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A Review on Cleanroom Gloves in Pharmaceutical Applications

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Abstract: This study intended to demonstrate the importance of having a standard quality of medical gloves and the requirement needed to meet the standard specifications set by regulatory authorities such as ASTM, EN, and ISO etc. The recent regulatory citations and warning letters revealed that major pharmaceutical companies in India had serious non-compliance issues in handling gloves into their receipt, testing, storage and issuance to production use. The gloves were tested to check the quality is within the limit as per ISO 2859-1.

The quality control test was carried out on sterile, non sterile and hypalon glove by following the ISO sampling procedure 2859-1. The tests include visual examination test, water leak test for pinhole detection, physical dimension test, and pressure drop test for hypalon glove. The result of those tests reveal that the gloves are meeting the standard requisites set by the different agency, hence the glove can be distributed and used in pharmaceutical clean room. Carrying out those tests will avail to avert the product from contamination, and transmission of disease between health care professional and the patient.

The reason behind the study on clean room glove is to demonstrate the importance of utilizing standard quality of clean room gloves. The recent regulatory citations and warning letters revealed that major pharmaceutical companies in India had serious non-compliance issues in handling gloves into their testing, storage and issuance to production use. It was found the use of non sterile glove in sterile area was in violation to cGMP. Clean room glove is one of the main sources of product contamination and using clean room glove as the contamination control kit can avail to reduce the product contaminations. In this study, the quality control tests for clean room glove were carried out as according to ISO, ASTM and EN.

Keywords: Clean room glove, Medical glove, Contamination.

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