Plasma sterilization of pharmaceutical products: from basics to production

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The decontamination of thermolabile pharmaceutical products by a plasma process is of growing interest in research and application. Available methods like toxics (ethylene oxide) or electron beam sterilization have either issues in handling and security or produce toxic remnants, which need to be taken care of in additional process steps. Also challenging for some decontamination methods are biomolecules like prions and pyrogens. Plasma sterilization poses an alternative treatment with several advantages, especially for thermolabile pharmaceutical goods.

An industrial process was developed in close cooperation with groninger & co. gmbh. It was presented for the first time on the last ICPM. Its application is the outer decontamination of syringe containing tubs before they are filled in a clean room. The tubs mainly consist of polystyrene and are sealed by Tyvek® foil on top. The process runs at pressures below 10 Pa. Plasma generation is achieved by two opposite coils, mounted at the top and bottom of the chamber, with 3-5 kW available RF power at each coil.

To understand basic principles of plasma sterilisation a laboratory set-up double inductively coupled plasma reactor (DICP) [1] is used. In this reactor the influence of different sterilization agents can be investigated, such as UV/VUV radiation or reactive species. Since the DICP is similar in dimensions and power coupling to the industrial reactor, theses experiments can be performed under nearly the same conditions.

In order to gain knowledge about optimization parameters, several plasma diagnostic methods have been applied to both reactors. Langmuir probe measurements provide spatially resolved information on electron density and temperature, hence discharge homogeneity. In combination with calibrated optical emission spectroscopy also the UV/VUV surface irradiation and gas temperature are determined. Investigated parameter variations include duty cycle, power input per coil, pulsing frequency, pressure and gas composition. Additionally, microbiological tests have been performed to investigate sterilization efficiency.

References

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