

INQUIRY – 17/PLX/2023

PURCHASER: **POLFARMEX S. A.**

99-300 Kutno; ul. Józefów 9

NIP **7750001711**

I. The inquiry is connected with the implementation of a R&D commercial project, co-financed from the government budget by the polish Medical Research Agency (Agencja Badań Medycznych).

II. SUBJECT OF CONTRACT: **Laboratory mixer-granulator**

Device characteristics:

1.1. Technological requirements

Designed for lab scale mixing and granulation of powders in the R&D scale. Device/Machine have to ensure repeatability of specific batches.

1.2. Functional requirements

- self-contained mobile unit functionality,
- bottom driven,
- the device has a 3-blade stirrer,
- the device has a side granulating head (chopper),
- the device has an integrated peristaltic pump with variable workflow (forward/reverse direction) and priming/purging control,
- the device has spray nozzle and hoses for dispensing solutions
- Each elements of the device in contact with the manufactured product must be made of stainless steel 316L,
- device equipped with process vessel with volume about 6 liters (welds grinded and polished, RA 0,127 µm)
- process vessel lid (cover) made of transparent material, which will allow to ongoing process observation; process vessel lid can be blocked and have a round aperture for granulation media addition;
- granulation media feeding/spray system consisting of: spray nozzle mounted in the dedicated aperture in the vessel cover, integrated peristaltic pump and set of needed transport hoses,
- the device allows for smooth adjustment of the speed of the granulating head (chopper) in the range of at least 300 to 3000 rpm,
- device has a product temperature sensor in the process vessel,
- automatic mode and in the manual mode,
- control system based on PLC driver and touchscreen colour operator panel,
- control panel with display screen presenting currently performed operation/action and enabling control of device work/operation with functions such as:
 - Main propeller speed setting

- Chopper speed setting
 - Mixing time setting
 - the device allows you to read the following parameters from the control panel:
 - ✓ speed of the main agitator and granulating head (chopper)
 - ✓ speed of the peristaltic pump [rpm],
 - ✓ work/process time - mixing, dosing [s, min]
 - ✓ product temperature [°C],
 - ✓ stirrer torque (Nm),
 - control system which should allow to point out following machine states and process parameters:
 - Main propeller speed [rpm]
 - Chopper speed [rpm]
 - Main propeller torque [Nm]
 - Product temperature [°C]
 - Warnings, hints, alarm communications
 - Process time
 - USB port for exporting process data,
 - emergency switch
 - suitable for work with both aqueous solutions and solutions based on organic (ATEX zone 2)
 - all components of the device must be brand new
 - equipped with all elements and utensils needed to use the working module
 - Technical documentation of the set, IQ/OQ together with the instruction manual in Polish and English, containing the description and characteristics of the set to the extent necessary for the user.
 - Certificates for all materials that may come into direct contact with the product.
 - EC declaration of conformity and CE mark (meeting the EU safety requirements for the product)
 - Assembly of the working module to the drive unit and mechanical test of operation throughout range of available rotational speeds carried out by a qualified person an employee of the Supplier in the presence of a representative of the Ordering Party,
 - Training of the ordering party's staff (at least three employees) in the field of operation and operation (including cleaning and maintenance), combined with the presentation of the operation and operation of the working module and the drive unit, conducted at the ordering party's premises.
 - Warranty card in Polish, minimum warranty period: 12 months from the date of protocol handing over the set for use.
 - Device is upgradeable to enable the purchase of upgrades for additional functionalities:
 - Upgrade possibility with single walled processing vessels 1–4L,
 - Upgrade possibility with double walled (cooled, heated) processing vessels 1-4L,
- The contracting authority ~~allows~~ / does not allow partial bids.

III. PLACE OF ORDER EXECUTION

POLFARMEX S. A.

99-300 Kutno; ul. Józefów 9

IV. ORDER COMPLETION DEADLINE

- Order completion date: up to 14 weeks from the date of placing the order.

V. TERMS OF PARTICIPATION IN THE PROCEEDINGS

- Assured warranty and post-warranty service in EU
- Experience in supplying pharmaceutical companies, documented by a minimum of three completed deliveries within the last year.

VI. DESCRIPTION OF THE PRICE CALCULATION

- The price should be calculated in net and gross values and entered in the bid form.
- Prices expressed in a currency other than PLN will be converted into PLN according to the average exchange rate of the National Bank of Poland as of the date of opening the proceedings.
- The price should include all costs related to the execution of the order.

VII. OFFER EVALUATION CRITERIA

- When evaluating tenders, the Ordering Party will be guided by the following criteria:
 - Price - weight 70%
 - Order completion date - weight 30%

The point evaluation of the offer will be made in accordance with the following formula:

$$O_P = P_C + P_T$$

where:

O_P - point evaluation of the offer

P_C - the number of points obtained under the "Price" criterion

P_T - the number of points obtained under the criterion "Order completion date"

C_B - net price of the examined offer

- The number of points (P_C) in the "Price" criterion will be calculated according to the formula:

$$P_C = \frac{C_N}{C_B} * 90$$

- order completion time less than 12 weeks - 30 points
- order completion time from 12 to 13 weeks - 20 points
- order completion time over 13 weeks - 0 points

• The tender with the highest number of points will be considered the most advantageous. The offer can get a maximum of 100 points. Calculations will be made with an accuracy of two decimal places.

VIII. DATE AND FORM OF SUBMISSION OF OFFERS

- Bids must be submitted by the deadline of July 12, 2023.
- The bid should be submitted electronically in the form of documents signed by the bidder or scans thereof to: oferty.polfarmex@polfarmex.pl

IX. OTHER ESSENTIAL TERMS OF THE ORDER

Payment terms: transfer, VAT invoice, payment term 21 days.

Contractual penalties: in case the bidder fails to complete the order within the declared period, the contractual penalty is up to 5% of the order value.