Feb. 5, 1957 H. A. HICKEY 2,780,444

AGITATOR APPARATUS FOR STERILE PROCESSING

Filed Jan. 7, 1955 2 Sheets-Sheet 1

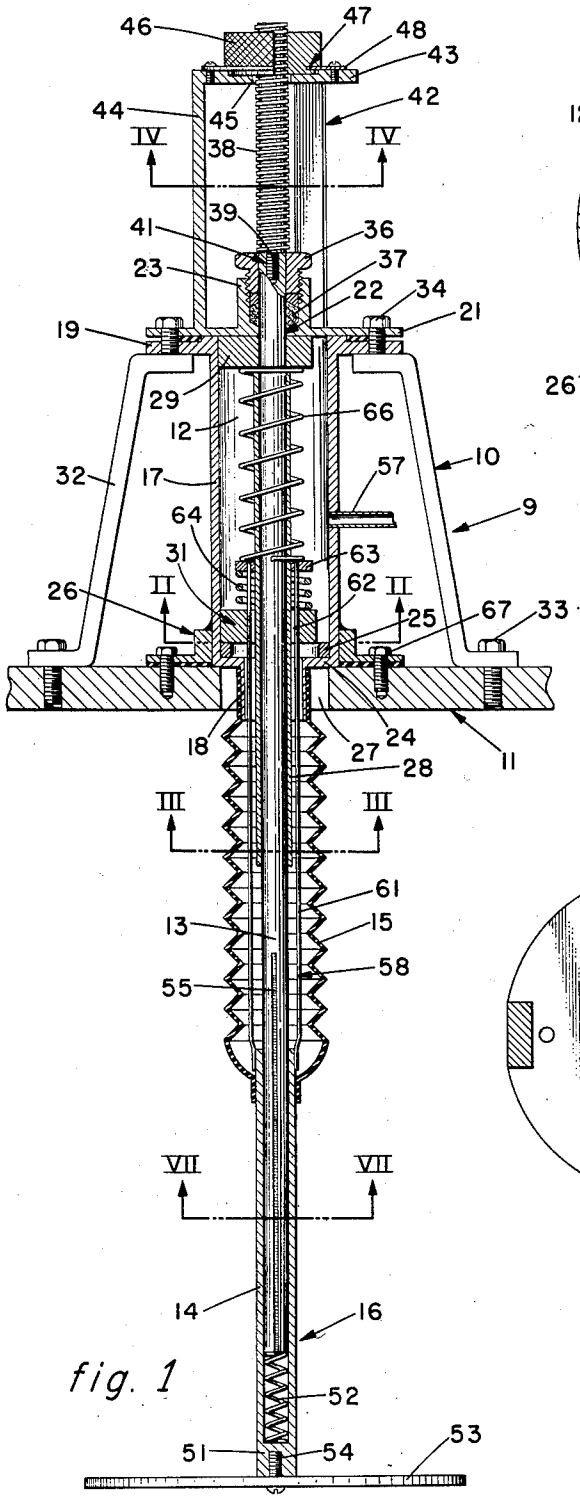


fig. 1

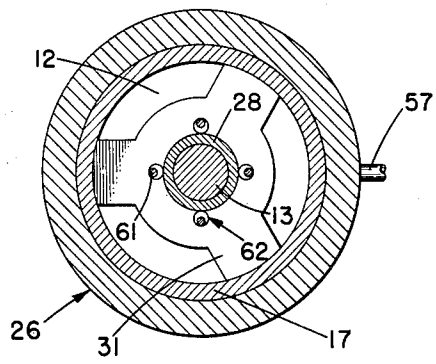


fig. 2

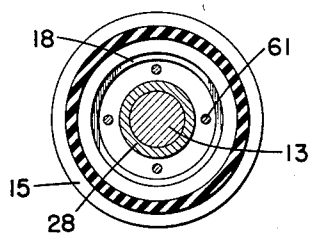


fig. 3

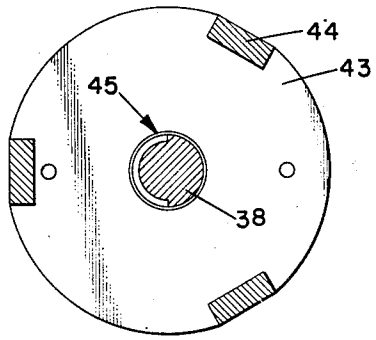


fig. 4

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Feb. 5, 1957 H. A. HICKEY 2,780,444

AGITATOR APPARATUS FOR STERILE PROCESSING

Filed Jan. 7, 1955 2 Sheets-Sheet 2

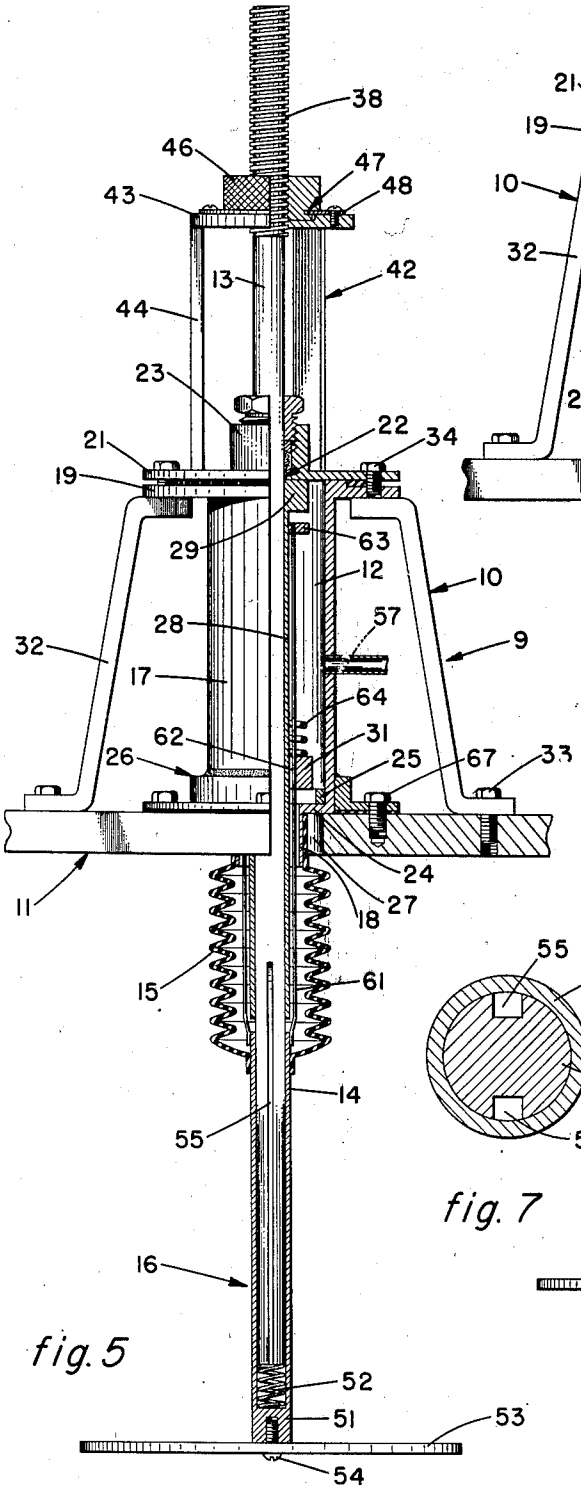


fig. 5

fig. 7

fig. 6

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AGITATOR APPARATUS FOR STERILE PROCESSING

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13 Claims. (Cl. 259—113)

This invention relates in general to an apparatus for agitating liquids, or similar materials, under completely sterile conditions, and more particularly to a type thereof having a reciprocable agitator operated by alternate applications of vacuum and atmospheric pressure to a chamber associated with said agitator.

