube 4 and the centring device 3 of the filling needle, by means of applying the magnetic retention force.

[0034] And wherein the extension element 8 is configured to enable the mounting of the needle protector on the filling needle 1, when the filling needle 1 is installed in the filling machine 3.

[0035] That is, according to this first embodiment, there is a system for protecting a filling needle 1, which enables it to be installed on the filling needle 1 in a simple and

removable manner, due to the magnetic force generated by a magnet 7 and applied to the centring device 2 of the filling needle 1, wherein the magnet 7 is located in the housing 6 of the protector of the filling needle 1.

[0036] Likewise, the protection system may remain installed at any time, both during the installation and fastening of the filling needle 1 in the filling machine 3, due to the extension element 8; and during the sterilisation step by means of autoclave or the like, due to the fact that the open end of the protective tube 4 prevents moisture from accumulating due to the condensation produced in the aforementioned sterilisation step of the assembly.

[0037] In a preferred embodiment, the housing 6 and/or the magnet 7 are covered by a sealing element 9, which prevents the entry of any type of moisture that could affect the operation and/or durability of the magnet 7.

[0038] Likewise, the magnet 7 is made of a material resistant to high temperatures, close to 250 °C, and comprises an attraction force greater than 500 grams, such that it is sufficient to maintain the protector of the filling needle 1 in its working position, during the sterilisation and assembly phases of the filling needle 1 in the filling machine 3.

[0039] Preferably, the needle protector is made of stainless steel, specifically 300 series stainless steel, such as AISI 316L.

[0040] Having sufficiently described the nature of the present invention, as well as the way of implementing it, it is not considered necessary to extend its explanation for any expert in the state of the art to understand its scope and the advantages which derive from it, specifying that, within its essential nature, it can be carried out in other embodiments that differ in detail from the one provided by way of example, and which are also covered by the requested protection, provided that they do not alter, change or modify its fundamental principle.

Claims

1. **A filling needle protection system** configured to be installed on a filling needle (1) **characterised in that** it comprises at least: a centring device (2) of the filling needle (1), configured to mount the filling needle (1) on the fork of the filling machine (3); and a needle protector, comprising:

- a protective tube (4) with an open end (5);
- a housing (6) located at the end opposite the open end (5) of the protective tube (4), which houses a magnet (7) therein, configured to carry out a removable joint between the protective tube (4) and the centring device (3) of the filling needle (1);
- and an extension element (8), located adjacent to the housing (6) of the magnet (7), configured

to enable the needle protector to be mounted on the filling needle (1) when the filling needle (1) is mounted on the fork of the filling machine (3).

2. **The filling needle protection system** according to the first claim **characterised in that** the housing (6) and/or the magnet (7) are covered by a sealing element (9).
3. **The filling needle protection system** according to the first claim **characterised in that** the needle protector is made of stainless steel.
4. **The filling needle protection system** according to the first claim **characterised in that** the magnet (7) is made of a material resistant to temperatures of up to 250 °C, and comprises an attraction force greater than 500 grams.

