

Zakroczym, on 06 February 2024
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 value 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: 20 February 2024.

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 non-pharmacopoeial standards, as described in the specification.*
2. The Ordering Party allows the submission of partial offers for individual items specified in the detailed description of the subject of the order
3. CPV CODE: 33696300-8 - Chemical reagents
4. Deadline for completion of the order: all indicated in point II. 5 items are planned to be ordered by 31 December 2024 and should be delivered to the ordering party within a maximum of 8 weeks from the date of concluding the contract / placing the order. The Ordering Party reserves the right to place partial orders until 31 December 2024.
5. Place of completion of the order: Przedsiębiorstwo Farmaceutyczne LEK-AM sp. z o.o., Zakroczym
6. Detailed order specification:

Requirements	
Part of the order	Specification
Part 1	<p>name: Indacaterol maleate reference standard spiked with impurities * (mixture)</p> <p>quantity: 3 x 20 mg</p> <p>quality requirements:</p> <ul style="list-style-type: none"> • appearance: white or almost white powder • related substances (by HPLC) as required: <ul style="list-style-type: none"> - known impurity (each) min. 0.08% relative to the main peak of the active substance - maximum other impurity $\leq 0.10\%$ - total impurities $< 1.0\%$ • potency of standard $\geq 90\%$ • expiration/re-test date - preferred min. 12 months (in the case of a re-test, information about the possibility of re-testing the standard yes/no)



Part 2	<p>name: Indacaterol maleate racemate (isomer R+ isomer S 50% + 50%) reference standard**</p> <p>quantity: 3 x 50 mg (preferred 2 x 25 mg)</p> <p>quality requirements:</p> <ul style="list-style-type: none"> • appearance: white or almost white powder • enantiomeric ratio 0.95 – 1.05 • purity (by HPLC) \geq 90.0% • expiration/re-test date - min. 6 months (in the case of a re-test, information about the possibility of re-testing the standard yes/no)
	Documentation
For parts 1 and 2	<p>For each of the deliveries, the contractor must provide a quality certificate confirming the fulfillment of the quality requirements set out in the description of the subject of the contract for the ordered standards (in accordance with point II.5 of this form). The certificate should be delivered in paper form with the delivery.</p>

*standard must contain Indacaterol maleate tj. (R)-5-(2-((5,6-diethyl-2,3-dihydro-1H-inden-2-yl)amino)-1-hydroxyethyl)-8-hydroxyquinolin-2(1H)-one maleate and three listed below impurities:

1 (IND 05)	(R)-5-(2-((5,6-diethyl-2,3-dihydro-1H-inden-2-yl)amino)-1-ethoxyethyl)-8-hydroxyquinolin-2(1H)-one
2 (IND 07)	(R)-8-(benzyloxy)-5-(2-((5,6-diethyl-2,3-dihydro-1H-inden-2-yl)amino)-1-hydroxyethyl)quinolin-2(1H)-one
3 (IND 08)	(R)-5-(2-((5,6-diethyl-2,3-dihydro-1H-inden-2-yl)amino)-1-hydroxyethyl)-8-hydroxy-3,4-dihydroquinolin-2(1H)-one

**standard must contain Indacaterol maleate as mixture of:

(R)-5-(2-((5,6-diethyl-2,3-dihydro-1H-inden-2-yl)amino)-1-hydroxyethyl)-8-hydroxyquinolin-2(1H)-one

and

(S)-5-(2-((5,6-diethyl-2,3-dihydro-1H-inden-2-yl)amino)-1-hydroxyethyl)-8-hydroxyquinolin-2(1H)-one

7. Evaluation

The selection of the Contractor will be made from among the Offers meeting the quality requirements indicated in point II.5 of this form. The offered price will be assessed.

Information template to be completed by the bidder:

Contractor's full name:

Contact details:

Contractor's address:

Date of the offer:

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

Payment terms.....

Contact person:

Quotation							Specification	Meeting the requirements of the specification YES/NO ²⁾
Part no.	Name of the subject of the order	The size of the offered package [mg]	Total net price for the whole (for each part)	Total gross price for the whole (for each part)	Delivery costs	Other costs ¹⁾		
1.	Indacaterol maleate reference standard spiked with impurities * (mixture) 3 x 20 mg						appearance: white or almost white powder	
							related substances (by HPLC) as required: - known impurity (each) min. 0.08% relative to the main peak of the active substance - maximum other impurity ≤ 0.10% - total impurities < 1.0%	
							potency of standard ≥ 90 %	
							expiration/re-test date - preferred min. 12 months (in the case of a re-test, information about the possibility of re-testing the standard yes/no)	



2.	Indacaterol maleate racemate (isomer R+ isomer S 50% + 50%) reference standard** 3 x 50 mg (preferred 2 x 25 mg)						appearance: white or almost white powder	
							enantiomeric ratio 0.95 – 1.05	
							purity (by HPLC) \geq 90.0%	
							expiration/re-test date - min. 6 months (in the case of a re-test, information about the possibility of re-testing the standard yes/no)	

¹⁾ specify the type of cost and price

²⁾ please enter YES or NO for each item of the specification.

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Date and place

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Signature