It is well known that there are numerous instances both in experimental science and in industry where materials, such as liquids, must be agitated within a relatively small, confined space, as in a container, under completely or relatively completely sterile conditions. One example of this is found in the pharmaceutical industry where even a trace of contamination often will destroy the results or product of a costly process. In many cases, the contamination may not manifest itself until other processing has been accomplished, thereby further increasing the loss. A principal route by which contamination may enter into a container is through the hole in the container wall through which an agitating mechanism is introduced into the container.

In meeting the above problem, a first requirement for providing agitating apparatus for chemical, especially pharmaceutical, use is that the apparatus be capable of attachment to the wall of the container by means of an airtight, therefore contamination tight, seal in order to prevent entrance of contamination through this connection during use. A further requirement is that it be possible to effect simultaneous sterilization, as by means of live steam or an autoclave, of both the container and the agitating apparatus after their preassembly and prior to their use.

Thus, the structure of the agitating device must be such that the parts thereof are fabricated from materials, and in a manner, that they can be exposed to the normal type of sterilization, as by means of an autoclave, without injuring any of said parts or otherwise affecting the operation of the entire device in an unfavorable manner. Further, agitating apparatus for chemical, especially pharmaceutical, uses should also meet the additional requirement of being capable of being easily and quickly disassembled from the container with which it is used for the purpose of cleaning both the agitating apparatus and the container prior to reassembly and resterilization for subsequent use in any process or operation.

An additional requirement which should be met by agitating apparatus for chemical, especially pharmaceutical, uses, is the elimination of rotating or other pressure seals which might be used to seal the container wall opening through which the agitating apparatus is introduced into the container, since contamination within the container could occur from particles ground off such rotating or other seals.

For the same reason, any form of bearing or other support of whatever nature for the agitating mechanism inside the container, which is in contact with the contents of the container, should be eliminated since contamination could occur from particles ground off of such support.

Accordingly, a primary object of this invention has been the provision of an apparatus for agitating materials under completely sterile conditions wherein the likelihood of contaminating said process by the parts or operation of said apparatus is substantially eliminated.

A further object of this invention is the provision of an apparatus, as aforesaid, which operates completely automatically, which can be easily and quick disassembled from a container with which it is used by persons having no particular or special skills with such equipment, and wherein said apparatus, either singly or in combination with the container, can be completely sterilized, as by an autoclave, prior to use without danger of material injury to the parts or operation of said apparatus.

A further object of this invention is the provision of an apparatus, as aforesaid, wherein the agitation stroke can be preselected and/or adjusted during the operation of the apparatus to provide a wide range of agitating action, including substantially imperceptible movements for very gentle agitation.

A further object of this invention is the provision of an apparatus, as aforesaid, which is relatively simple in operation, positive in action, easily maintained and which can be satisfactorily operated by any person capable of conducting a process in which this type of apparatus is used.

Other objects and purposes of this invention will become apparent to persons familiar with this type of equipment upon reading the following specification and examining the accompanying drawings in which:

Figure 1 is a central cross-sectional view of an agitator apparatus embodying the invention and shown with the agitator in its fully extended position.

Figure 2 is a sectional view taken along the line II—II of Figure 1.

Figure 3 is a sectional view taken along the line III—III of Figure 1.

Figure 4 is a sectional view taken along the line IV—IV of Figure 1.

Figure 5 is a partially side elevation and partially central cross-sectional view of said agitator apparatus with the agitator in its fully retracted position and with the agitator adjusted for a longer stroke.

Figure 6 is a fragmentary view similar to Figure 5 showing the agitator in another position.

Figure 7 is a sectional view substantially as taken along the line VII—VII of Figure 1.

