ULTRASONIC PRE-TREATMENT FOR ENHANCED AIR FILTRATION IN PHARMACEUTICAL CLEANROOMS

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Abstract

High-efficiency filters such as HEPA and ULPA are widely used but face challenges related to cost, pressure drop, and service life. The RESPIRATION project, implemented under the Horizon 2020 programme, addresses this issue by introducing ultrasonic pre-treatment before the filtration stage. The method relies on acoustic resonators embedded in the airflow path to induce agglomeration of PM2.5 and smaller particles, making them easier to capture and reducing the load on final filters. A novel simulation approach was developed to model ultrasonic emitter behaviour and sound field propagation using ANSYS software. The multi-module framework included Modal and Harmonic Acoustic analyses, with CFD implementation through boundary condition transfer. The proposed method enables more accurate energy distribution modelling and supports the design of scalable, energy-efficient pre-filtration units.

Keywords: *ultrasonic pre-treatment, acoustic agglomeration, CFD, ANSYS*

Introduction. Air purification is a basic necessity in pharmaceutical manufacturing to keep products safe from airborne contamination. Even tiny particles or microbes in the air can ruin a whole batch, reduce shelf life, or put patients at risk. That's why regulations strictly require clean, controlled air in all critical areas—especially where sterile or high-risk drugs are made. Clean air isn't just a best practice, it's a non-negotiable condition for making safe and effective medicine (EU GMP Annex 1, 2022; USP <797>, 2023; Ukrainian GMP Guidelines, Ministry of Health of Ukraine, 2020).

The air purification process in pharmaceutical manufacturing is built on a clear, step-by-step system designed to keep indoor air clean, stable, and compliant. It starts with drawing in outside air, which is immediately passed through pre-filters to remove large dust particles. Next, medium-efficiency filters (like MERV 8–13) help trap smaller particles and protect the finer filters downstream. Air then enters the air handling unit (AHU), where it is heated or cooled to the required temperature, and humidity is adjusted using humidifiers or dehumidifiers. Fans inside the AHU maintain a stable airflow rate. The final and most critical stage is high-efficiency filtration: HEPA filters (≥99.97% for 0.3 μm particles) or ULPA filters (≥99.999% for 0.12 μm) clean the air before it enters the cleanroom. Inside production areas, the air is distributed through ceiling or wall diffusers to ensure either laminar or turbulent flow, depending on cleanliness class. Used air is partially exhausted and partially recirculated back to the AHU for re-treatment, which improves energy efficiency and keeps environmental conditions stable (EU GMP Annex 1, 2022; ISO 14644-1:2015; ASHRAE Standard 170; USP <797>, 2023).

This multi-stage air treatment process is typically managed by a dedicated unit known as a Make-up Air Handler (MAH). The MAH is responsible for conditioning and delivering clean, temperature- and humidity-controlled air into the cleanroom to replace the air exhausted by the ventilation system. It integrates key components such as pre-filters, cooling/heating coils, humidifiers or dehumidifiers, could include HEPA and ULPA filters, and supply fans—all within a single controlled system (fig. 1). By precisely regulating the volume and quality of incoming air, the MAH plays a central role in maintaining pressure differentials, preventing cross-contamination, and ensuring the cleanroom consistently meets GMP and ISO standards (ASHRAE Standard 170; USP <797>, 2023).