Figure 1

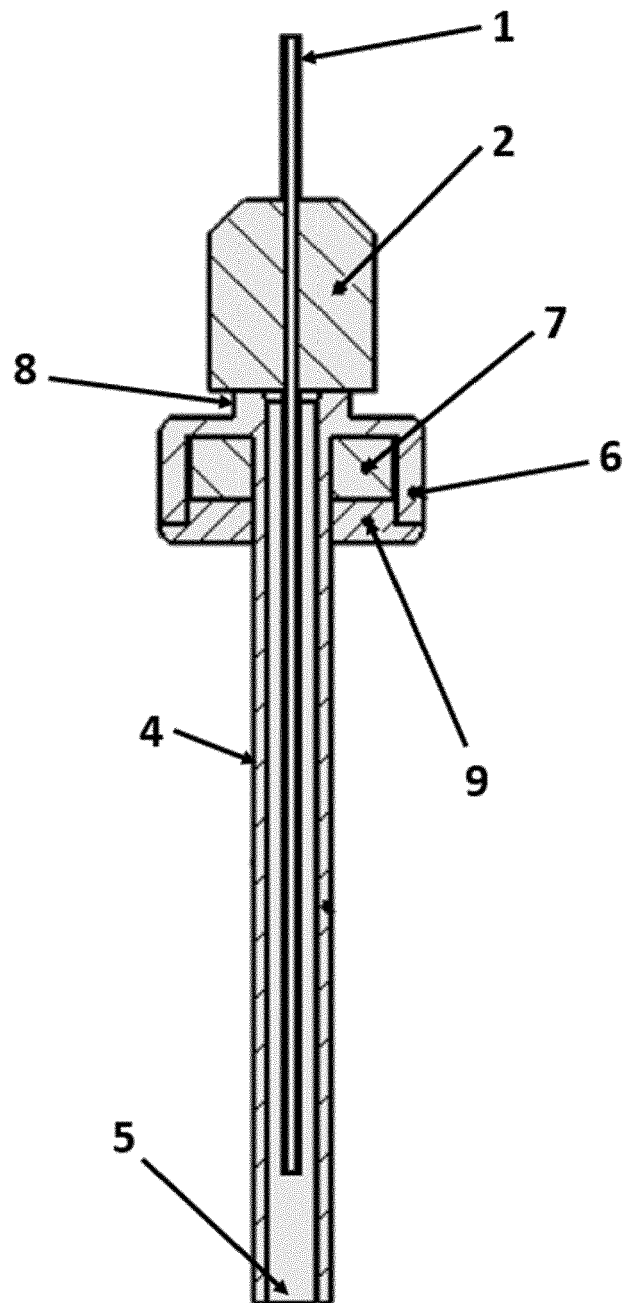


Figure 2

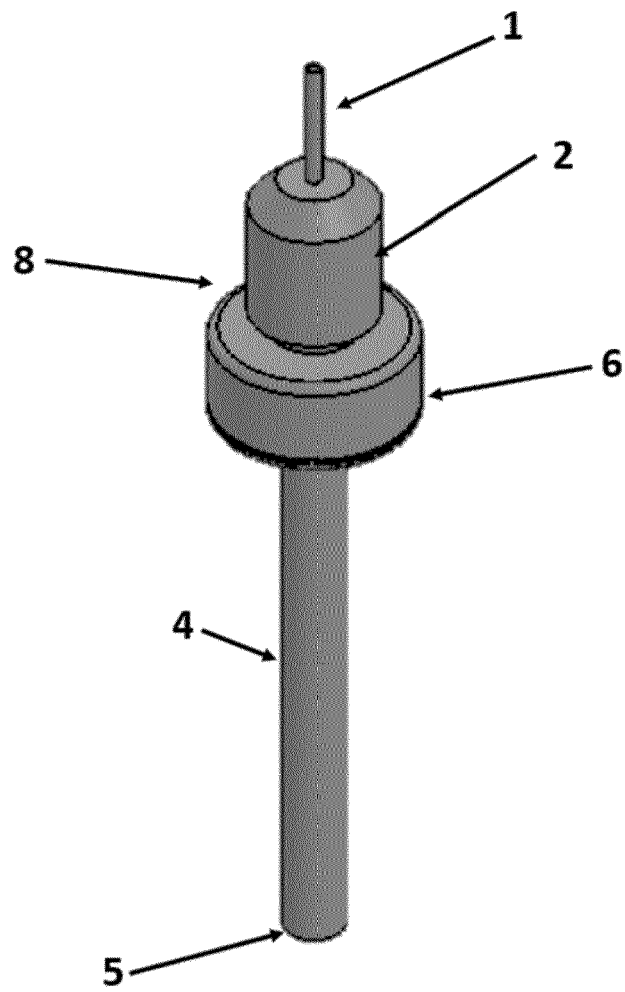


Figure 3

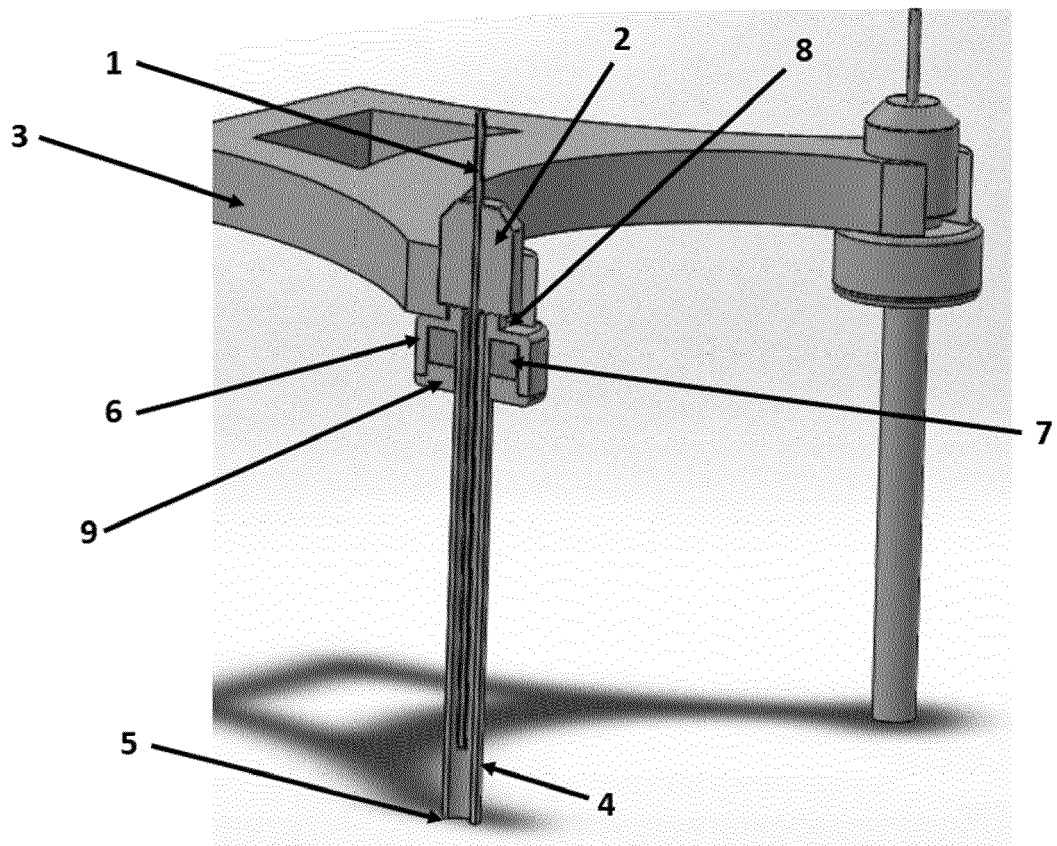
