

Claims

- 5 1. A time-pressure-filling system (110) for filling at least one liquid drug product into containers (111), comprising:
- A. at least one storage vessel (112) for storing the liquid drug product;
 - B. at least one surge vessel (114), wherein the surge vessel (114) is configured for
10 single use, wherein the surge vessel (114) is at least partially made of at least one rigid plastic material;
 - C. at least one supply line (116) for feeding the liquid drug product from the storage vessel (112) into the surge vessel (114) in a pressurized fashion;
 - D. at least one pressure control line (118) for applying a control pressure to the surge vessel (114);
 - 15 E. at least one dispenser (120) for dispensing the liquid drug product into the containers (111);
 - F. at least one dispensing line (122) connecting the surge vessel (114) to the dispenser (120);
 - G. at least one pressure sensor (124) for determining a pressure in the dispensing
20 line (122); and
 - H. at least one valve (126) for controlling a flow of the liquid drug product through the dispensing line(122).
- 25 2. The time-pressure-filling system according to the preceding claim, wherein the time-pressure-filling system (110) comprises at least one manifold (134), wherein the manifold (134) provides one inlet port (156) and a plurality of outlet ports (158), wherein the plurality of outlet ports (158) of the manifold (134) have a smaller diameter than the inlet port (156).
- 30 3. The time-pressure-filling system (110) according to any one of the preceding claims, wherein the time-pressure-filling system (110) comprises at least one sterile filter (130).

4. The time-pressure-filling system (110) according to any one of the preceding claims, wherein the components of the time-pressure-filling system (110) are connectable via couplings.
5. The time-pressure-filling system (110) according to any one of the preceding claims, wherein the time-pressure-filling system (110) is surrounded by at least one isolator (128), wherein the isolator (128) provides a sterile surrounding for the time-pressure-filling system (110).
6. The time-pressure-filling system (110) according to any one of the preceding claims, wherein the time-pressure-filling system (110) further comprises at least one control unit (123), wherein the control unit (123) specifically is configured for at least one of: controlling a filling level of the surge vessel (114); controlling the control pressure applied to the surge vessel (114); controlling an opening time of the valve (126).
7. A surge vessel (114) for use in a time-pressure-filling system (110) according to any one of the preceding claims, wherein the surge vessel (114) is configured for single use, wherein the surge vessel (114) is at least partially made of at least one rigid plastic material, the surge vessel (114) comprising:
- a. a rigid cylindrical vessel sidewall (138);
 - b. a rigid vessel bottom plate (140);
 - c. a rigid vessel top plate (142);
 - d. at least one supply pipe (144) penetrating the rigid vessel bottom plate (140), wherein the supply pipe (144) has at least one portion (146) protruding into an interior space (148) of the surge vessel (114) and wherein the supply pipe (144) further has at least one inlet connecting branch (150) protruding from the rigid vessel bottom plate (140) outside the interior space (148) for connecting a supply line (116) to the supply pipe (144);
 - e. at least one outlet connecting branch (152) protruding from the rigid vessel bottom plate (140) outside the interior space (148) for connecting at least one dispensing line (122); and
 - f. at least one pressure control branch (154) protruding from the rigid vessel top plate (142) outside the interior space (148) for connecting at least one pressure control line (118).

8. The surge vessel (114) according to the preceding claim, wherein the at least one rigid plastic material comprises at least one material selected from the group consisting of: polypropylene; polyethylene; polycarbonate.
- 5 9. The surge vessel (114) according to any one of the preceding claims referring to a surge vessel (114), wherein the rigid plastic material is at least partially transparent.
- 10 10. The surge vessel (114) according to the preceding claim, wherein the surge vessel (114) comprises at least one optical sensor (117), wherein the at least one optical sensor (117) is disposed outside the interior space (148), and wherein the optical sensor (117) specifically is sensitive in at least one of the visible and the infrared spectral range.
- 15 11. The surge vessel (114) according to the preceding claim, wherein the at least one optical sensor (117) is configured for detecting a filling level of the surge vessel (114).
- 20 12. A time-pressure-filling method for filling at least one liquid drug product into containers (111), comprising:
- 25 i. providing the time-pressure-filling system (110) according to any one of the preceding claims referring to a time-pressure-filling system (110);
- iii. feeding the liquid drug product from the storage vessel (112) into the surge vessel (114) in a pressurized fashion;
- 25 iii. controlling the pressure in the surge vessel (114) by applying a control pressure to the surge vessel (114);
- iv. determining the pressure in the dispensing line (122) by using the pressure sensor (124); and
- v. dispensing predetermined amounts of the liquid drug product into the containers (111) by controlling an opening time of the valve (126).
- 30 13. The method according to the preceding claim, wherein a batch of the liquid drug product is defined by a predetermined amount of the liquid drug product, wherein the method comprises exchanging the surge vessel (114) after filling the batch of the liquid drug product into the containers (111) and disposing of the surge vessel (114).
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14. The method according to the preceding claim, wherein the time-pressure-filling system (110) comprises a plurality of the surge vessels (114), wherein the surge vessels (114) are used subsequently one after the other for different batches, wherein used surge vessels (114) are disposed of.
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15. A use of at least one of the time-pressure-filling system (110) according to any one of the preceding claims referring to a time-pressure-filling system (110) and the surge vessel (114) according to any one of the preceding claims referring to a surge vessel (114), for filling at least one of the following liquid drug product into containers (111): a pharmaceutical product; a steroid product; a liquid drug product for subcutaneous application; a liquid drug product for intravenous application; a high-potent liquid drug product; an aqueous protein solution.
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