**REQUEST FOR PROPOSALS FOR MICRONIZATION OF EC313 COMPOUND**

Case ZO-06-2019

Commencing a job within project no, POIR.01.01.01-00-0123/16 entitled ***"Development of Selective Endometriosis Therapy Based on Mesoprogestins"*** we invite to submit a tender for **MICRONIZATION PROCESS OF EC313 COMPOUND**.

1. **CONTRACTING ENTITY:**

Evestra Onkologia Sp. z o.o., seated in Łódź at ul. Jana Muszyńskiego 2 lok. 3. 22, 90-151 Łódź, KRS 0000544596, NIP 5311691730, REGON: 360861230, e-mail: [zamowienia@evestraonkologia.pl](mailto:mwierzbicki@evestraonkologia.pl);

1. **PROCEDURE TYPE:**

The procedure is in the form of a request for proposals according to the competitiveness rule, pursuant to art. 70¹ - 705 of the act of 23rd April 1964 – the Civil Code (Journal of Laws of 2018, item 1025, as amended.).

1. **GENERAL INFORMATION:**

The order is co-financed from the Smart Development Operating Programme 2014-2020 within the project no. POIR.01.01.01-00-0123/16 entitled ***"Development of Selective Endometriosis Therapy Based on Mesoprogestins"*** The project key objective is to validate a new active substance on in vitro and in vivo models and to perform clinical trials for further development of a new form of endometriosis therapy.

1. **DESCRIPTION OF THE SUBJECT OF THE PROCUREMENT:**
2. The subject of the procurement includes services of **MICRONIZATION PROCESS FOR EC313 COMPOUND** which is the subject of the project entitled: "Development of Selective Endometriosis Therapy Based on Mesoprogestins" A detailed scope of the procurement has been included in Attachment no. 3 hereto.
3. The Contracting Authority currently is aiming to develop a new endometriosis treatment option – antiprogestin EC313 and is looking for a subcontractor for micronization and analytical analysis of milled drug substance.
4. Target is to micronize the different scales of batch (100g-10000g) with GMP manufacturing process. 4. The Contractors shall present the offer - micronization package that will include analytical analysis of both not micronized and micronized drug substance. In the final offer following activities must be included:
5. For not micronized powder:

* X-Ray Powder Diffractometry (XRPD) analysis
* Differential Scanning Calorimetry (DSC) analysis

1. For micronized powder:
   * X-Ray Powder Diffractometry (XRPD) analysis
   * Differential Scanning Calorimetry (DSC) analysis
   * Comparison of XRPD analyses for both micronized and not micronized EC313
   * Comparison of DSC analyses for both micronized and not micronized EC313
   * Target values: d1o≤1µm; d5o≤4µm; d90≤8µm;
   * The offer should include the price for Micronization of following quantity of not micronized material.
2. The Contracting Authority allows to tender partial offers to the following tasks:

**TASK 1 – Mikronization 100g**

**TASK 2 – Mikronization 250g**

**TASK 3 – Mikronization 500g**

**TASK 4 – Mikronization 1000g**

**TASK 5 – Mikronization 1500g**

**TASK 6 – Mikronization 2000g**

**TASK 7 – Mikronization 3000g**

**TASK 8 – Mikronization 4000g**

**TASK 9 – Mikronization 5000g**

**TASK 10 – Mikronization 7000g**

**TASK 11 – Mikronization 10000g**

**5.** The Contracting Authority allows to award orders according to the competitiveness rule, pursuant to art. 67 pkt. 1 ppkt. 6 i 7 of the act of 29rd January 2004 – Public procurement law (consolidated text Journal of Laws 2019, item 1843), with a value not exceeding 50% of the basic contract.

1. Procurement Classification according to Common Procurement Vocabulary (CPV): 73.10.00.00 –3 Research, experiment and development services.
2. **DELIVERY DATE:**

The order shall be completed till 31 of December 2021.

1. **PROCEDURAL INFORMATION:**
2. Contractors who meet the following criteria can take part in proceedings:
3. in respect of available resources necessary for the due performance of the procurement, the Contractor shall be obliged to show it has a dedicated laboratory with equipment which allows for the performance of the tests with GMP standard;

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| **This condition shall be assessed based on a submitted statement** |

b) in respect of economic or financial situation necessary for the due performance of the procurement, the Contracting Entity has set no special condition.

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| **Evaluation of the fulfilment of the above condition will be made by means of the "fulfilment / non fulfilment" method based on the submitted statement concerning the fulfilment of conditions for participation in the procedure.** |

1. The following shall not cause exclusion from the procedure:
2. circumstances listed in Guidelines Chapter 6 sect. 6.5.1 item 8;
3. liquidation or no bankruptcy declared, excluding contractors who after being declared bankrupt executed a composition agreement approved by a legally valid court decision, if the agreement does not provide for satisfaction of creditors by liquidation of the bankrupt's assets.

