Rzeczpospolita Polska

AGENCJA BADAŃ MEDYCZNYCH

Zakroczym, 05.December 2023 r.
place and date

MARKET INSIGHT FORM

I. Purpose of the form:

In relation to the execution of the project entitled **"Development of a two-component medicinal product used for the therapy of chronic obstructive pulmonary disease (COPD)"** co-financed from the national budget funds as part of the competitions organized by the Medical Research Agency, **we would like to ask you to provide the price of the planned order described in detail under item II below**.

Please sign this Market Insight Form and send a scan (in the pdf format) by e-mail to: zapytaniaofertowe@lekam.pl by: 13 December 2023.

If you need additional information, please contact us by e-mail: zapytaniaofertowe@lekam.pl.

II. Order specification:

1. The planned order concerns the delivery of the active substance.' micronized indacaterol maleate, as described in the detailed order specification.
2. CPV CODE: 24000000-4 Chemical products
3. Deadline for completing the subject of the order**: the subject of the order is planned to be delivered within:**

   – part 1 or the entire order: maximum 4 months from signing the contract;

   – part 2 (unless the entire amount was transferred in the first transport): maximum 4 months from the next campaign, but no later than one year from signing the contract.
4. By part we mean:

   – part 1: any amount of product, but not less than 340 g;

   – part 2: remaining quantity of the product necessary to complete the entire order (0.71 kg).
5. Place of completion of the order:
   Przedsiębiorstwo Farmaceutyczne LEK-AM sp. z o.o., Zakroczym
6. Detailed order specification:

Requirements
Specification

Raw material name: indacaterol maleate

Quantity: 0,71 kg

Raw material characteristics:

- ➢ Micronized substance;
- ➢ Substance in crystalline (form Q alfa);
- ➢ Particle size:
  - ➢ D(10) NMT ≤ 1 µm
  - ➢ D(50) NMT 1,5 – 2,5µm
  - ➢ D(90) NMT < 5 µm;
- Quantity of amorphous form specified on the manufacturer's certificate ≤ 5 %.

Doumentation

The following documents concerning the subject of the order should be delivered to the Ordering Party along with the raw material delivery:

certificate of analysis meeting the requirements of a specification compliant with the ICH Q6A requirements, containing the PSD results, amorphous form content results and microbiological testing data which confirm the microbiological quality for non-sterile substances for pharmaceutical purposes in accordance with the following requirements:

- ➢ TAMC NMT 10" CFU/g or CFU/mL
- ➢ TYMC NMT 10' CFU/g or CFU/mL PSD histogram and MSDS

Declaration on the size of the manufactured batch

- ➢ Declaration stating that the tests presented in the CoA were conducted using validated methods and/or in accordance with Ph. Eur.

Additional requirements

1. Retest period:
   a. Retest period for the micronized active substance of at least 3 years, supported by stability testing results for the micronized substance, including particle size distribution results and amorphous form content results

2. Transport conditions:
   in accordance with ASMF requirements

7. In order for the bid to be considered, the Bidder is obliged to submit the following documents along with the bid created according to the Information Template specified under item III or to state in this form that the relevant documents have been submitted to LEK-AM during previous cooperation:

- ➢ Complete EU ASMF documentation (open part) for the micronized substance with quality compliant with the requirements of EMA and ICH guidelines
- ➢ Confirmation of meeting the GMP requirements for its manufacturing in the form of a

GMP certificate for both the micronized active substance and the manufacturing of its intermediates (preferred confirmation by the European agency)

- Written confirmation of compliance with GMP (WC) in accordance with the Directive 2011/62/EU, if manufactured outside of Europe
- Nitrosamine risk analysis report compliant with ICH and EMA requirements
- Elemental impurity residue risk analysis report compliant with the ICHQ3D and EMA requirements
- Stability testing results for the micronized active substance batch. The provided results should include the particle size distribution (PSD) parameter.

III. Information template to be completed by the bidder:

Contractor's full name:……

Contractor's address: ……..

NIP (Numer Identyfikacji Podatkowej [Tax ID Number]):……..

Contact person: …….

Bid drafting date: …….

Offered pack size: ……

Net cost of the subject of the order:……

Total net cost of order completion: ……

Total gross cost of order completion: …….

Deadline for completion of the order: …….

Payment terms: …….

Next campaign date: …….

Net cost of one gram of the substance:……..

Total net cost of order completion: ……..

Total gross cost of order completion: ……..

Payment terms: …….

I hereby declare that the documents specified under item II.6 have been submitted by the Contractor to Przedsiębiorstwo Farmaceutyczne LEK-AM sp. z o.o. during previous cooperation. YES / NO*

**If NO is selected, please attach a complete document package to your bid.*

Rzeczpospolita Polska

AGENCJA BADAŃ MEDYCZNYCH

……

Date and place

……

Signature