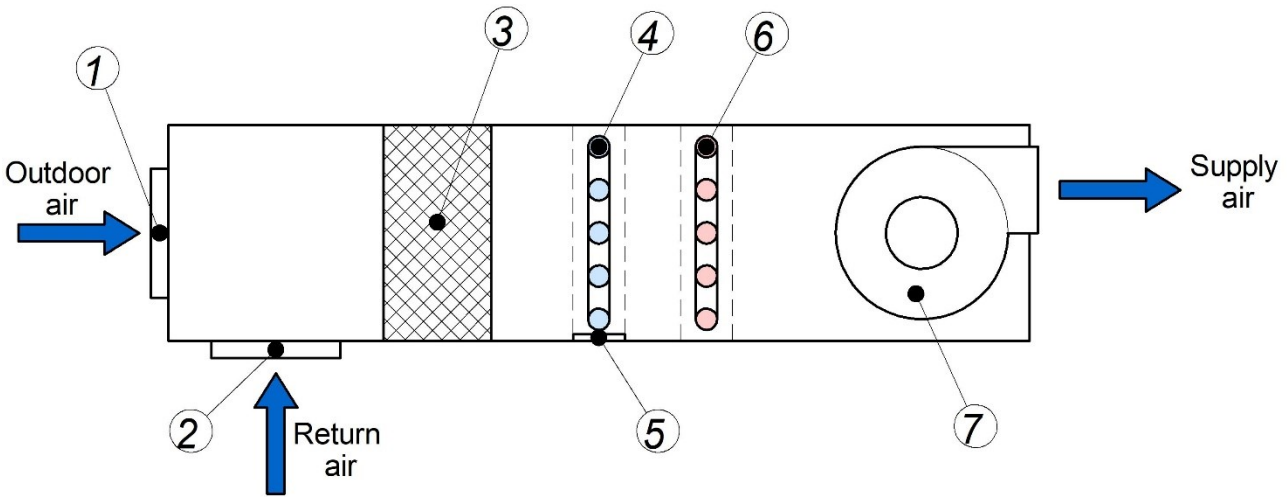

Fig. 1. Scheme of the MAH without HEPA and ULPA filters: 1 – Outdoor air inlet; 2 – return air inlet; 3 – pre-filter; 4 – cooling element; 5 – drain pan; 6 – heating element; 7 – fan.

Materials and methods. HEPA and ULPA filters are highly effective but also costly components of pharmaceutical cleanroom systems. Their fine pore structure allows them to capture particles as small as 0.3 μm (or even 0.12 μm), but this also makes them prone to clogging. Over time, especially in environments with high particulate load or humidity, these filters can become saturated, increasing pressure drop across the system and reducing airflow. In particular, exposure to moisture can lead to fiber swelling or microbial growth, further increasing hydraulic resistance and compromising performance. As a result, filters must be replaced periodically—an expensive and labor-intensive process [1].

To extend the life of HEPA/ULPA filters and reduce operating costs, several pre-treatment strategies can be applied before final filtration. These include ultrasonic agglomeration, electrostatic or magnetic separation, and chemical conditioning. Each method helps reduce particulate load on the filters, delays clogging, and maintains system performance [2].

One of this pre-treatment strategies realized in the RESPIRATION project under the Horizon 2020 framework. The idea proposed in the project is to enhance air purification efficiency by applying ultrasonic pre-treatment directly before the filtration stage. This concept is based on the use of acoustic resonators integrated into the airflow path to induce particle agglomeration through resonance effects (fig. 2).

The resulting larger particle clusters are more easily captured by standard filters, reducing the load on HEPA/ULPA units and extending their service life.

