

## Evaluation of cleanroom functional parameters (A case study in a pharmaceutical industry)

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### **Abstract**

**Introduction:** Nowadays, many modern industries require an environment with no contamination by particles and bacteria. An enclosed clean room environment is a place where parameters such as airborne particles, temperature, humidity, air pressure and air flow pattern is controlled. The aim of this study was to evaluate functional parameters of a clean room in a selected pharmaceutical industry.

**Material and Method:** This study was an experimental study conducted in 2015 in a pharmaceutical industry. The air flow rate and flow rate with airflow capture hood was used and multi sensor devices for measuring temperature, humidity and pressure of multi-sensor device. HEPA filter leakage test and counting concentration of particles in the cleanroom was done according to the ISO 14644 – 3(2005) standards using aerosol photometer and aerosol generator. In this study, 6 clean room relating to the 3 cleanliness classes B, C and D (in accordance with standard EU GMP) were evaluated. Meanwhile, both the 2 and 3-dimensional flow model using Computational Fluid Dynamics Software was simulated in this study.

**Result:** Measuring the parameters flow rate and air velocity, temperature (average temperature 20 ° C), relative humidity (below 50%), pressure (pressure less than 15 psi) for every three classes of cleanliness are all acceptable and less than the proposed standard. Furthermore, the results of modelling showed that the pattern of air flow in the room is correct paths in circulation. In the case of leakage test filters, the filter 29 filters tested 5 was leaking and ultimately determine the HEPA filters remove particles that average efficiency is 99.99%.

**Conclusion:** This study showed that the high volume and good quality of air entering the clean room affect the optimal efficiency and air flow rate, pressure drop and air penetration of the HEPA filters Also, the results of study show that the concentration of airborne particles in clean room is depend on the air flow rate and speed and adopting a good air flow pattern will affect the particle concentration.

**Key words:** *Modeling, Airflow Pattern, Particle, Cleanroom*

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