As pharmaceutical manufacturers develop and produce increasing numbers of highly potent active pharmaceutical ingredients (HPAPIs), they also must maintain worker safety. Depending on the level of safety required, companies must often make additional facility and engineering accommodations, including provisions for water, air handling, dust collection, feeding, and discharging.

Selecting a tabletting system for HPAPI applications requires many choices and involves an array of potentially confusing terms and acronyms. For example, the terms wash-in-place (WIP) and clean-in-place (CIP) are very similar, but WIP usually requires some level of disassembly and manual cleaning, while CIP implies a more fully automated process with little or no disassembly. While CIP can greatly mitigate the risk of inhaling hazardous compounds, it’s generally not practical for cleaning a tablet press, because some areas inside the press can’t be fully cleaned while the press is assembled.

Here are some additional terms and acronyms you may encounter when choosing tablet compression equipment for an HPAPI application:

- **Occupational Exposure Banding (OEB)** is a process that assesses chemicals for toxicological concentration and potentially adverse health effects through prolonged exposure. Chemicals are categorized into specific “bands” that correlate with increasing levels of risk.

- **Occupational Exposure Limit (OEL)** is an upper limit on the acceptable concentration of an airborne particulate chemical in terms of the risk associated with an individual’s exposure. OEL is usually expressed as a value of micrograms per cubic meter (µg/m³).

- **Permitted Daily Exposure (PDE)** is the amount of a specific substance that’s unlikely to cause an adverse effect in a person exposed to that amount or less each day for a lifetime.

- **Personal Protective Equipment (PPE)** is clothing, respirators, or other equipment that creates a protective barrier between an operator and a potentially toxic substance.

- **Standardized Measurement of Equipment Particulate Airborne Concentration Committee (SMEPAC)** is a part of the International Society for Pharmaceutical Engineering (ISPE) and has created a good practice guide for measuring the performance of containment systems.

Tablet press vendors offer a variety of containment options, which they can generally tailor to specific OEB- or OEL-based needs. For example, if a particular set of containment-related requirements necessitates dry-clean, low-dust production, a vendor may specify a press fitted with glove and rapid-transfer ports along with appropriate process equipment. By using split-valve technology for charging the press, HEPA filtration, and low-dust discharge chutes, a system can efficiently provide safety up to OEB level 3.

Protecting operators and the manufacturing environment up to OEB levels 4 or 5 generally requires a wet-clean, WIP tableting system that provides a higher degree of protection. WIP technology reduces exposure risk as well as cleaning time, and integrated spray and dust extraction wands allow operators to clean the compression zone mid-campaign without compromising containment. For the most extreme OEB level 5 applications, you can install process equipment in isolators, ensuring that the entire tableting system is safe and efficient. Some vendors also offer optional, software-controlled air-management systems to achieve the very highest level of protection.

Some tablet press vendors now offer testing programs that establish and certify a tableting system’s containment level. Generally, the vendor will perform the tests at their facility and will offer several potential solutions depending on the target permissible exposure values the end user wishes to maintain and considering other causal factors, such as the end user’s facility, equipment, and safety procedures. These tests can bolster internal risk-assessment processes the end user conducts under the SMEPAC guidelines because they represent a standardized, objective, and reproducible determination of the system’s capabilities.

The vendor may issue a certificate stating the tested system’s containment performance with respect to OEB level under the stated lab conditions in the vendor’s facility. The vendor can also provide related test documentation to the end user at the time of purchase.

Identifying the correct level of containment to comply with your established risk assessment is imperative for protecting your employees. An experienced tablet press vendor with an objective testing program can help you ensure that the equipment you select has the specific containment capabilities your application requires.