Claims

1. An apparatus for converting a liquid feedstock comprising a target substance and impurities into a product stream containing purified target substance and one or more waste stream comprising at least some of the impurities, the apparatus comprising at least two processing units arranged in series such that the feed stream of the second and any subsequent units comprises the product stream from an upstream unit, wherein each processing unit comprises the following components (i) to (vi):
   (i) an inlet (1) for the liquid feedstock;
   (ii) a multiple inlet flow-controller (4) comprising two or more variable flow inlet valves (4a) for providing at least two liquids in a desired ratio;
   (iii) a mixing means (8);
   (iv) a device (12) for performing a processing operation which separates at least some of the impurities from the target substance;
   (v) a means (6) for imparting the flow of liquids through the unit; and
   (vi) a switchable bypass assembly (31) for causing liquids passing through the unit to either flow into the mixing means (8) or bypass the mixing means (8).

2. An apparatus according to claim 1 wherein the means (6) for imparting the flow of liquids through the unit is located downstream of the multiple inlet flow-controller (4) and upstream of the mixing means (8).

3. An apparatus according to any one of the preceding claims wherein each unit comprises only one means (6) for imparting the flow of liquids through that unit.

4. An apparatus according to any one of the preceding claims wherein the switchable bypass assembly (31) comprises tubing and two or three valves which direct the flow of the liquid feedstock and/or the at least two other liquids either to the mixer means (8), or to the device (12) without passing through the mixer means (8).

5. An apparatus according to any one of the preceding claims wherein each unit comprises a flowpath assembly in which provides for:
   (a) the liquid feedstock to flow into the unit through inlet (1);

(b) the at least two liquids to flow through multiple inlet flow-controller (4);

(c) the liquid feedstock and the at least two liquids be either mixed in the mixer means (8) or to bypass mixer means (8), in either case to enter device (12) where a processing operation is performed which separates at least some of the impurities from the target substance to give a product stream and optionally a waste stream; and

(d) a path for the product stream, and waste stream when present, to exit the unit.

6. An apparatus according to any one of the preceding claims which comprises at least one unit comprising components (i) to (vi) for performing chromatography.

7. An apparatus according to any one of the preceding claims which comprises at least one unit comprising components (i) to (vi) for performing viral inactivation.

8. An apparatus according to any one of the preceding claims which comprises at least one unit comprising components (i) to (vi) for removing any viruses from its liquid feedstock.

9. An apparatus according to any one of the preceding claims which comprises at least two units comprising components (i) to (vi) for performing chromatography.

10. An apparatus according to claim 9 wherein the chromatographic purifications performed in each of the at least two of the units for performing the processing operation of chromatography unit use different conditions and/or chromatography columns packed with different resins to the chromatography columns to those used in the other of said units.

11. An apparatus according to any one of the preceding claims which comprises at least one unit comprising components (i) to (vi) for performing affinity chromatography, cation exchange chromatography, anion exchange chromatography, mixed-mode chromatography, hydrophobic interaction chromatography, reverse-phase chromatography, expanded bed chromatography, mixed-mode chromatography, membrane chromatography or size exclusion chromatography.

12. An apparatus according to any one of the preceding claims wherein each unit comprises a means for preparing a mixed bioprocessing liquid.

13. An apparatus according to any one of the preceding claims wherein each unit comprises a single pump (6) for imparting the flow of liquids through that unit.

14. An apparatus according to any one of the preceding claims which comprises at least one unit comprising components (i) to (vi) for performing diafiltration of its product stream in order to buffer the target material at a pH at which the target material is stable.

15. An apparatus according to any one of the preceding claims which comprises the following units arranged in series, preferably in the order listed, each unit comprising the components (i) to (vi) and with the product feed of each unit except for the final unit being used as the feedstock for the next unit:
    a. a unit for performing chromatographic purification of the target substance, preferably by affinity chromatography; and
    b. a unit for inactivation of any viruses which may be present in the liquid feedstock.

16. An apparatus according to any one of the preceding claims which comprises the following units arranged in series, preferably in the order listed, each unit comprising the components (i) to (vi) and with the product feed of each unit except for the final unit being used as the feedstock for the next unit:
    a. a unit for performing chromatographic purification of the target substance, preferably by affinity chromatography;
    b. a unit for inactivation of any viruses which may be present in the liquid feedstock; and
    c. a unit for performing chromatographic purification of the target substance by cation exchange chromatography.

17. An apparatus according to any one of the preceding claims which comprises the following units arranged in series, preferably in the order listed, each unit comprising the components (i) to (vi) and with the product feed of each unit except for the final unit being used as the feedstock for the next unit:

a. a unit for performing chromatographic purification of the target substance, preferably by affinity chromatography;
b. a unit for inactivation of any viruses which may be present in the liquid feedstock;
c. a unit for performing chromatographic purification of the target substance by cation exchange chromatography; and
d. a unit for performing chromatographic purification of the target substance by anion exchange chromatography.