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| **This condition shall be assessed based on documents listed in item 2 point 1, lett. a) and b)).** |

1. Apart from the declaration on meeting the criteria to participate in the proceedings which constitutes Attachment no. 1 hereto, the Contractor shall submit:
2. In order to confirm no grounds to exclude from the proceedings due to a conflict of interests, the Contractor shall submit:
3. a declaration according to a specimen which constitutes Attachment no. 2 hereto – regardless of its organisational and legal status;
4. In order to confirm the fulfilment of the condition described in pt. 1 pt. 1, the Contractor shall submit a copy of the GMP certificate or other equivalent document confirming possession of competence or authority to carry out activities in the scope covered by the subject of the order. A written statement of Contractor is regarded as fulfilling this requirement.

**The value of the offer should include all costs related to the implementation of the subject of the order, with the reservation that the Contracting Entity allows changes in the value of remuneration resulting from the need to purchase additional materials, raw materials, etc. to carry out the activities provided for in the order**

The Contractor may submit only one tender for the whole scope of the contract.

The offer should be made in the Polish or English, in a permanent way which guarantees that the content can be read.

1. The Contracting Entity recommends the tender to be prepared using forms which constitute attachments hereto or exactly according to the Offer Form which constitutes Attachment no. 1 hereto.
2. The Contracting Entity recommends numbering all the pages in the tender and securing them against getting disassembled by stapling or binding - for offers submitted in writing.

***“REQUEST* FOR PROPOSALS FOR MICRONIZATION PROCESS OF AN INVESTIGATIVE MEDICINAL SUBSTANCE INTENDED FOR CLINICAL RESEARCH USE.**

***Do not open before 16 01 2020. "***

1. **The Contracting Entity allows Contractors to submit motions and enquire about the contents hereof.** To this end, the Contracting Entity has established the following forms of communication with Contractors: electronic, to the address: zamowienia@evestraonkologia.pl. A written form shall always be acceptable. Enquiries should be submitted by December 31, 2019. Inquiries that should be received by the Ordering Party after the expiry of the above deadline should not be considered.
2. Any information regarding the proceedings shall be published by the Contracting Entity on its own website and in the competitiveness base under the address: bazakonkurencyjności.funduszeeuropejskie.gov.pl
3. Individuals authorised to contact Contractors:
4. for substantive issues:

- Prof. Katarzyna Błaszczak-Świątkiewicz

e-mail: kblaszczak@evestraonkologia.pl

- dr Ze'ev Shaked,

e-mail: zshaked@evestraonkologia.pl;

- Dr Maciej Wierzbicki,

e-mail: [mwierzbicki@evestraonkologia.pl](mailto:mwierzbicki@evestraonkologia.pl) ;

b) for formal issues:

- Robert Kochański, MA

e-mail: [rkochanski@evestraonkologia.pl](mailto:robertkochanski@evestraonkologia.pl) ;

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| **All electronic correspondence should be addressed CC: zamowienia@evestraonkologia.pl** |

1. The Contracting Entity may introduce changes in the terms and conditions of the proceedings. Provisions of point 12 shall apply respectively.
2. The Contracting Entity shall correct the offer in respect of obvious spelling errors, calculation mistakes considering calculation consequences resulting from the changes and other mistakes which make the offer incompliant with the request, provided this does not introduce essential changes in the offer.
3. The Contracting Entity shall request the contractor to remedy any deficiencies in the offer, and in particular the documents named in Chapter 6.
4. The Contracting Entity can invalidate the proceedings without providing any reason or terminate the proceedings without an outcome during each phase.
5. **The agreement should be concluded subject to the approval of the National Centre for Research and Development and it's approval of further research.**

