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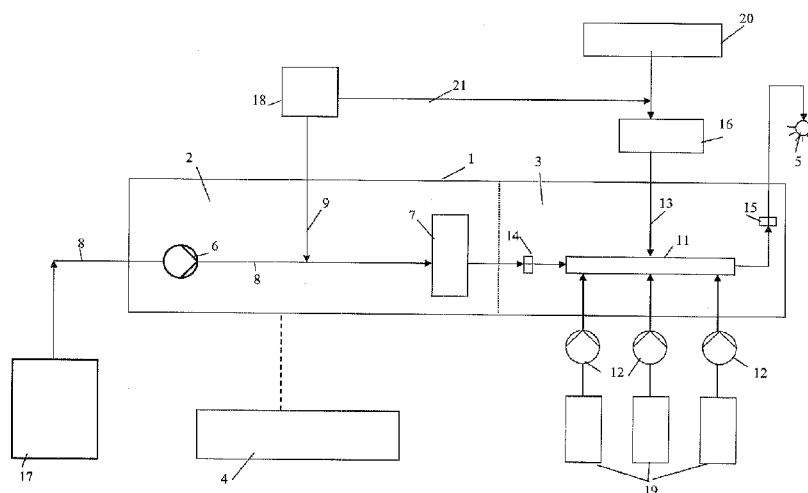


FIG. 1

(57) Abstract: The present invention relates to an apparatus for preparing a sterile composition comprising a) a unit containing a sterile water filtration section and a mixing section, b) a programme control system, and c) a nozzle system.

APPARATUS FOR PREPARING A STERILE COMPOSITION

BACKGROUND OF THE INVENTION

[0001] The present invention relates to an apparatus for preparing a sterile composition, the use of such an apparatus for preparing a sterile composition and to a method for preparing a sterile composition employing such an apparatus.

[0002] Sterile compositions can be applied in various fields. They play, for example, a major role in producing and/or maintaining clean room conditions. Clean room conditions have to be considered, for example, in a hospital or at the filling processes of filling beverages or foods into containers, such as bottles or cartons. Very often, such a filling process has to be carried out under clean room or aseptic conditions.

[0003] The operation of filling plants for filling beverages or drinks, such as mineral water, juices or beer, or foods into containers such as bottles, beer barrels or the like, is subject to stringent regulations under the law on foodstuffs. In this connection, an essential aspect is the cleanness of the plant and of the containers. Where filling takes place into reusable containers, e.g. into already used returnable or one way drinking bottles, these must be intensively cleaned.

[0004] Likewise, at specified intervals, in particular after completion of a filling period, it is necessary to clean most intensively the filling plant, namely the filler from which the containers are filled, and specifically from the inside as well as from the outside, as well as the conveying device for the containers to and from the filler, which device is also designated as a conveyor. In this case, these cleaning operations are carried out in or on the filling plant itself, without there being any requirement to undertake noteworthy alterations thereof for the purposes of cleaning. In this case, the cleaning solutions, including rinsing solutions, are moved past the surfaces to be cleaned by means of pumps, or are sprayed on via suitable spray units (heads). This type of cleaning has become known as CIP cleaning (cleaning in place).

[0005] In the state of the art, there are several examples for an apparatus or a machine which can be employed for aseptic filling. EP-A 1 468 959, EP-A 0 893 396 or EP-A 1 561 722 disclose different types of such filling machines, which contain at least some parts or rooms held under aseptic conditions. However, they contain no information on how the aseptic or clean room conditions within said filling machines can be obtained.

[0006] EP-A 0 903 320 discloses a CIP-system for cleaning a filling plant. Since it is not required that CIP-cleaning has to be carried out under aseptic or clean room conditions, the CIP-system disclosed in EP-A 0 903 320 does not contain any means for obtaining such conditions. However, if this CIP-system has to be operated under aseptic conditions, it has to be connected to further (external) devices or means not being incorporated into said system. The cleaning system of EP-A 0 903 320 comprises within a common central cleaning circuit a common supply station comprising as components a fresh water container, a storage container, a heating station and a dosing station. This components can be selectively connected to and disconnected from the cleaning circuit by means of valves and rotary flaps. The whole system additionally contains a programme control system and a common partial line system.

