energies, since the energy necessary for sterilisation will be applied to each portion according to the characteristics of said portion, specifically its thickness.

The invention will be explained below with reference to the figures, in which:

Fig. 1 is a perspective view of an empty flexible bag suitable for containing human plasma proteins.
Fig. 2 is a view from above of the sterilisation zone of one embodiment of the electron beam sterilisation device according to the present invention.
Fig. 3 is a view from above of the sterilisation zone of another embodiment of the electron beam sterilisation device according to the present invention.

An example of the flexible bags to be sterilised using the sterilisation device of the present invention is shown in Fig. 1. Said bags can have a volume of 50 mL to 500 mL. Fig. 1 shows an empty bag -2- that contains a port/cap structure. The walls -1- of said bag can be approximately 130 µm thick, the tube of the outlet port -4- of the bag can be approximately 1.24 mm thick, whilst the twist-off cap -3- can have a thickness of approximately 3 mm.

In a first aspect, the present invention relates to a device for sterilising flexible bags, the device comprising a sterilisation zone formed by at least two electron accelerators configured to emit electron beams at different energies from one another; at least one accelerator configured to emit an electron beam at an energy of between 450-500 keV and at least one other accelerator configured to emit an electron beam at an energy of 700-750 keV.

In a first embodiment, said sterilisation device comprises at least one accelerator that emits an electron beam at an energy of between 400-500 keV and at least one other accelerator that emits an electron beam at an energy of 1-2 MeV. Preferably, said sterilisation device has one accelerator that emits an electron beam at an energy of between 400-500 keV and another accelerator that emits an electron beam at an energy of 1-2 MeV.

Fig. 2 is a view from above of the sterilisation zone of one embodiment of the sterilisation device according to the present invention. Said sterilisation zone is formed by a lower-energy electron beam accelerator or emitter -5- (400-500 keV), a higher-energy electron beam accelerator or emitter -6- (1-2 MeV) and a zone -7- in which the flexible bags to be sterilised are placed. In this embodiment, the two accelerators are positioned on opposite sides of the bags in a position facing each other.

Fig. 3 is a view from above of the sterilisation zone of another embodiment of the sterilisation device according to the present invention. Said sterilisation zone is formed by a lower-energy electron beam accelerator or emitter -5- (400-500 keV), a higher-energy electron beam accelerator or emitter -6- (1-2 MeV) and a zone -7- in which the flexible bags to be sterilised are placed. In this embodiment, the two accelerators are positioned on opposite sides of the bags in a position in which they do not face each other.

In embodiments, the present invention discloses a method for sterilising flexible bags containing a solution of human plasma proteins by electron beam,. Said method is characterised in that it comprises the following steps:

a) at least one emission of an electron beam at an energy of between 450-500 keV;
b) after a period of approximately of 10 ns, emission of at least one second electron beam pulse at an energy of between 700-750keV.

A person skilled in the art will understand that the higher-energy electron beam is aimed at the zone of the bag of greatest thickness, i.e. at the tube of the outlet port and the cap, whereas the lower-energy electron beam is aimed at the walls of the bag.

In one embodiment of the electron beam accelerator device of the present invention, the distance from the flexible bag to be sterilised to the irradiation source is between 1.5 cm and 7 cm. Preferably, said distance is 4 cm.

The sterilisation method of the present invention can be carried out before or after filling the bag and is preferably performed in a sterile environment.

The flexible bag to be sterilised by the method of the present invention can be made from any of the materials that are appropriate for the pharmaceutical industry and known in the state of the art.

Furthermore, said flexible bag can contain pharmaceutical solutions of biological origin, such as blood or blood products such as plasma, serum, red blood cells, albumin, α1-antitrypsin, von Willebrand factor, coagulation factors such as factor VII, factor VIII and factor IX, immunoglobulins, plasminogen, plasmin, antithrombin III, fibrinogen, fibrin, thrombin or combinations thereof. It is also provided for the pharmaceutical liquid or product to be of non-biological origin, and obtained by any other process or method known in the state of the art, for example, chemical synthesis, recombinant production or transgenic production.