In meeting the objects and purposes set forth hereinabove, as well as others related thereto, I have provided a support structure **10** (Figure 1) which is mountable upon the wall **11** of a container (not further shown). The apparatus has a substantially air-tight chamber **12** with a pair of aligned openings at the opposite ends thereof. This chamber **12** is affixed to the container wall **11** in a substantially air-tight, and therefore contamination-tight, closure by means of a flange **26** welded to, or otherwise in tight connection with, the chamber **12** and attached to the container wall **11** by means of the bolts **67**. An adjustment rod **13** is axially adjustably mounted upon the structure **10** and extends through the openings at the opposite ends of said chamber **12**. Said rod then extends through a further aligned opening in the wall **11** of said container to extend down within said container. An gitator sleeve **14** is slidably supported upon the lower end of said rod **13** and is secured near its upper end to one end of a bellows **15** the upper end of which is secured to and communicates with the chamber **12**. Thus, evacuation of the chamber **12** effects a collapse of the bellows **15** thereby drawing the sleeve **14** upwardly to the extent permitted by the rod **13**. It will be recognized that the agitator apparatus **9** is here shown as disposed for vertical reciprocation of the agitator **16**. However, this is for illustrative purposes

only and is not intended to limit the use of the invention to vertical installations.

For purposes of convenience in description, the terms "upper," "lower" and derivatives thereof will have reference to the apparatus and parts thereof as appearing in Figures 1, 5 and 6. The terms "inner," "outer" and derivatives thereof will have reference to the axis of reciprocation of the agitator apparatus.

Construction

The support structure **10** of the agitator apparatus **9** (Figures 1, 5 and 6) is, in this particular embodiment, comprised of an axially vertical cylinder **17** having a nipple **18** at its lower end and a radially outwardly extending annular flange **19** at its upper end. A circular cap member **21** having a central opening **22** is preferably of substantially the same diameter as said annular flange **19** and is disposed above and adjacent thereto. A packing collar **23** is preferably integral with and extends upwardly from the circular cap **21** co-axially with and spaced radially outwardly from the central opennig **22** in said cap **21**. The collar **23** is co-axial with the nipple **18** and is preferably, but not necessarily, co-axial with the cylinder **17**. An annular wall **24** is secured to and extends between the lower end of the cylinder **17** and the nipple **18** thereof, and is engaged upon its upper surface, hence within the chamber **12**, by a spacer ring **25**. The lower surface of said annular wall **24** preferably, but not necessarily, bears against the external surface of the upper wall **11** of the container and adjacent to an opening **27** therein. Thus, the nipple **18** extends downwardly through the cover opening **27** as shown in Figures 1, 5 and 6.

The cover opening **27** is sealed in a substantially air-tight and therefore contamination tight, seal by the flange **26**, preferably accompanied by a suitable gasket, and the bolts **67**.

An elongated bearing sleeve **28** is co-axially positioned within the cylinder **17** and extends downwardly through, but is spaced radially inwardly from both the spacer ring **25** and the nipple **18**, and it extends therebelow a distance discussed in greater detail hereinafter. Said bearing sleeve **28** is positioned within the cylinder **17** by means of a pair of substantially identical spiders **29** and **31** (Figures 1 and 2). The upper spider **29** is adjacent to the circular cap **21** and is secured, as by welding or brazing, to the upper end of the bearing sleeve **28**. The lower spider **31** is secured, in a similar manner, to said bearing sleeve **28** between the upper and lower ends thereof and adjacent to the spacer ring **25**. Thus, the spiders **29** and **31** bearing against the circular cap **21** and spacer ring **25**, respectively, prevent axial movement of the bearing sleeve **28** with respect to the cylinder **17**. As shown in Figure 1, the upper spider **29** has a central opening therethrough which is co-axial with, and of substantially the same diameter as, the internal diameter of the bearing sleeve **28**. A central opening in the lower spider **31** snugly embraces the external surfaces of said bearing sleeve **28**.