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| **PLEASE NOTICE!** |
| According to art. 13 para. 1 and 2 of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of individuals with regard to the processing of personal data and on the free movement of such data and repealing Directive 95/46 / EC (general regulation on data protection) (OJ L 119, 04.05.2016, page 1), hereinafter "RODO", The Contracting Entity inform that: |
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| 1. the administrator of your personal data is Evestra Onkologia Sp. z o.o., ul. Jana Muszyńskiego 2 lok. 3.22, 90-151 Łódź, |
| 1. Your personal data will be processed on the basis of art. 6 par. 1 lit. c RODO for the purpose related to the public procurement procedure to carry out the development of micronization of drug substance for use in a clinical trial, case mark ZO-06-2019 |
| 1. recipients of your personal data will be persons or entities to whom the documentation of proceedings based on art. 8 and art. 96 para. 3 of the Act of January 29, 2004 - Public Procurement Law (Journal of Laws of 2017, item 1579 and 2018), hereinafter the "Act"; |
| 1. Your personal data will be stored, in accordance with art. 97 ust. 1 of the Act, for a period of 4 years from the date of completion of the procurement procedure, and if the duration of the contract exceeds 4 years, the storage period covers the entire duration of the contract; |
| 1. the obligation to provide your personal data directly to you is a statutory requirement set out in the provisions of the Act, related to participation in the public procurement procedure; the consequences of failure to provide specified data result from the Act; |
| 1. f. in relation to your personal data, decisions will not be taken in an automated manner, application to art. 22 RODO; |
| 1. you have: |
| * + 1. based on Article. 15 RODO the right of access to your personal data relating to; |
| * + 1. based on Article. 16 RODO right to rectify your personal data; |
| * + 1. based on Article. 18 RODO the right to request the administrator to restrict the processing of personal data, subject to the cases referred to in art. 18 para. 2 RODO; |
| * + 1. the right to file a complaint to the President of the Office for Personal Data Protection, if you decide that the processing of your personal data concerning you violates the provisions of the GDPR; |
| 1. you are not entitled to: |
| 1. in connection with art. 17 sec. 3 lit. b, d or e RODO right to delete personal data; |
| 1. the right to transfer personal data referred to in art. 20 RODO; |
| 1. based on Article. 21 RODO right to object to the processing of personal data, as the legal basis for the processing of your personal data is art. 6 par. 1 lit. c RODO. |

1. **PRINCIPLES OF PERSONAL DATA PROCESSING:**
2. In accordance with Article 13(1) and (2) of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of individuals with regard to the processing of personal data and on the free movement of such data and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 04.05.2016, p. 1), hereinafter referred to as "the GDPR", I hereby inform you that:
3. the administrator of your personal data is Evestra Onkologia Sp. z o.o., with its registered office in Łódź at ul. Jana Muszyńskiego 2 lok. 3.22, post office 90-151 Łódź, KRS 0000544596, NIP 5311691730, REGON: 360861230,
4. Your personal data will be processed on the basis of Article 6(1)(c) of the GDPR for the purpose of this procurement procedure,
5. the recipients of your personal data will be persons or entities to whom the documentation of conduct in accordance with the requirements of the horizontal guidelines will be made available,
6. Your personal data will be stored. for a period of 4 years from the date of completion of the contract award procedure, and if the duration of the contract exceeds 4 years, the storage period covers the entire duration of the contract,
7. your obligation to provide personal data directly to you is a statutory requirement in connection with your participation in a public procurement procedure; the consequences of not providing certain data result from the PUBLIC TENDER Act,
8. in relation to your personal data, decisions will not be taken by automated means, applying to Article 22 of the GDPR,
9. You have:

(a) the right of access to your personal data pursuant to Article 15 of the GDPR;

(b) The right to rectify your personal data pursuant to Article 16 of the GDPR;

(c) the right under Article 18 of the OROD to require the controller to restrict the processing of personal data, except in the cases referred to in Article 18(2) of the GDPR;

(d) the right to lodge a complaint with the President of the Office for the Protection of Personal Data if you consider that the processing of your personal data concerning you is in breach of the provisions of the GDPR.

1. You are not entitled to it:

(a) In conjunction with Article 17(3)(b), (d) or (e), the right to erasure of personal data;

(b) the right to transfer personal data as referred to in Article 20 of the GDPR,

1. The right to object to the processing of personal data pursuant to Article 21 of the GDPR as the legal basis for the processing of your personal data is Article 6(1)(c) of the GDPR.
2. **OFFER VALIDITY TERM:**

The Contractor shall be bound by the submitted tender for a period of 90 days. The 90-day period shall commence on the elapse of the deadline for tender submission.

1. **DEADLINE FOR THE SUBMISSION OF TENDERS:**
2. Tenders shall be submitted **till 16th of January 2020 12:00 hrs** – date and hour of reception by the Contracting Entity shall be binding.
3. The tenders shall be sent in an electronic format to the following address:[zamowienia@evestraonkologia.pl](mailto:zamowienia@evestraonkologia.pl). If the tender is sent in an electronic form, the Contractor shall safeguard the tender so that its content cannot become acquainted with before the elapse of the deadline for tender submission. Provisions of point 9 Chapter VI shall apply
4. The Contracting Entity does not provide for a public opening of tenders. According to the transparency rule of the proceedings, the Contracting Entity, upon a request from the Contractor, shall make the minutes from tenders' opening available.
5. **ASSESSMENT CRITERIA:**
6. The Contracting Entity shall evaluate the tenders according to the following tender assessment criterion:
7. Financial criterion (price) – weight 100 %;

The Contracting Entity shall score by dividing the value of the cheapest tender by the analysed offer value and then multiplying the outcome by the weight, according to the following formula: **WP= (WONC /WOB) x weight,** where WP – score value in the financial criterion, WONC – value of the cheapest tender, WOB – value of the analysed tender.