In an embodiment, the present invention relates to an in-line method for filling flexible bags with human plasma proteins, which comprises a step of electron beam sterilisation using a device as mentioned above.

Said in-line method for filling flexible bags comprises the steps of:

a) labelling the bags;
b) sterilising the bags by electron beam, using the method according to the second aspect;
c) filling the bags with the solution of human plasma proteins in a sterile environment; and
d) sealing the bags.

The flexible bags that can be sterilised by the method of the present invention can have a volume of 50 mL to 500 mL. Fig. 1 is a perspective view.

Furthermore, said flexible bag can contain pharmaceutical solutions of biological origin, such as blood or blood products such as plasma, serum, red blood cells, albumin, α1-antitrypsin, von Willebrand factor,

CLAIMS

1. Device for sterilising flexible bags, the device comprising:

a sterilisation zone formed by at least two electron accelerators configured to emit electron beams at different energies from one another;

at least one accelerator configured to emit an electron beam at an energy of between 450-500 keV and

at least one other accelerator configured to emit an electron beam at an energy of 700-750 keV.

2. Device for sterilising flexible bags according to claim 1, wherein the accelerators are positioned on opposite sides of the bags in a position facing each other.

3. Device for sterilising flexible bags according to any one of claims 1 or 2, wherein the accelerators are positioned on opposite sides of the bags in a position in which they do not face each other.

4. Method for sterilising flexible bags containing a solution of human plasma proteins by electron beam, the method comprising:

a) providing the device as claimed in any one of claims 1-3;

b) placing a bag in the sterilisation zone;

c) at least one emission of a first electron beam, via the at least one accelerator, at an energy of between 450-500 keV;

d) after a period of approximately of 10 ns, emission of at least one second electron beam pulse, via the at least one other accelerator, at an energy of between 700-750 keV.

5. Method according to claim 4, wherein the distance from the flexible bag to be sterilised to the irradiation source is between 1.5 cm and 2.5 cm.

6. Method according to claim 5, wherein the distance from the flexible bag to be sterilised to the irradiation source is 2 cm.

7. Method according to any one of claims 4 to 6, wherein the bags to be sterilised can contain a volume of 50 mL to 500 mL.

8. Method according to any one of claims 4 to 7, wherein the solutions contained in said flexible bag are pharmaceutical solutions of biological origin, such as blood or blood products such as plasma, serum, red blood cells, albumin, α1-antitrypsin, von Willebrand factor, coagulation factors such as factor VII, factor VIII and factor IX, immunoglobulins, plasminogen, plasmin, antithrombin III, fibrinogen, fibrin, thrombin or combinations thereof.

9. Method according to claims 4 to 8, wherein the pharmaceutical solutions are obtained by chemical synthesis, recombinant production or transgenic production.

10. In-line method for filling flexible bags, the method comprising:

a) labelling the bags;
b) sterilising the bags by electron beam, using the method according to claims 4 to 9;
c) filling the bags with the solution of human plasma proteins in a sterile environment; and
a) sealing the bags.

11. Method according to claim 10, wherein the bags to be sterilised can contain a volume of 50 mL to 500 mL.

12. Method according to either claim 10 or claim 11, wherein the solutions contained in said flexible bag are pharmaceutical solutions of biological origin, such as blood or blood products such as plasma, serum, red blood cells, albumin, α1-antitrypsin, von Willebrand factor, coagulation factors such as factor VII, factor VIII and factor IX, immunoglobulins, plasminogen, plasmin, antithrombin III, fibrinogen, fibrin, thrombin or combinations thereof.

13. Method according to claims 10 to 12, wherein the pharmaceutical solutions are obtained by chemical synthesis, recombinant production or transgenic production.