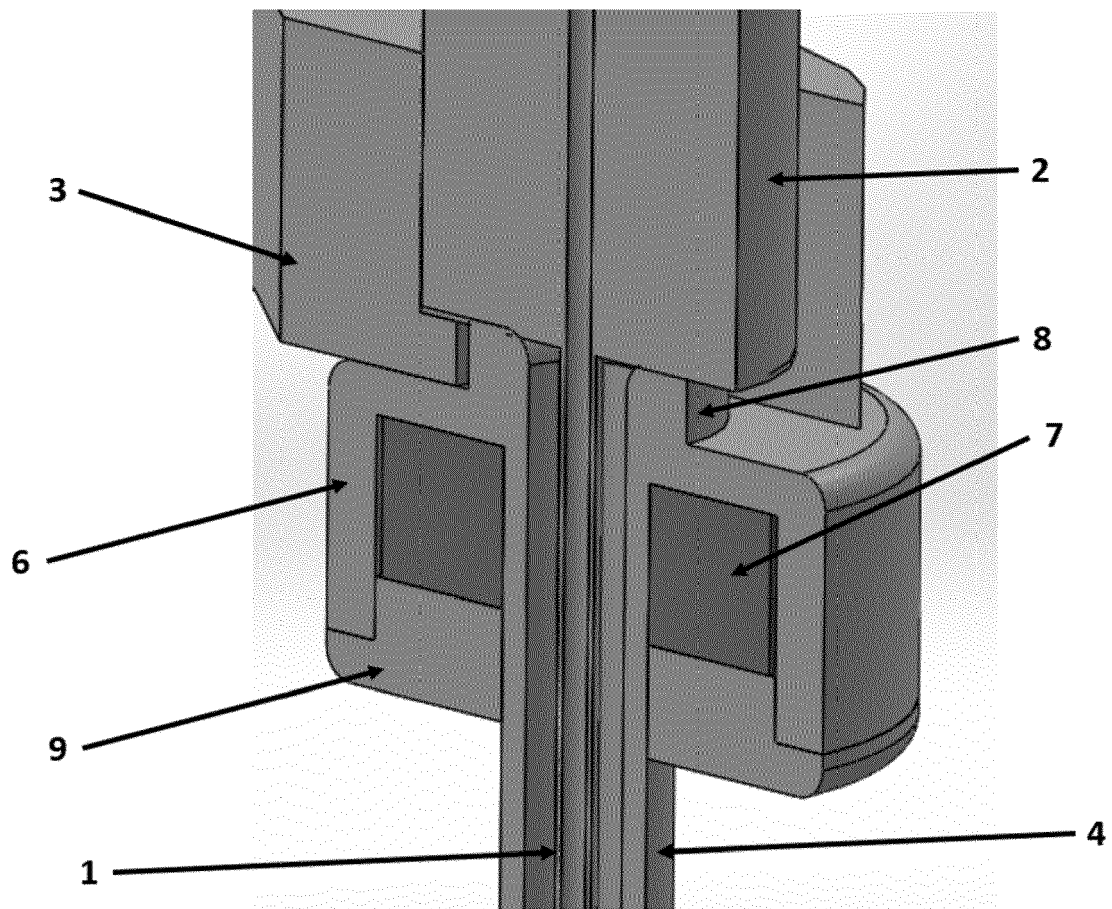


Figure 4



REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

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