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Qualification of Autoclave

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Abstract: In accordance with GMP, each pharmaceutical company should identify what qualification work is required to prove that the critical aspects of their particular operation are controlled. The key elements of a qualification and validation programme of a company should be clearly defined and documented. Qualification is the integral part of GMP and there is no effective QA program without qualification. Now-a-days it is mandatory to incorporate qualification activity for any system in the manufacturing premises for all pharmaceutical industries.

The purpose of this study is to initially develop the sterilization process parameter for the porous load articles then implement the sterilization process for the porous articles. The process development included qualification of equipment and the articles. The auto clave cum bung processor which is used for the cleaning and sterilizing rubber stoppers, garments and machine parts. This was followed by performing the qualification of the equipment which describes the entire test right from Vacuum leak test, Bowie dick test, heat distribution test and heat penetration test were equipment passes all test and the equipment is suitable for sterilization purpose which meeting its predetermined specification and quality attributes.

Keywords: Autoclave qualification, Sterilization, Vacuum leak test, Bowie-dick test, Heat distribution test, Heat penetration test.

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