What is a sterilization autoclave?

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ABSTRACT: This short article by the Italian sterilization practitioner Vittorio Mascherpa is an introduction to the basic selection of sterilization autoclaves. It defines this type or equipment, resumes the varieties of it and the preliminary problems to cope with in specification and design of sterilization autoclaves.

KEYWORDS: Sterilization, autoclave, saturated steam; counterpressure sterilization, pressure vessels.

GENERALS

Both thermal and chemical actions are suitable for sterilization. Thermal sterilization of pharmaceutical products may be obtained by dry heat or moist heat. A Sterilization Autoclave is a Pressure Vessel intended to perform a Sterilization Process, i.e. the complete inactivation of all viable microorganisms inside pharmaceutical products *for human or animal use* and / or on the external and internal surfaces of items to be used in health care or pharmaceutical production environments.

Moist-heat sterilization demands for the presence of condensing steam in intimate contact with the microorganisms to be inactivated, at a process temperature generally between 110°C and 140°C. This involves a process pressure between 0.5 bar and 4 bar above the atmospheric pressure at sea level, i.e. between 1.5 abs bar and 5.0 abs bar.

PURE SATURATED STEAM AUTOCLAVES

The level of the process pressure may be dictated one-to-one by the choice of the sterilization temperature. This applies to *pure saturated steam sterilization processes*, i.e. mainly to sterilization of hard / porous goods: in these processes, the steam fed into the chamber shall both heat the load and sterilize it at the specified conditions.

Pure saturated steam processes are also used for small vials and ampoules filled with solutions to be terminally sterilized. In pure steam sterilization, the intimate contact necessary between condensing steam and the microorganisms to be inactivated demands for the total removal of the air initially surrounding the items to be sterilized.

Nowadays, a vacuum pump connected with the autoclave generally obtains this removal. Next to air removal, pure saturated steam *of known, suitable and repeatable quality* is fed into the autoclave and the so called “exposure time” begins.

Finally, drying and/or cooling phases are performed, to allow a safe extraction of the sterilized items from the autoclave and their conservation under sterile conditions.

“COUNTERPRESSURE” AUTOCLAVES

When liquids are sterilized inside sealed containers of larger volume (e.g. LVPs), or if they are isolated by movable closures (e.g. pre-filled syringes), it can be necessary to select and control the process pressure at a higher value than the saturation pressure of the pure steam at the sterilization temperature. This should prevent the product from mechanical damage and / or from damaging the autoclave. This applies to *“counterpressure” sterilization processes*, for which, in most cases, the air is not removed from the autoclave and contributes to the overall internal pressure.

In the cases of sterilization of liquids in sealed or isolated containers, the steam fed into the chamber shall heat the product up to the specified conditions, but the liquid water necessary for sterilization of the product is, more often even if not always, already present in the product itself.

In addition, a sterilizing effect of the chamber steam may still be demanded for the outer surfaces of the containers and / or in the case of special products, as for instance complex blood bags or filters for dialysis. Depending mainly on

the material of containers, but also on the possible demand for final drying, a “counterpressure” sterilization process may be performed either in a “superheated water” (also: “water cascade”, or “water rain”) autoclave, or in a “steam & air” (also: “air-over-steam”) autoclave.

If these autoclaves are not intended also for pure saturated steam processes, it is not necessary that they withstand vacuum, because the processes do not generally include phases under vacuum; but combined autoclaves are becoming more and more frequent.

VESSELS, LAY-OUT AND EQUIPMENT SPECIFICATION

A Sterilization Autoclave is generally a quadrangular or cylindrical vessel made of high-quality stainless steel, with one or two large doors to allow the loading and the extraction of the items to be sterilized. Quadrangular vessels are more frequently adopted when the autoclave shall run both under pressure and in vacuum, i.e. for pure saturated steam processes. Cylindrical vessels are preferred when there is no demand for vacuum: as the outer shape of the load is always quadrangular, they also provide some additional space:

a) in superheated water autoclaves, for water spray bars on the top and on the sides, and a circulation water buffer on the bottom;

b) in steam & air autoclaves, for circulation fans, internal heat exchangers, and collection of the condense.

If the autoclave has two doors, the product is frequently loaded from a non-sterile ambient and unloaded into a sterile ambient. To define correctly the layout of the sterilization facility and loading, as well as loading and unloading patterns, is a very critical step for a successful autoclave specification.

Detailed process requirements are obviously of an utmost importance: they typically include (but are not limited to):

a) type of products to be processed

b) product packaging and mechanical properties

c) resistance to temperature of product and packaging

d) expected physical parameters for sterilization

e) expected output of the sterilization autoclave

Standardization and regulatory requirements, both process and mechanical/electrical, need specifications also at the very first stage. The technical *expertise* of an autoclave manufacturer consists both of mechanical and process capabilities, and mainly out of:

a) the skillfulness in the building of the pressure vessel in the required shape

b) with all the required surface properties;

c) a *deep knowledge of the processes involved*;

d) the capability of coping with User’s Requirements for special products;

e) the capability of coping with User’s Requirements for standardization and regulatory demands.