These physicochemical effects induce biological effects in the particular case of the living organisms of which the structure is strongly hydrated and has a high level of organization. But, like all methods of sterilization, irradiation involves a compromise between inactivation of the contaminating microorganisms and damage to the product being sterilized.

The imparted energy, in the form of γ-photons, X rays, or electrons, does not always differentiate between molecules of the contaminating microorganism and those of the pharmaceutical substrate.

The potential consequences of irradiation on the stability of the active principal ingredient (API) may be restricted when combined with the freeze-drying. Indeed, the latter, by eliminating water, limits the formation of radio-induced free radicals and their propagation responsible for the radiolysis reactions that can lead to the degradation of the of therapeutic preparations.

Various studies dealing with radiation sterilization of therapeutics have been reported in the literature. Some of them prove its effectiveness for freeze-dried pharmaceuticals radio sterilization and the absence of significant deleterious effect (7). The industrial applications of radio sterilization of therapeutic products are in strong progress.

IRRADIATION TECHNIQUES

Ionizing Radiation Used in Industry

Radiation sterilization appeared from the second half of the 20th century. In 1949, Charles Artlandi gave the bases of the electron beam (corpuscular radiation) sterilization using a 2 MeV Van de Graaff electron accelerator. This research allowed the installation of the first commercial irradiators in 1956 with accelerated electrons and in 1964 with γ rays (electromagnetic radiation).

The idea to use the X rays (electromagnetic radiation) to sterilize medical devices was born in the 1960s (8).

Radiation sterilization is a clean process that does not leave toxic residues in the products and makes it possible to sterilize products conditioned in their final packaging with a weak increase of temperature only. It is therefore known as the "the process of 'cold' sterilization."

The energy of the radiation usable in industry is limited to 5 MeV for the electromagnetic radiation and 10 MeV for the electron beams. However, higher energies can be implemented with the obligation to demonstrate the integrity of the treated product in terms of induced radioactivity. Taking into account their nature and these limitations, these radiations cannot disturb the nucleus of the atom and so can in no way induce in the irradiated matter a significant amount of radioactivity (9).

Electron Beams

The electron beams are generated by electric accelerators, machines, allowing by "construction" the control of the characteristics (energy and intensity) of the beam. The electron acceleration principles, to near the speed of light, are varied (high-frequency or electrostatic techniques), but the principal components of these machines remain always the same: source of electrons, accelerating tube or cavity, and scanning horn with electron beam shape device.

The sterilization industry employs mainly medium powerful beams (20–300 kW) from 5 to 10 MeV produced by high-performance accelerators.