A plurality of support legs **32** (Figures 1 and 2) extend downwardly from the annular flange **19** to the wall **11** where they are secured thereto by any convenient means, such as the bolts **33**. The upper ends of said legs **32** may be secured to the annular flange **19** by the same bolts **34** as secure the cap **21** upon the annular flange **19**.

An adjustment rod **13** extends through the packing collar **23**, the central opening **22** in the cap **21**, the upper spider **29** and through the bearing sleeve **28** and extends downwardly below the lower end of said bearing sleeve **28**. A packing gland **36** slidably but snugly embraces the upper end of the adjustment rod **13** above the circular cap **21** and threadedly engages the packing collar **23** in a conventional manner to compress an annular sealing element **37** against the rod **13**. A screw **38** extends upwardly from and co-axially with the rod **13** and is secured thereto by any convenient means, such as by a threaded stem **39** at the lower axial end of said screw **38** which is threadedly received into an internally threaded recess **41** in the upper end of the rod **13**. The same purposes may be accomplished by providing an external screw thread upon the upper end of the rod **13**.

An adjustment bracket **42** having a mounting plate **43** and a plurality of legs **44** (Figures 1 and 4) extending downwardly therefrom is supported upon the circular cap **21**. In this particular embodiment, the lower ends of the legs **44** may be integral with or welding to said circular cap **21**. The mounting plate **43** is provided with a central opening **45** through which the screw **38** is slidably and rotatably received. An externally knurled nut **46** is threadedly engaged with the screw **38** on the upper side of the mounting plate **43**. Said nut **46** is provided with an annular groove **47** into which a retaining ring **48** is slidably received and secured to the mounting plate **43** to prevent axial movement of the nut **46** upwardly from the mounting plate **43**. Accordingly, rotation of the nut **46** effects an axial movement of the screw **38**, hence the adjustment rod **13**, upwardly or downwardly depending upon the direction of said rotation. Thus, the amount by which the adjustment rod extends below and beyond the lower end of the bearing sleeve **28** is controlled by the screw **38** and the nut **46**.

An agitator sleeve **14** having a closed lower end wall **51** is slidably and snugly mounted upon the lower end of the adjustment rod **13**, for movement toward and away from the bearing sleeve **28**. A resilient device, such as the coiled spring **52** is within the sleeve **14** between said lower end wall **51** and the lower end of the rod **13** for reasons appearing hereinafter. The length of the sleeve **14**, the amount by which the bearing sleeve **28** extends downwardly along the rod **13**, and the adjustment of the screw **38** are such that contact between said sleeve **14** and said bearing sleeve **28** may be, and normally is, positively prevented. An agitator element **53** is secured by any convenient means, such as the bolt **54**, to the lower end of the agitator sleeve **14**.

A substantially cylindrical bellows **15** (Figures 1 and 3) surrounds and is spaced radially outwardly from the rod **13** between the cylinder **17** and the agitator sleeve **14**. Said bellows is preferably, but not necessarily, of a resilient material, as rubber. The upper end of said bellows **15** is tightly secured upon the nipple **18** and the lower end of said bellows is secured to the upper end of the agitator sleeve **14**. The bellows **15** is of such length that it will permit the agitator sleeve **14** to move from a position as shown in Figure 6, where the coiled spring **52** is not under compression and the sleeve **14** is fully extended, to a position (Figure 5) where the sleeve **14** is fully retracted. A pair of longitudinal grooves **55** and **56** (Figures 1, 5 and 7) are provided in the outer surface of the rod **13** at the lower end thereof. These grooves extend upwardly beyond the upper edge of the sleeve **14** in all positions thereof and permit air to pass from within the bellows **15** freely down into the space in the sleeve **14** occupied by the coiled spring **52**.