SUMMARY OF THE INVENTION

[0007] The object of the present invention is to provide an apparatus, which can be employed for preparing a sterile composition in an easy and cost-effective way.

[0008] The object is achieved by an apparatus for preparing a sterile composition comprising

- a) a unit (1) containing a sterile water filtration section (2) and a mixing section (3),
- b) a programme control system (4), and
- c) a nozzle system (5).

[0009] The apparatus according to the present invention is advantageous in several aspects. Since the sterile water filtration section and the mixing section is combined into a single unit, significant synergies can be generated, mostly in respect of cost savings, time savings and, very important, space savings. Since both sections are contained in the same unit and not as individual units, the two sections can run simultaneously. This results in less production downtime and also for a significant benefit for the bottler, if employed within a filling procedure.

[00010] The apparatus according to the present invention requires less connecting lines or further equipment or means for operation than a system, which has individual units for the sterile water filtration and the mixing. The apparatus according to the present invention can be operated in a more easy way, for example, in respect of production preparation or internal self-cleaning processes. In addition, it is much easier to build up and start the operation of a system, for example a filling system, which requires clean room conditions, due to the

employment of an apparatus comprising a single unit containing a sterile water filtration section and a mixing section. Last but not least, the internal self-cleaning of the apparatus according to the present invention is much easier due to the space-saving concept of combining the sterile water filtration section and the mixing section into a single unit. Since steam or air are used either as mandatory or optional components for preparing a sterile composition within the sterile water filtration section and the mixing section, the apparatus of the present invention requires less connecting lines to the respective steam or air supply, since both sections are combined in one unit. Furthermore, the filters, preferably filter membranes, have a longer standing time, mostly due to the easier self-cleaning procedure.

[00011] The apparatus of the present invention can be successfully employed for preparing a sterile composition. Such a sterile composition can be employed for cleaning, sanitizing or sterilization of rooms or equipment. By consequence, it is a big advantage of the present invention that the apparatus can be employed for producing or maintaining clean room conditions or aseptic conditions.

BRIEF DESCRIPTION OF THE DRAWING

[00012] FIGURE 1 The apparatus of the present invention is illustrated.

DETAILED DESCRIPTION

[00013] The sterile water filtration section (2) comprises at least one pump (6), at least one filter (7), a connection line (8) to a water supply (17) and a connection line (9) to a steam supply (18). The water supply (17) and the steam supply (18) are both not part of the sterile water filtration section (2) or the apparatus (as such) of the present invention. The water supply (17) and the steam supply (18) are individual units, which are known by a person skilled in the art and can be easily connected to the sterile water filtration section (2) by known methods.

[00014] The filter (7) can be any filter known by a person skilled in the art to be employed for sterile water filtration. However, in some cases it is appropriate to employ different types of filters. By consequence, two, three or more filters (of the same or different type) can be contained within the sterile water filtration section (2). The filter (7) is on one side connected with the water supply (17) by a connection line (8), and on the other side it is connected to the mixing section (3). The sterile water filtration section (2) or the apparatus of the present invention, respectively, are constructed in such a way that on this side of the filter (7), which is oriented towards the mixing section (3), sterile or clean room conditions are obtained

(sterile side of the filter). If two or more filters are employed, sterile conditions are obtained (at least) after the water has passed the last filter. However, sterile conditions may already be obtained after passing the first or second filter out of a row of three filters.

