**PRILOG I. / ATTACHMENT** *I.*

**Specifikacija korisničkih zahtjeva (SKZ) /**

*User Requirements Specification (URS)*

**Uređaj za sušenje raspršivanjem /**

*Spray dryer*

# INTRODUCTION

The scope of this document is:

* To define the requirements for the equipment
* To define services to be rendered by the supplier
* To specify documentation that must be included with equipment

# OVERVIEW

Machine will cover application in pharmaceutical area, installed in cleanroom classified as “D” area following current EU GMP regulations.

Machine will be used for drying solute dissolved in water solvent with possibility of machine upgrade for drying solute dissolved in organic solvent.

Unless prescribed differently, requirements defined in user requirement specification (URS) represent minimal technical characteristics that requested equipment needs to fulfill.

# REQUIREMENTS

## 3.1. Directives and standards compliance

The machine has to be designed, manufactured and tested following current CE Guidelines.

## 3.2. General requirements

| **URS ID** | **Required specification** | **YES** (if offered specification is equal to one required) / or **WRITE OFFERED SPECIFICATION DETAILS** | **Notes, remarks, references** |
| --- | --- | --- | --- |
|  | All parts in contact with the product must be designed to ensure that there is no possibility of defect on product |  |  |
|  | All parts that are in contact with any part of the product have to be made of materials which have no impact on product quality |  |  |
|  | Machine must be equipped with all safety devices required by the current CE standard |  |  |

# MACHINE DESIGN REQUIREMENTS

| **URS ID** | **Required specification** | **YES** (if offered specification is equal to one required) / or **WRITE OFFERED SPECIFICATION DETAILS** | **Notes, remarks, references** |
| --- | --- | --- | --- |
|  | Spray drying system for laboratory use must contain all necessary parts for functional work (nozzles, drying chamber, cyclone, air/nitrogen compressor, pipes, filters, collection bottle…) |  |  |
|  | Product transfer system to spray dryer must be easy to use.  Product must be transferable from different size bottles (100 ml bottles (H: 10 cm) – 5 L bottles (H: 35 cm)) or if machine have solution vessel for inlet product, vessel must process same volume of intake solution (100 ml – 5 L).  Solution vessel must be easily removable and cleanable. |  |  |
|  | Machine must have inlet and outlet air/nitrogen filter |  |  |
|  | | | |
|  | Minimal process parameters which can be adjusted must include:   * Feed solution speed * Inlet temprerature * Nozzle gas pressure * Spray air/nitrogen flow |  |  |
|  | Minimal process parameters that can be recorded:   * Outlet temperature |  |  |
|  | Machine can have air/nitrogen compressor delivered with machine or as a separate unit. In both cases air/nitrogen compressor must have as little as possible noise footprint |  |  |
|  | Supplier must provide technical installation requirements on site for normal use of machine |  |  |
|  |  |  |  |
|  | Supplier has to provide at minimum the following maintenance instructions:   * All sub-systems provided (Maintenance and operation manuals of vendor equipment); * Supplier shall supply two copies of Operation, Installation and Maintenance manuals as well as electronic copy of those documents |  |  |
|  | Supplier must provide initial maintenance and qualification in the year of signing the contract (year n), as well as 1 qualification and maintenance with disposable material for a period of 18 months from the signing of the contract (n + 1 years). |  |  |

# OPTIONAL SPECIFICATIONS (non mANDATORY)

Technical specifications in Section 5 of this USR are not mandatory to offer but will be scored according to the selection criteria stated in the procurement document “Invitation for submission of offer”, section 6.1.

Points will be awarded to those Bidders who meet the required specification in accordance with a requested parameter.

If bidder does not offer any or all specification in this Section, column for offered specification can be left empty.

| **URS ID** | **Request specification** | **YES** (if offered specification is equal to one required) / or **WRITE OFFERED SPECIFICATION DETAILS** | **Notes, remarks, references** |
| --- | --- | --- | --- |
|  | Spray dryer is upgradable to process common organic solutions like:   * Alcohols (methanol, ethanol, propanol, butanol) * Ketones (acetone) * Acids (Acetic acid)   But is not limited to these solutions. |  |  |
|  | Spray dryer have more than one spray nozzle to obtain powder of different size |  |  |
|  | | | |
|  | Supplier can provide the number of years and fixed annual maintenance price for regular yearly maintenance and qualification with disposable material for period of n+2, n+3 and n+4 years starting after second qualification in n+1 year (as stated in required specification, point 4.9.) |  |  |

# QUALIFICATION

The supplier is responsible for preparation of qualification protocols including Installation Qualification (IQ); Operation Qualification (OQ), and Process Qualification (PQ). These protocols shall cover all design and safety aspects as well as complete functionality of the equipment according to JGL’s User Requirement Specification (URS) and other relevant specifications and guidelines. The supplier shall provide the qualification protocols for preliminary review to JGL before the delivery of the equipment. The protocols shall be approved by JGL before the qualification activities commence. The Supplier is responsible for the execution of the qualification activities together with JGL employees. Final results and qualification reports also have to be approved by JGL before final commissioning of the equipment.

All qualification documentation shall be in English language.

## TRAINING

Selected Supplier shall provide appropriate training for personnel from R&D and Maintenance department. Training duration shall be at least 8 hours. The training shall include practical workshops directly on supplied equipment.