Thus, an air tight confined space is provided by and within the cylinder **17**, the bellows **15** and the portion of the agitator sleeve **14** which is not occupied by the adjustment rod **13**. Accordingly, as it will be seen in more detail later on, evacuation of the cylinder **17**, by means not shown, operating through the pipe **57** will effect a collapse of the bellows **15** from its Figure 1 or Figure 6 position into its Figure 5 position, thereby raising the agitator **16**.

A guide mechanism **58** (Figures 1, 2 and 3) for preventing movement downwardly of the agitator sleeve **14** beyond the limits of the bellows **15** is provided by a plurality of rods **61** which are secured at their lower ends, as by welding, to the upper end of the sleeve **14** inside of the bellows **15**. Said rods **61** extend upwardly in substantially parallel relationship in the space provided between said bellows **15** and the bearing sleeve **28** through

the nipple portion 18 of the cylinder 17 and through an equal number of properly arranged rod openings 62 (Figure 2) in the lower spider 31. The upper ends of said rods 61 are secured, as by welding, to an end plate 63 (Figure 1) having a central opening slidably encircling the bearing sleeve 28. Resilient means, such as the coil spring 64, encircles the bearing sleeve 28 and the rods 61 between the lower spider 31 and the end plate 63. The rods 61 are of such length that they will stop the sleeve 14 and begin to compress the spring 64 prior to the extension of the bellows 15 beyond safe limits.

A spring 66 may be positioned if desired between the upper spider 29 and the end plate 63 to provide further urging of the agitator sleeve 14 away from the chamber 17.

Operation

The agitator apparatus 9 is normally adjusted as desired prior to operation thereof by turning the nut 46 to effect the proper positioning of the adjustment rod 13 which in turn determines the stroke of the agitator 16. However, it will be seen that such adjustment can be altered without difficulty during the operation of the apparatus. Also, such adjustment can be accomplished either while the apparatus is mounted, as shown in Figure 1, upon the upper wall 11 of a suitable container or when said apparatus is disengaged therefrom.

Having made such adjustments, the pipe 57 is then connected to suitable means, not shown, for alternately applying vacuum to the cylinder 17, hence to the bellows 15 and the inside of the agitator sleeve 14, and readmitting air thereinto. Each such application of vacuum effects a collapse of the bellows 15 from its Figure 6 position to its Figure 5 position with a resultant upwardly movement of the agitator 16. It will be understood that, with the adjustment rod 13 in its lowered position (Figure 1), the resultant movement of the agitator 16 will be a very slight movement in this instance. For larger strokes the adjustment rod 13 is moved upwardly by the nut 46 and screw 38 as set forth hereinabove. In all cases the spring 52 cushions the shock at the end of the upward stroke of the sleeve 14.

Upon the release of the vacuum from the pipe 57 and the readmission of air therethrough, the agitator sleeve will move downwardly, partially by its own weight and, where the bellows 15 is of a resilient material, partially in response to their resiliency. The spring 64 cushions the shock at the end of the downward stroke.

Thus, alternate application of vacuum and air to the pipe 57 will effect upward and downward movement of the agitator 16 through a distance selected by adjustment of the nut 46.

Since only the external surfaces of the bellows 15 and the agitator 16 are exposed to the interior of the container 11, there is no chance for contamination of the contents of said container 11 by any lubricants required for effecting smooth reciprocation of the agitator sleeve 14 upon the rod 13.

By disconnecting the bolts 33 from the container wall 11, disconnecting the sealing flange 26 from the container wall 11 by removing the bolts 67 and disconnecting the agitator element 53 from the agitator sleeve 14 the entire agitator apparatus 9 can be disconnected from the wall 11 and placed in a suitable sterilizing device, such as an autoclave, without damaging any of the operating parts of said apparatus. Alternatively, the pipe 57 can be disconnected from its source of vacuum and the entire wall 11 and agitator apparatus 9 secured thereto may be placed in a sterilizing unit as a single item with the same satisfactory results.