[00015] The water obtained from the water supply (17) can be any type of water, preferably it is ordinary (drinking) water provided from a city or a community. The water is passed over at least one filter (7) to obtain sterile water. Preferably, this is carried out under pressure. The pump (6) is always on the non-sterile side of the filter (7). The non-sterile side always lies on the opposite side of the filter (7) compared to the sterile side. However, the connection line (9) to the steam supply (18) can be on either sides of the pump (6). If demanded, two or more pumps (6) can be employed within the sterile water filtration section (2). For example, a pump can also be contained within the connection line (9) to the steam supply (18). The connection line (9) may also contain at least one filter which can be used in connection with steam. Preferably, the connection line (9) from the steam supply (18) is connected with the lines (8) for transporting the water on the non-sterile side of the sterile water filtration section (2). However, the connection line (9) may also be connected with the connection from the filter (7) to the mixing section (3), since the steam as such is (usually) also sterile.

[00016] The mixing section (3) comprises at least one mixer (11), at least one connection line (12) to a storage container (19) and a connection line (13) to a gas supply (20). The mixer (11) is connected with the sterile water filtration section (2) and with the nozzle system (5).

[00017] The mixer (11) may be any mixer (mixing unit) to be employed for mixing individual compounds. A person skilled in the art knows suitable mixers. The size and dimension of the mixer depends on the components to be mixed. Due to the sterile water filtration section (2), one of the components to be mixed is sterile water. However, the other components of the sterile composition to be mixed within said mixer (11) can be employed as a liquid, as a solid or as a gas. By consequence, the mixer (11) may also contain further mechanical equipment such as a stirrer or a rotor. In one embodiment of the present invention, the mixer (11) is a pipe itself. The diameter of said pipe can be the same or different to that of the connection with the filter (7) or the connection to the nozzle system (5). The mixer (11) may also be directly connected with the filter (7) without using any additional pipes or tubes as a connection line.

[00018] The mixer (11) is connected with at least one storage container (19) by at least one connection line (12). The storage container (19) as such is not part of the mixing section (3)

or the apparatus (as such) of the present invention, but it is a separate unit known by a person skilled in the art. The mixing section (3), preferably the mixer (11), may be connected with several individual storage containers (19), whereby each individual container is connected by at least one individual connection line (12). Preferably, each component to be mixed into the sterile water for preparing a sterile composition is contained in an individual storage container (19). Each connection line (12) may contain a dosing unit and/or a pump.

[00019] The mixing section (3) contains at least one connection line (13) to a gas supply (20). The gas supply (20) is not part of the mixing section (3) or the apparatus (as such) of the present invention. The gas supply (20) as such is known by a person skilled in the art, preferably the gas supply (20) is designed for supplying a gas, preferably air into the apparatus of the present invention. Preferably, the connection line (13) is connected with the mixer (11). However, the connection line (13) may also be connected with the connection between the mixer (11) and the nozzle system (5). In the latter case, the connecting line (13) may alternatively be connected with said line outside of the mixing section (3) or the unit (1), respectively.

[00020] The connection line (13) preferably contains one or more filters (16). A person skilled in the art knows suitable filters (16) to be employed for sterilizing the gas, preferably air, transported from the gas supply (20) via connecting line (13) into the mixing section (3). The connection line (13) may also be connected with the steam supply (18) by connection line (21). Preferably, only one steam supply (18) is employed in connection with the apparatus of the present invention. However, two or more individual steam supplies (18) can be used. Preferably, the connection line (21) enters the connection line (13) between the gas supply (20) and the filter (16). The filter (16) may either be part of the mixing section (3) or it may be positioned outside of the mixing section (3) or the unit (1), respectively. If appropriate two or more individual filters (16) may be employed. The steam supply (18) may also be directly connected via at least one connection line (21) with the mixer (11) and/or the connecting line from the mixer (11) to the nozzle system (5) without being connected to the connection line (9).

[00021] In one embodiment of the present invention, the apparatus may contain at least one dosing unit. A dosing unit (14) may be introduced into the connection between the filter (7) and the mixing section (3) and/or a dosing unit (15) is introduced into the connection between the mixer (11) and the nozzle system (5). The same type of dosing units can be employed for the dosing units (14) and (15), which are preferably integrated into the mixing section (3).

