

Zakroczym, 08.07.2024  
place and date

## MARKET INSIGHT FORM

### I. Purpose of form:

In connection with the implementation of the project entitled “Development of a two-component medicinal product for the therapy of chronic obstructive pulmonary disease (COPD)”, co-financed by the national budget as part of competitions held by the Medical Research Agency, **we would like to request again the value of the planned order described in detail below, under point II, and the information indicated in Annex 1 to this form.**

**Please affix your signature to this Market Insight Form and send a scan of it (in pdf format) by email to: [zapytaniaofertowe@lekam.pl](mailto:zapytaniaofertowe@lekam.pl) by 15.07.2024**

**Please include in the subject line of your e-mail: *COPD validation of the Raman method***

If you require any further information, please contact us by email: [zapytaniaofertowe@lekam.pl](mailto:zapytaniaofertowe@lekam.pl)

### II. Description of the subject of the contract:

1. The planned order relates to *validation of the Raman method for the determination of the amorphous form and the determination/confirmation of the crystalline form of the active substances, i.e. indacaterol maleate and glycopyrronium bromide, in an inhaled medicinal product containing both of these active substances and lactose monohydrate.*
2. CPV CODE: **73100000-3 - Research and experimental development services**
3. Deadline for completion of the subject of the contract: **31.06.2025 at the latest.**
4. Detailed description of the subject of the contract:

#### Subject of the contract

The subject of the service will be:

**1. Validation of a Raman method** for the determination of the percentage of the amorphous form and determination/confirmation of the crystalline form of the active substances i.e. indacaterol maleate and glycopyrronium bromide in the inhalation medicinal product Indacaterol + Glycopyrronium, 85 µg + 43 µg/capsule, powder for inhalation in hard capsules and lactose monohydrate. The method validation will include, as a minimum, the following parameters: specificity, accuracy (by estimation of recovery; 3 measurements in 3 replicates), precision (6 measurements in 3 replicates) and intermediate precision (3 independent measurements in 3 replicates each).

The subject matter of the contract should also include the need to record Raman spectra of the standards (amorphous and crystalline active substances, lactose monohydrate) necessary for its implementation. This will not be necessary if these spectra are held in the Contractor's database.



**2. To carry out analyses** to determine the content of the amorphous and crystalline forms of the active substances in the medicinal product as part of stability studies. Number of samples tested: 8 (each in triplicate), min. 2 samples per order, number of orders min. 3.

Tests from point 1 and 2 must be performed in the 3000 x 3000  $\mu\text{m}$  area, with a spectral resolution of approx.  $3\text{ cm}^{-1}$ .

#### Additional requirements

The Raman mapping process must be carried out on a Raman spectrometer equipped with the detector and software necessary to record and process the data in accordance with Ph. Eur. 2.2.48.

A report in English in accordance with ICH Q2 guidelines will be issued from the validation of the Raman method (point 1).

The research described above in the object of the contract (item 2) will be finalized by a report in English, which must include at least:

- the conditions of the measurement carried out;
- the percentage of amorphous and crystalline forms of the active substance in the samples;
- recorded images (maps) showing the samples under study.

(At this stage, the Contractor will only be responsible for taking measurements, the storage of the product samples in the stability chambers itself is the responsibility of the Client. Suitable samples will therefore be supplied successively by the Contractor).

The subcontractor undertakes to sign:

- Confidentiality Agreement (if not already signed)
- A quality agreement defining the scope of activities and responsibilities, which is necessary for the qualification of the subcontractor according to the GMP quality system (if not already signed)
- Consent to conduct a qualitative survey (if not previously conducted)

Materials provided by the Principal:

- patterns of the amorphous and crystalline forms of indacaterol maleate and glycopyrronium bromide
- example Raman spectra of standards: indacaterol maleate (crystalline and amorphous form), glycopyrronium bromide (crystalline and amorphous form), lactose; results from a reference product.

#### 5. Conditions for participation in the market research

#### Requirements for the contractor

Type of requirements	Description of requirements	Method of verification
Technical requirement	The contractor must be able to carry out tests on a Raman mapping spectrometer equipped with a confocal microscope and detector	The conditions will be verified on the basis of the bidder's declaration as per Annex 1 to this form.



	rapid and sensitive imaging and software for particle distribution and size analysis, differentiation and identification	
Experience requirements	The contractor should have a minimum of 3 years' experience in carrying out studies analogous to the subject of the contract at the closing date for submission of tenders.	The conditions will be verified on the basis of the bidder's declaration as per Annex 1 to this form.
Personnel requirements	The contractor must have a team of persons meeting the following requirements in total: <ul style="list-style-type: none"><li>• a university degree in chemistry or physics;</li><li>• experience in carrying out studies similar to the subject of this contract;</li><li>• knowledge of the analytical tools necessary for the execution of this contract;</li><li>• knowledge of the Raman spectroscopic method.</li></ul>	The conditions will be verified on the basis of the bidder's declaration as per Annex 1 to this form.

*Annex 1 to the market inquiry form*

**Information to be completed by the bidder:**

Full name of Contractor: .....

Contractor's address: .....

VAT No.: .....

Contact person: .....

Date of offer: .....

*Please indicate the currency in your offer!*

Study	Performed in cooperation with YES/NO	Net price per sample	Gross price per trial	Completion date*
<p>Validation of a Raman method for the determination of the percentage of the amorphous form and determination/confirmation of the crystalline form of the active substances i.e. indacaterol maleate and glycopyrronium bromide in the inhalation medicinal product Indacaterol + Glycopyrronium, 85 µg + 43 µg/capsule, powder for inhalation in hard capsules and lactose monohydrate. The method validation will include, as a minimum, the following parameters: specificity, accuracy (by estimation of recovery; 3 measurements in 3 replicates), precision (6 measurements in 3 replicates) and intermediate precision (3 independent measurements in 3 replicates each). Tests must be performed in the 3000 x 3000 µm area, with a spectral resolution of approx. 3 cm<sup>-1</sup>.</p>	X			
<p>Carrying out analyses to determine the content of the amorphous and crystalline forms of the active substance in the medicinal product as part of stability studies. Number of samples tested: 8 (each in triplicate), min. 2 samples per order, number of orders min. 3. Tests must be performed in the 3000 x 3000 µm area, with a spectral resolution of approx. 3 cm<sup>-1</sup>.</p>				

*\* calculated in weeks from the date of conclusion of the contract/order*

We declare that we will comply with the following conditions of the subject matter of the contract at the date of commencement of the work:

1. We will sign\*\* a confidentiality agreement with the Principal prior to the commencement of the assignment.
2. We will sign/have signed\*\* the quality agreement necessary to qualify the subcontractor according to the GMP quality system.
3. We agree to conduct a qualitative survey.
4. We have the opportunity to carry out research on a Raman mapping spectrometer, equipped with a confocal microscope and a fast and sensitive imaging detector, as well as software to analyse the distribution and size of particles, their distinction and identification.
5. As at the closing date for submission of offers, we have a minimum of 3 years' experience in carrying out studies analogous to the subject of the contract.
6. We have people available who meet the following requirements:
  - a university degree in chemistry or physics;
  - experience in carrying out studies similar to the subject of this contract;
  - knowledge of the analytical tools necessary for the execution of this contract;
  - knowledge of the Raman spectroscopic method.

*\*\* delete as appropriate*

.....  
*Date and place*

.....  
*Signature*