**Technical specification**

**Fluid-bed equipment with the coating pan module and high-speed mixer**

 **PURPOSE AND SUBJECT MATTER OF THE PUBLIC PROCUREMENT**

The purpose of this public procurement is to supply equipment for the production of solid dosage forms in the form of a high-shear mixer for the preparation of dry and wet mixtures with a subsequent fluid bed device capable of fluid bed granulation, coating of solid microparticles (e.g., granules, pellets, and small tablets), and fluid bed drying. A closed-coating pan coater will be required for larger tablets or hard capsules. Equipment with an intensive air supply, in this case, the fluid bed device and coating pan, must be capable of creating a production module or possibly being integrated into a production unit (modular arrangement).

The equipment must be suitable for pharmaceutical production under GMP conditions. The equipment will be used to train PhD students in Pharmacology and Toxicology and other related fields. It will serve to develop and produce pilot and clinical batches of drugs for human or veterinary use or other purposes.

The subject of the supply is complete, new, and fully functional equipment, including complete installation and operational qualification (IQ/OQ), documentation, commissioning, and operator training at the delivery site.

The offer must meet all the requirements and parameters specified by the Contracting Authority. In the case of parameters defined by a minimum or maximum level or range of values, the offer must meet at least the specified required level.

 **MINIMUM TECHNICAL REQUIREMENTS**

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| **Parameter** | Parameter offered by the supplier |
| Manufacturer |  *The supplier specifies the manufacturer.* |
| Type/Model |  *The supplier specifies the type and model.* |

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| **Minimum required technical specifications** | **Technical parameters offered by the supplier\*** |
| Bottom-driven High-Speed Mixer (HSM) for dry and wet powder blending | *The supplier indicates YES/NO and offers a technical solution/specification* |
| Fluid Bed Dryer (FBD) with top and bottom spray capability for granulation, coating and drying solid dosage forms, particularly microparticles and small tablets, featuring a Wurster column. | *The supplier indicates YES/NO and offers a technical solution/specification* |
| Closed-system of Pan Coater (PC) for coating tablets and hard capsules, allowing the application of coatings through spraying and drying processes. | *The supplier indicates YES/NO and offers a technical solution/specification* |
| Combined processing unit for at least FBD and PC modules with motor/engine, control, air handling, and spray functions. | *The supplier indicates YES/NO and offers a technical solution/specification* |
| The chamber volume of the HSM is between 4 and 8 liters. | *The supplier indicates YES/NO and offers a technical solution/specification* |
| The HSM includes a comprehensive spray system composed of a nozzle and a pump. | *The supplier indicates YES/NO and offers a technical solution/specification* |
| Regulation and measurement of the rotational speed of both impeller and chopper in a HSM. | *The supplier indicates YES/NO and offers a technical solution/specification* |
| Measurement of the torque resistence (Ampere load) of the impeller in a HSM. | *The supplier indicates YES/NO and offers a technical solution/specification* |
| The chamber volume of the FBD is between 4 and 10 liters. | *The supplier indicates YES/NO and offers a technical solution/specification* |
| The FBD module includes a Wurster coating system (column) or an equivalent device. | *The supplier indicates YES/NO and offers a technical solution/specification* |
| FBD with a filter unit equipped with an automated cleaning system. | *The supplier indicates YES/NO and offers a technical solution/specification* |
| FBD filters designed for handling powders, agglomerates, and dosed forms. | *The supplier indicates YES/NO and offers a technical solution/specification* |
| At least two spray nozzle positions for top spraying in FBD. | *The supplier indicates YES/NO and offers a technical solution/specification* |
| The chamber volume of the PC module is between 4 and 10 liters. | *The supplier indicates YES/NO and offers a technical solution/specification* |
| Perforated pan/drum in the PC. | *The supplier indicates YES/NO and offers a technical solution/specification* |
| Regulation and measurement of the rotational speed of the PC. | *The supplier indicates YES/NO and offers a technical solution/specification* |
| Measurement of air pressure and flow rate at both the inlet and outlet of the supplied air for the FBD and PC modules. | *The supplier indicates YES/NO and offers a technical solution/specification* |
| Operating temperature range for modules (FBD and PC) is at least from 25 to 80 °C. | *The supplier indicates YES/NO and offers a technical solution/specification* |
| Measurement and user-adjustable settings of atomizing air for both the FBD and PC modules. | *The supplier indicates YES/NO and offers a technical solution/specification* |
| A sampling point and probe that allow sample collection without interrupting the process in both the FBD and PC modules. | *The supplier indicates YES/NO and offers a technical solution/specification* |
| Measurement of product temperature within the FBD and PC modules. | *The supplier indicates YES/NO and offers a technical solution/specification* |
| Measurement of both inlet and outlet air temperatures within the FBD and PC modules.  | *The supplier indicates YES/NO and offers a technical solution/specification* |
| Dedicated pump for liquid media supply to all equipment (HSM, FBA and PC). | *The supplier indicates YES/NO and offers a technical solution/specification* |
| The capability to expand the equipment for the use of explosive organic solvents in FBD and PC processes. | *The supplier indicates YES/NO and offers a technical solution/specification* |
| The maximum weight for each individual unit (HSM; FBD; PC) is 1000 kg.  | *The supplier indicates YES/NO and offers a technical solution/specification* |
| The maximum height for any part of the equipment (HSM; FBD; PC) is 2 meters. | *The supplier indicates YES/NO and offers a technical solution/specification* |
| The equipment can be modularly expanded with a sieving and mixing module in the future. | *The supplier indicates YES/NO and offers a technical solution/specification* |
| Each aquipment (HSM; FBD; PC) is suitable for drug production under GMP conditions. | *The supplier indicates YES/NO and offers a technical solution/specification* |
| The supplier will provide installation qualification (IQ) and operational qualification (OQ). | *The supplier indicates YES/NO and offers a technical solution/specification* |
| The equipment (HSM; FBD; PC) is equipped with a control system that allows recipe storage and touchscreen operation. | *The supplier indicates YES/NO and offers a technical solution/specification* |
| The control system allows backups to USB drive or PC. | *The supplier indicates YES/NO and offers a technical solution/specification* |

**\* The supplier is required to indicate YES/NO and provide the requested information.**

**The supplier is obligated to submit, in addition to the technical specification provided in this table, its technical specification or description of the equipment.**