[00022] As indicated above, it is a big advantage of the present invention that the sterile water filtration section (2) and the mixing section (3) are contained within the same unit (1). Within the present invention, the term "same unit" means that said two sections are closely connected to each other. There is no space between these two sections, which may be incorporated into the same housing or box. In Figure 1 this is indicated by a dotted line. For example, the unit (1) is integrated on one skit. By consequence, the two individual sections (sterile water filtration section and mixing section) contained within unit (1) are only connected by rather short connecting lines. In one embodiment of the present invention, the distance between the filter (7), which belongs to the sterile water filtration section (2), and the mixer (11), which belongs to the mixing section (3), within the unit (1) is less than 1 meter, preferably less than 0.5 meter.

[00023] The apparatus according to the present invention additionally contains a programme control system (4). The programme control system (4) may be any programme control system known by a person skilled in the art, for example, a computer or a computer system. The programme control system (4) is used to operate the individual components of the apparatus as such. Preferably, the operation is carried out automatically, for example, by a suitable software programme. The programme control system (4) is connected with the unit (1) and optionally with the nozzle system (5). However, the programme control system (4) can also be used for operation of further units, for example, the water supply (17), the steam supply (18), the storage container (19) and/or the gas supply (20).

[00024] The nozzle system (5) may contain any nozzle known by a person skilled in the art. It may comprise one, two, three or even more individual nozzles. The term "nozzle" comprises any mean, which can be used for cleaning, sanitizing, or sterilization of rooms or equipment or for producing or maintaining clean room conditions. The sterile composition prepared within the apparatus of the present invention is transferred via the nozzle system (5) in or on the rooms or equipment to be treated. Preferably, the sterile composition is sprayed via the nozzle system (5) onto said rooms or equipment.

[00025] In one embodiment of the present invention, the nozzle system (5) is partially or completely integrated into a filler. The filler is preferably a filler known by a person skilled in the art within filling processes of filling beverages or foods into containers, such as bottles.

[00026] Another subject of the present invention is the use of the apparatus described above. The apparatus according to the present invention can be used for preparing a sterile composition. The sterile composition may be, for example, a cleaning solution or a disinfection solution. The sterile composition can be (further) used for cleaning, sanitizing or

sterilization of rooms or equipment. It can be also used for producing or maintaining clean room conditions or in connection with aseptic filling processes. The equipment, which can be cleaned, sanitized or sterilized, may be a filler. Alternatively, the clean room conditions relate to a filler. Said filler is preferably a filler of a cleaning-in-place (CIP) system or a filler employed in a conveyor belt system. Said fillers are usually employed for filling and/or refilling of bottles or containers, which are, for example, transported on a conveyor belt system. The clean room aseptic or sterile conditions on the surface or inside said equipment, for example a filler, are obtained due to the treatment of said items with the sterile composition obtained from the apparatus of the present invention. However, the apparatus may be, for example, temporarily operated by only transporting the sterile water without involving a mixing step for producing a sterile composition such as a cleaning solution. This can be done in order to temporarily rinse, for example, a filler with sterile water.

[00027] A further subject of the present invention is a method for preparing a sterile composition employing the apparatus as described above. This method comprises the following steps:

- a) producing sterile water by passing water over at least one filter (7) contained in the sterile water filtration unit (2),
- b) transferring the sterile water from the sterile water filtration unit (2) into the mixer (11) of the mixing section (3),
- c) adding at least one compound via at least one connection line (12) to the sterile water contained in the mixer (11) to obtain the sterile composition

[00028] Besides the steps a) - c), which are carried out in the indicated order, the method according to the present invention may contain at least one further step d) - f). According to step d), sterile gas, preferably sterile air is added to the sterile composition. The sterile composition is sprayed via the nozzle system (5) into (or onto the surface of) a filler (step e)). The sterile composition may be sprayed as a foam or a liquid. Preferably, the sterile composition is sprayed as a foam. The foam is preferably obtained by adding a sterile gas, preferably sterile air to the sterile composition. If the sterile composition is sprayed as a foam, the killing of bacteria or germs is more efficiently. This is especially the case, if the sterile composition contains at least one acid and/or at least one base.