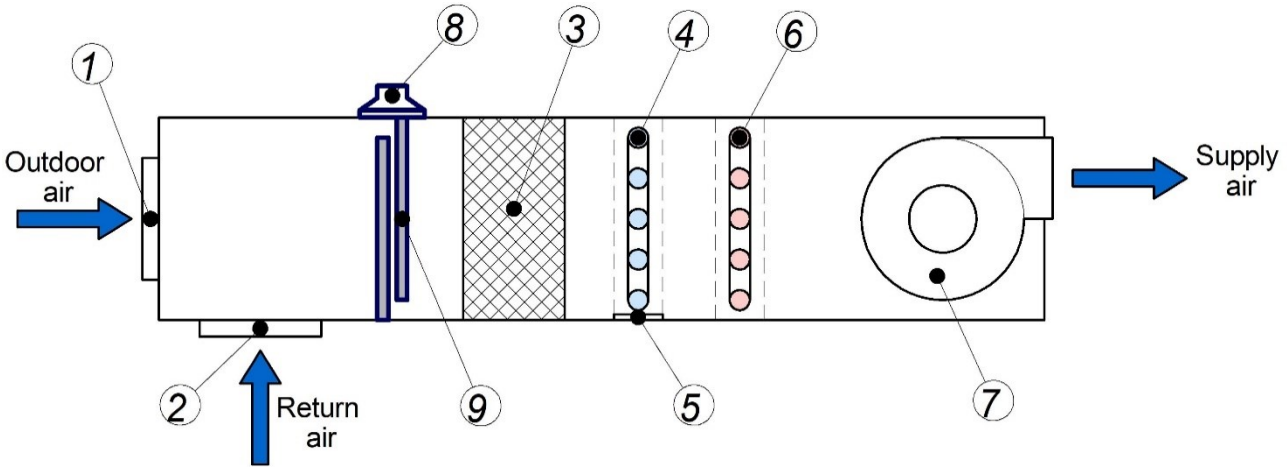

Fig. 2. Scheme of the MAH with resonators and ultrasound pre-treatment: 1 – Outdoor air inlet; 2 – return air inlet; 3 – pre-filter; 4 – cooling element; 5 – drain pan; 6 – heating element; 7 – fan; 8 – ultrasound emitter; 9 – resonators.

As part of the RESPIRATION project advanced computer modelling was created to investigate how high-frequency ultrasound interacts with fine particles suspended in airflow in duct with resonators. The main objective of the simulation was to understand and quantify how resonant acoustic fields influence particle agglomeration and how this effect can be enhanced by introducing resonator structures into the flow channel. Particular attention was paid to airflow conditions relevant for pre-filtration treatment in pharmaceutical environments.

Results and discussion. A new simulation method was developed in the project to accurately model the mechanical behavior of the ultrasonic emitter and its coupling with the surrounding air. The main task of this method was to calculate the directional surface displacement of the emitter and apply it as a boundary condition in a computational fluid dynamics (CFD) solver. The process started with Modal analysis in ANSYS to determine the emitter's natural frequencies and identify the mode shapes with maximum displacement in desired directions.

After selecting the appropriate frequency, Harmonic Acoustic analysis was used to simulate the interaction between the vibrating emitter and the acoustic domain, allowing precise determination of surface deformation along all three axes under realistic boundary conditions. These displacement values were then exported as a .csv file and imported into ANSYS Fluent or CFX as a User Defined Function (UDF).

In the CFD stage, these values were used to define time-dependent sinusoidal wall motion that represents high-frequency oscillations of the emitter surface. This multi-module simulation chain provided a physically accurate description of sound field generation and its transfer into the fluid domain, which is critical for modelling acoustic agglomeration effects in airflow (fig. 3).

The new simulation technique improved the precision of energy distribution modelling and enabled better prediction of resonance zones within the duct. As a result, it allows to achieve a more realistic representation of the operating conditions and

provided critical insights for refining the physical design of the acoustic pre-treatment unit.