Although I have disclosed a particular preferred embodiment of my invention for illustrative purposes, it will be understood that modifications or variations thereof which lie within the scope of the invention are fully contemplated unless specifically stated to the contrary in the appended claims.

I claim:

1. Drive mechanism for a reciprocable agitator, said agitator being within a container, the combination comprising: structure defining a chamber; a rod extending through and at each end beyond said chamber and in substantially air-tight relationship therewith at a first end thereof and in air-pervious relationship at a second end thereof; an agitator sleeve slidably sleeved upon the one end of said rod extending beyond said second end of said chamber, said sleeve being spaced from said chamber and closed at its outer end; a bellows encircling said rod and providing a connection and an air-tight communication between said sleeve and said chamber, application of diminished pressure to said chamber effecting axial movement of said sleeve toward said chamber and increase in pressure within said chamber causing said sleeve to move away from said chamber; stop means limiting movement of said sleeve away from said chamber, said rod limiting movement of said sleeve toward said chamber; and means on said sleeve for receiving an agitator thereon; whereby the entire agitator mechanism is free from sliding or rotating contact with any portion of the container; the entire agitator mechanism being entirely free from any support whatever by the interior of the container.

2. Drive mechanism for a reciprocable agitator comprising: structure defining a chamber; means for mounting said chamber in air-tight relationship to the wall of a container; a rod extending through and at each end beyond said chamber and in substantially air-tight relationship therewith at a first end thereof and in air-pervious relationship at a second end thereof; an agitator sleeve slidably sleeved upon the one end of said rod extending beyond said second end of said chamber, said sleeve being spaced from said chamber and closed at its outer end; a bellows encircling said rod and providing a connection and an air-tight communication between said sleeve and said chamber, application of diminished pressure to said chamber effecting axial movement of said sleeve toward said chamber and increase in pressure within said chamber causing said sleeve to move away from said chamber; stop means limiting movement of said sleeve away from said chamber, said rod limiting movement of said sleeve toward said chamber; and means on said sleeve for receiving an agitator thereon; whereby the entire agitator mechanism is free from sliding or rotating contact with any portion of the container and the entire agitator mechanism is free from any support whatever by the interior of the container.

3. Drive mechanism for a reciprocable agitator having an adjustable stroke, comprising: structure defining a chamber; means for mounting said chamber in air-tight relationship to the wall of a container; a rod extending through and at each end beyond said chamber and being in axially slidable relationship therewith, and in substantially air-tight relationship therewith at a first end thereof and in air-pervious relationship at a second end thereof; an agitator sleeve co-axially and slidably sleeved upon the one end of said rod extending beyond said second end of said chamber, said sleeve being spaced from said chamber and closed at its outer end; a bellows encircling said rod and providing a connection and air-tight communication between said sleeve and said chamber, application of vacuum to said chamber effecting a collapse of said bellows and axial movement of said sleeve toward said chamber and readmission of air to said chamber permitting said sleeve to move away from said chamber; stop means limiting movement of said sleeve away from said chamber, said rod limiting movement of said sleeve toward said chamber; means for axially adjusting said rod with respect to said chamber; and means on said sleeve for receiving an agitator thereon.

4. The device of claim 1 including resilient means positively and continuously urging said sleeve in a direction away from said chamber.

5. Drive mechanism for a reciprocable agitator having an adjustable stroke, comprising: structure defining a substantially air-tight chamber having a pair of aligned openings in the opposite ends thereof; means for mounting said chamber in air-tight relationship to the wall of a container; a rod extending through said openings and substantially beyond said opposite ends of said chamber; means slidably supporting said rod for axial movement and against radial movement; a co-axial tube axially slidably embracing one end of said rod, said tube being closed at the outer end thereof; a bellows encircling said rod and providing a connection and air-tight communication between the adjacent ends of said tube and said chamber, evacuation of said chamber effecting a collapse of said bellows and axial movement of said tube toward said chamber; stop means limiting the movement of said tube away from said chamber, said rod limiting the movement of said tube toward said chamber; seal means between said rod and the other end of said chamber; and means on said tube for securing an agitator thereto.

