PRACTICAL ASPECTS DURING STERILIZATION VALIDATION FOR MEDICAL DEVICES AT IRASM MICROBIOLOGICAL LABORATORY

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The state of being free of living microorganisms is called sterility. The sterility state can be achieved by different means of sterilization. In practice the results of the process cannot be fully verified by tests, so the efficacy of the sterilization process must be validated.
ISO 11137 established regulations for setting or substantiating the dose for achieving the desired sterility assurance level.
The validation studies can be designed in particular for different types of product. Each product needs distinct protocol for bioburden determination and sterility testing.
During time, the Microbiological Laboratories from Multipurpose Irradiation Center deals with different types of products, mainly for VD_{max}^{25} method. When it comes to microbiological evaluation the most challenging was cotton gauze. Special situation for establishing the sterilization validation method appears in cases of cotton, packed in large quantities. VD_{max}^{25} method can not be applied for items with average bioburden more than 1000 CFU / pack, no matter which is the weight of the package. This is a method limitation and implies increased costs for manufacturer, when choosing other method.
For microbiological tests, culture condition should be selected in both cases the bioburden and sterility testing. These are time and money consuming. The costs can be reduced if taking into account some aspects. Reason for performing the bacteriostasis-fungistasis just for sterility testing will be given.
The present study puts forward aspects during the validation studies for medical devices (cotton wool, cotton gauze, surgical sutures, dental screws), at IRASM Microbiological Laboratory.