[00029] The apparatus itself is sterilized by feeding steam into the apparatus (step f)). Steam is usually obtained by heating water, which may contain further components or additives. Step f) can be carried out in certain time intervals. Such time intervals may be, for example, once a week, once a day, or even several times a day. Preferably, the process for

preparing a sterile composition according to steps a) - c) and optionally d) and e) is stopped and the apparatus of the present invention is transferred into an empty condition. The steam employed in step f) usually originates from the steam supply (18). The steam can be introduced at various locations into the apparatus of the present invention. Preferably, the steam is introduced via connection line (9) and optionally via connection lines (21) and (13).

[00030] The compounds to be added in step c) of the process according to the present invention may be any compound known by a skilled person to be employed within a sterile composition. Preferably, said compound is at least one compound selected from a disinfecting agent, an acid or a base. Such compounds are known by a person skilled in the art. If the sterile composition contains at least one acid, it preferably contains no or only a much smaller molar amount of a base and vice versa. The type and amount of an acid or a base usually depend on the pH-value of the sterile compositions. Since each individual component, which may be present within said sterile composition, is preferably contained in an individual storage container (19), the apparatus of the present invention usually contains at least one storage container (19) for an acid and at least one storage container (19) for a base in parallel. In addition, it usually contains at least one storage container (19) for a disinfecting agent. However, the apparatus may contain further storage containers (19) depending on the type and amount of additional components of the sterile composition to be prepared.

[00031] In one embodiment of the present invention, at least two individual sterile compositions are prepared. For example, the sterile composition in the acidic pH-range is prepared and employed. Afterwards, a sterile composition in the alkaline pH-range is prepared and employed. Between the preparation of these two different sterile compositions, the apparatus itself may optionally be sterilized by feeding steam into the apparatus. However, the method of preparing a sterile composition according to the present invention may be at least temporarily interrupted by performing, for example, rinsing steps.

CLAIMS

1. An apparatus for preparing a sterile composition comprising:
 - a) a unit containing a sterile water filtration section and a mixing section,
 - b) a programme control system, and
 - c) a nozzle system.
2. The apparatus according to claim 1, wherein the sterile water filtration section comprises at least one pump, at least one filter, a connection line to a water supply and a connection line to a steam supply, and wherein the filter is connected to the mixing section.
3. The apparatus according to claim 2, wherein the mixing section comprises at least one mixer, at least one connection line to a storage container and a connection line to a gas supply and wherein the mixer is connected to the sterile water filtration section and to the nozzle system.
4. The apparatus according to claim 3, wherein the mixer is a pipe and/or a dosing unit is introduced into the connection between the filter and the mixing section and/or a dosing unit is introduced into the connection between the mixer and the nozzle system.
5. The apparatus according to claim 3, wherein the distance between the filter and the mixer within the unit is less than 1 meter.
6. The apparatus according to claim 1, wherein at least the nozzle system is partially or completely integrated into a filler.
7. The apparatus according to claim 1, wherein the mixing section is connected to a steam supply and/or a filter is introduced into connection line.
8. The use of an apparatus according to claim 1 for preparing a sterile composition, for cleaning, sanitizing or sterilization of rooms or equipment, for producing or maintaining clean room conditions or in connection with aseptic filling processes.
9. The use according to claim 8, wherein the equipment is a filler or the clean room conditions relate to a filler, preferably a filler of a cleaning-in-place (CIP) system or a filler employed in a conveyor belt system for (re)filling of bottles or containers.

10. A method for preparing a sterile composition employing an apparatus according to claim 1 and comprising the following steps:
 - a) producing sterile water by passing water over at least one filter contained in the sterile water filtration unit,
 - b) transferring the sterile water from the sterile water filtration unit into a mixer of the mixing section,
 - c) adding at least one compound via at least one connection line to the sterile water contained in the mixer to obtain the sterile composition.
11. The method according to claim 10, wherein sterile gas is added to the sterile composition and/or the sterile composition is sprayed via the nozzle system into a filler, preferably as a foam.
12. The method according to claim 10, wherein the apparatus itself is sterilized by feeding steam into the apparatus.
13. The method according to claim 10, wherein in step c) at least one compound is selected from a disinfecting agent, an acid or a base.