6. The device defined in claim 1 including a bracket extending from said structure beyond the first end of said chamber, and screw means affixed to said end of said rod extending beyond the first end of said chamber, said screw means threadedly engaging said bracket for axial adjustment of said rod.

7. The device defined in claim 1 including also resilient means located between said one end of said rod and the closed end of said sleeve for cushioning the upward stroke of said sleeve.

8. The device defined in claim 1 including a limit rod, having its first end connected to said sleeve and its second end positioned intermediate the ends of said chamber, a stop arranged at the second end of limit rod and resilient means engaging said stop and resiliently resisting movement of said stop in a direction corresponding to the extension of said bellows, whereby to cushion the downward stroke of said sleeve.

9. The device defined in claim 1 including a limit rod reciprocable in a direction parallel with said first above-mentioned rod, means affixing one end of said limit rod to said sleeve and means engageable with the other end of said limit rod for resiliently resisting movement of said limit rod in a direction corresponding to the extension of said bellows, whereby to cushion downward movement of said sleeve.

10. Drive mechanism for a reciprocable agitator comprising: structure defining a chamber; said chamber having an opening at one end thereof; means for mounting said chamber in air-tight relationship to the wall of a container; a rod partially within said chamber and extending through said opening; an agitator sleeve slidably sleeved upon that end of said rod extending out of said chamber, said sleeve being spaced from said chamber and closed at a point beyond the end of said rod, a bellows encircling said rod and providing a connection and an air-tight communication between said sleeve and said chamber, whereby application of vacuum to said chamber will effect axial movement of said sleeve toward said chamber and readmission of air to said chamber will permit said sleeve to move away from said chamber.

11. Drive mechanism for a reciprocable agitator comprising: structure defining a chamber; a rod in said chamber, said rod having a portion thereof extending beyond an end of said chamber, said portion of said rod being in air-pervious relationship with respect to said end; an agitator sleeve slidably sleeved upon said portion of said rod, said sleeve being movable with respect to said chamber; a bellows encircling said rod and providing a connection and an air-tight communication between said sleeve and said chamber; application of diminished pressure to said chamber effecting axial movement of said sleeve toward said chamber and increase in pressure within said chamber causing said sleeve to move away from said chamber; and means on said sleeve for receiving an agitator thereon.

12. In a drive mechanism for a reciprocable agitator, said agitator being within a container, the combination comprising: structure defining a chamber; means for mounting said chamber in air-tight relationship to the wall of said container; a rod in said chamber, said rod having a portion thereof extending beyond an end of said chamber and into said container, said portion of said rod being in air-pervious relationship with respect to said end; an agitator sleeve slidably sleeved upon said portion of said rod, said sleeve being movable with respect to said chamber; expansible means responsive to fluid pressure, said expansible means encircling said rod and providing a connection and an air-tight communication between said sleeve and said chamber; means for applying fluid pressure to said chamber; stop means for limiting movement of said sleeve toward and away from said chamber; and means on said sleeve for receiving an agitator thereon.

13. In a drive mechanism for a reciprocable agitator, said agitator being within a container, the combination including: structure defining a chamber; means for mounting said chamber in air-tight relationship to the wall of said container; a rod, means for mounting said rod on said wall, said rod having a portion thereof extending through said wall into said container; an agitator sleeve slidably sleeved upon said portion of said rod; expansible means responsive to fluid pressure connected to said sleeve and to said chamber and providing an air-tight communication between said sleeve and said chamber, application of diminished pressure to said chamber effecting axial movement of said sleeve toward said chamber and increase in pressure within said chamber causing said sleeve to move away from said chamber; stop means for limiting movement of said sleeve toward and away from said chamber; and means on said sleeve for receiving an agitator thereon.

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