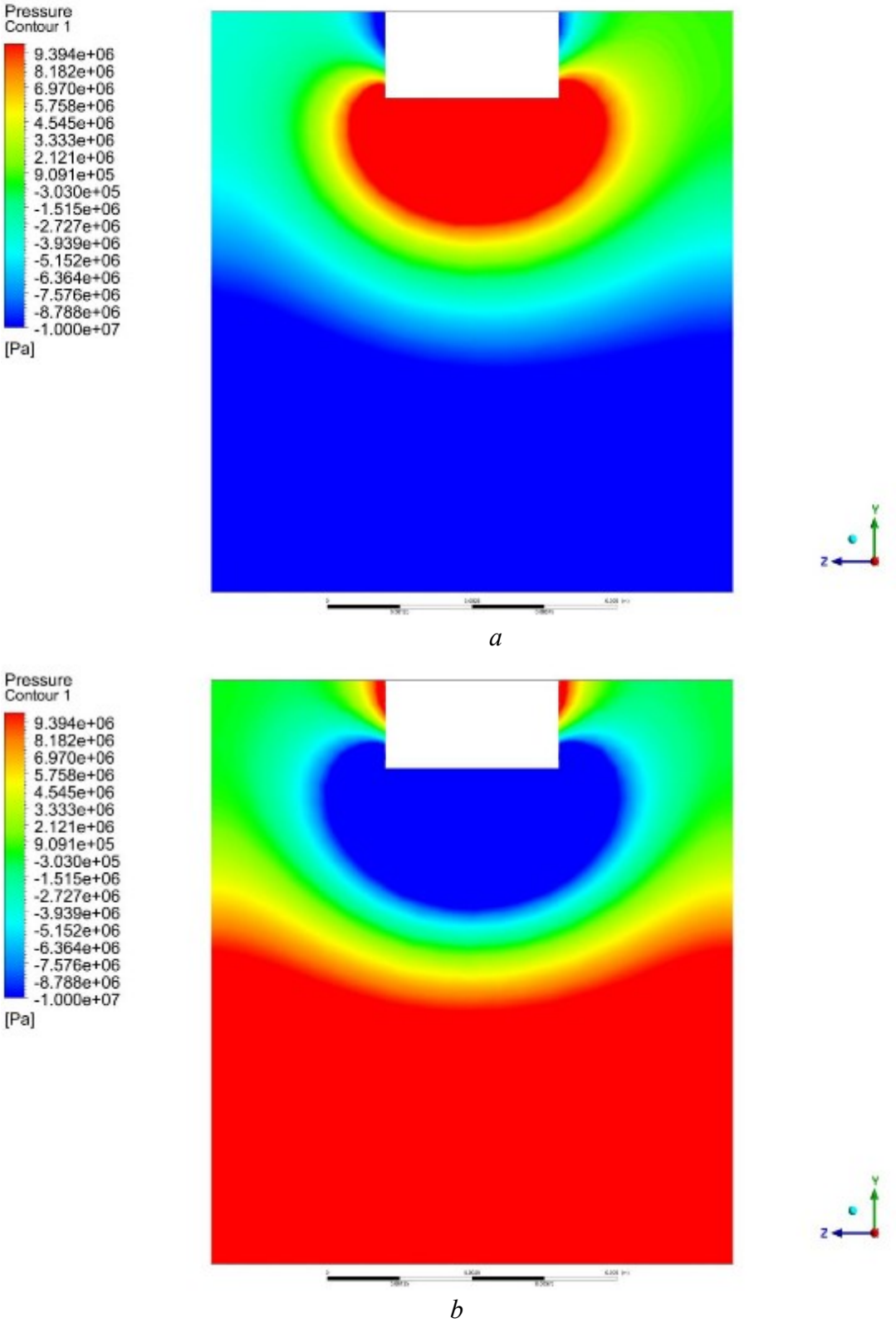

Fig. 3. Pressure contours: a – compression phase; b – expansion phase.

Conclusions. A novel simulation technique was created to accurately model the surface motion of ultrasonic emitters and its interaction with the airflow. The combination of Modal, Harmonic Acoustic, and CFD modules in ANSYS enabled the prediction of acoustic pressure distribution and resonance zones within the duct.

The obtained results confirm that ultrasonic pre-treatment can reduce the particle load on final filters, potentially lowering operational costs and extending service intervals without compromising cleanroom air quality.

Future work will focus on optimizing resonator geometry, validating the simulation results through physical experiments, and evaluating the system's integration into scalable filtration units for industrial applications.

Acknowledgement

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References:

1. Zhang X. et al. An efficient strategy to enhance air filtration through the synergistic effects of ultrasonics and seed particles // Separation and Purification Technology. 2025. Vol. 353. P. 128600. 10.1016/j.seppur.2024.128600

2. Korobiichuk I. et al. Determination of regularities that influence the acoustic pressure and accuracy of inertial sensors // Ultrasonics. 2024. Vol. 136. P. 107169. 10.1016/j.ultras.2023.107169