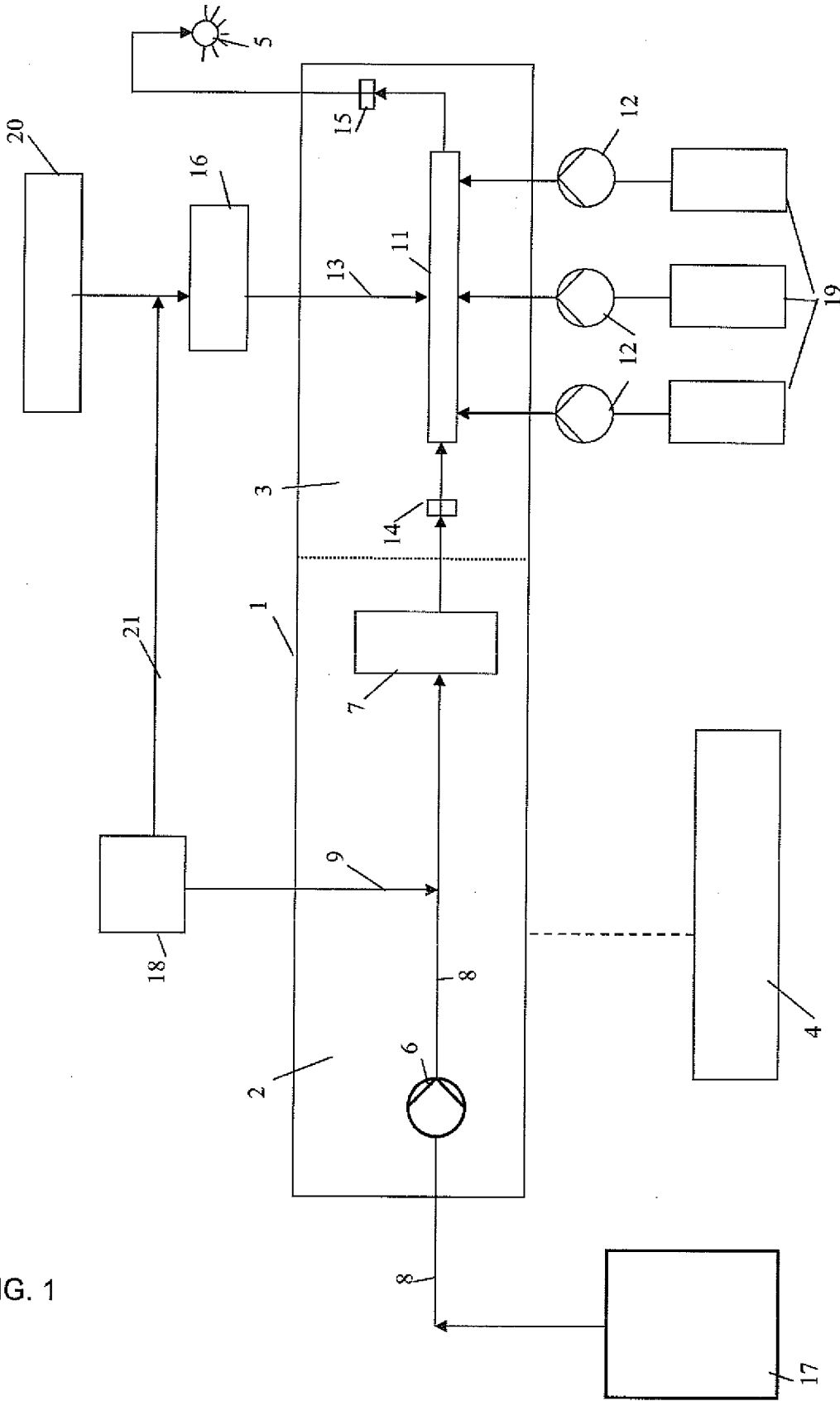


FIG. 1