18. An apparatus according to any one of the preceding claims which comprises the following units arranged in series, preferably in the order listed, each unit comprising the components (i) to (vi) and with the product feed of each unit except for the final unit being used as the feedstock for the next unit:
    a. a unit for performing chromatographic purification of the target substance, preferably by affinity chromatography;
    b. a unit for inactivation of any viruses which may be present in the liquid feedstock;
    c. a unit for performing chromatographic purification of the target substance by cation exchange chromatography;
    d. a unit for performing chromatographic purification of the target substance by anion exchange chromatography; and
    e. a unit for removal of any inactivated viruses.

19. An apparatus according to any one of the preceding claims which comprises the following units arranged in series, preferably in the order listed, each unit comprising the components (i) to (v) and with the product feed of each unit except for the final unit being used as the feedstock for the next unit:
    a. a unit for performing chromatographic purification of the target substance, preferably by affinity chromatography;
    b. a unit for inactivation of any viruses which may be present in the liquid feedstock;
    c. a unit for performing chromatographic purification of the target substance by cation exchange chromatography;
    d. a unit for performing chromatographic purification of the target substance by anion exchange chromatography;

e. a unit for removal of any inactivated viruses: and
f. a unit for concentrating and/or performing buffer exchange of the product stream from the preceding unit.

20. An apparatus according to any one of the preceding claims wherein:
(A) each unit comprises a flowpath assembly; and
(B) the flowpath assembly used in at least half of the units (preferably all of the units) have substantially the same configuration.

21. An apparatus according to claim 20 wherein the flowpath assembly is constructed from a plastics material.

22. An apparatus according to any one of the preceding claims wherein at least 75% of the component parts of each unit other than the device (12) are identical to the component parts used in at least 80% of the other units of the apparatus.

23. An apparatus according to any one of the preceding claims wherein all of the component parts of each unit except for the device (12) are identical to the all of the component parts used in all of the other units of the apparatus

24. An apparatus according to any one of the preceding claims wherein the flowpath assembly through each unit is substantially identical to the flowpath assembly through all of the other units.

25. A flowpath assembly comprising the following components (i) to (vi):
(i) an inlet (1) for a liquid feedstock;
(ii) a multiple inlet flow-controller (4) comprising two or more variable flow inlet valves (4a) for providing at least two liquids in a desired ratio;
(iii) a mixing means (8);
(iv) an outlet for feeding liquid to a device (12) for performing a processing operation and an inlet for receiving liquid from the device (12);
(v) a means (6) for imparting the flow of liquids through the flowpath assembly; and
(vi) a switchable bypass assembly (31) for causing liquids to either flow into the mixing means (8) or to bypass the mixing means (8).

26. The flowpath assembly according to claim 25 wherein component (v) is upstream of component (iii) and downstream of component (ii).

27. The flowpath assembly according to claim 25 or 26 wherein component (iii) is downstream of component (ii).

28. The flowpath assembly according to any one of claims 25 to 27, which further comprises one or more blocks for receiving a conductivity meter, pH meter and/or a pressure sensor.

29. The flowpath assembly according to claim 28, wherein at least one of the one or more blocks is located downstream of the means (6) and upstream of the mixing means (8).

30. The flowpath assembly according to claim 28 or 29, wherein the at least one of the one or more blocks is located downstream of the device (12).

31. The flowpath assembly according to any one of claims 28 to 30, wherein at least one of the one or more blocks is located downstream of the device (12) and is adapted to receive a conductivity meter, pH meter and a pressure sensor.

32. The flowpath assembly according to any one of claims 25 to 31, which is constructed of a plastics material.

33. The flowpath assembly according to any one of claims 25 to 32, which is constructed of material which permits sterilisation by gamma radiation.

34. The flowpath assembly according to any one of claims 25 to 31, which is constructed of stainless steel.

35. The flowpath assembly according to any one of claims 25 to 34, which is sterile.

36. An apparatus according to any one of claims 1 to 24, which comprises a flowpath assembly according to any one of claims 25 to 35.

37. A unit for converting a liquid feedstock comprising a target substance and impurities into a product stream containing purified target substance and one or more waste stream comprising at least some of the impurities, the unit comprising the following components (i) to (vi):
    (i) an inlet (1) for the liquid feedstock;
    (ii) a multiple inlet flow-controller (4) comprising two or more variable flow inlet valves (4a) for providing at least two liquids in a desired ratio;
    (iii) a mixing means (8);
    (iv) a device (12) for performing a processing operation which separates at least some of the impurities from the target substance;
    (v) a means (6) for imparting the flow of liquids through the unit; and
    (vi) a switchable bypass assembly (31) for causing liquids passing through the unit to either flow into the mixing means (8) or bypass the mixing means (8).

38. The unit according to claim 37 wherein component (v) is upstream of component (iii) and downstream of component (ii).

39. The unit according to claim 37 or 38 wherein component (iii) is downstream of component (ii).

40. The unit according to any one of claims 37 to 39 which comprises only one means (6) for imparting the flow of liquids through the unit.