**NOTE:**

**Should the contractor provide prices in currencies other than PLN, the Contracting Entity shall use an NBP exchange rate of the date of publication of the request for proposal in the Competitiveness Base of the Ministry of Development. Exchange rate tables are available at:**  [**http://www.nbp.pl/home.aspx?f=/Kursy/kursy.htm**](http://www.nbp.pl/home.aspx?f=/Kursy/kursy.htm) **;**

**Should a tender be submitted which generates a tax obligation on the part of the Contracting Entity, according to the regulations on tax on goods and services, in order to evaluate such an offer, the Contracting Entity shall add the value added tax to the price provided therein which must be accounted for according to the said regulations. When submitting the tender, the Contractor shall advise the Contracting Entity whether its offer shall generate a tax obligation on the part of the Contracting Entity providing the name (type) of goods or services whose supply shall involve the tax and their net value. Should a tender be submitted which generates a tax obligation on the part of the Contracting Entity, according to the regulations on tax on goods and services, the price of the best or cheapest price shall be increased by the value added tax to the price provided therein which must be accounted for by the Contracting Entity according to the said regulations. Therefore, in such an instance, the price provided in the tender by such a contractor as "gross price" must not include VAT which the Contracting Entity shall be obliged to account for.**

the sum of all points scored for all the tests in a given task shall constitute the basis for assessment, based on the following formula: WP = (WTBO/WMAX) x weight, where: WP – point score for reports delivery criterion, WTBO – number of points scored for the proposed reports' delivery date. WMAX – maximum number of points within the completion date criterion.

1. **AMENDMENT OF THE CONTRACT:**

The Contracting Entity may amend the contract between the Contracting Entity and a Contractor, in case of:

1. changes which result from updating commonly applicable law;
2. reducing the fee amount due to limitation or exclusion of a part of the procurement by the Contracting Entity;
3. extension of the price of the contract, if additional micronization shall be provided, including repeating the micronization process for same amount a number of times;
4. change of the Contract term, in case the Project deadline varies;
5. change of the Contract term, in case the API availability is limited,
6. extension of the Contract term due to organisational issues on the part of the Contracting Entity or technical issues;
7. changes of the price of the contract due to changes to the API amount subject to micronization provided for in the Contract;
8. changes in individuals in charge of contacts and supervision over the contract.
9. occurrence of any events as a result of force majeure;
10. changes in a co-financing contract the Contracting Entity shall execute with an Intermediate Body;
11. **FINAL PROVISIONS:**

The procedure shall be governed by the Polish law. In any matters not stipulated herein, provisions of the act of 23rd April 1964 – the Civil Code (i.e. Off. J. of 2018, item 1025, as amended) and provisions of current Guidelines on Eligibility of Expenses within the European Regional Development Fund, European Social Fund and Cohesion Fund for the years 2014-2020.

Attachment no. 1 to the Request for proposal

Case ZO-06-2019

**Contracting Entity:**

**Evestra Onkologia Sp. z o.o.**

**ul. Jana Muszyńskiego 2 lok. 3.22**

**90-151 Łódź**

**TENDER FORM\***

**(copy for each task)**

Acting for and on behalf of the Contractor:

…............................................................................................................................................................

(CONTRACTOR'S NAME AND SURNAME/FULL NAME)

seated in / residence address \*\*…........................................................................................................

(RESIDENCE ADDRESS / SEAT ADDRESS)

…............................................................................................................................................................

(PHONE, FAX, E-MAIL)

in response to the request for proposal published on ………………………. at bazakonkurencyjności.funduszeeuropejskie.gov.pl and on the Contracting Entity's website, I am submitting a tender within the proceedings for **MICRONIZATION PROCESS FOR EC313 COMPOUND**, run in the form of a request for proposal.

I am offering the performance of the order within task no. …. for the price of: PLN ……………………………………………… gross (say: …………………………………………………........................................................................................).

The tender value includes all and any costs related to the performance of the order.

I declare that the order shall be completed till .............. (i.e. within ......... weeks from actual commencement).

I declare that I have experience needed for the due performance of the order.

I declare that I have infrastructure needed for the performance of the order.

I declare that I have qualified staff experienced in running micronization process.

I declare that I shall complete the order without / with subcontractors\*\* (if yes, provide the scope of the order which shall be subcontracted).

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I declare that I have obtained all and any information needed for the due performance of the order.

I shall be bound by this offer for a period of 90 days from the deadline for tenders' submission.

The tender together with attachments counts ……… pages.

\* - submit a separate form for each task for which the tender is submitted

\*\* - delete not applicable

…......................................... ………………………………………………………………………

Place, date: signature and personal stamp of the authorised signatory

Attachment no. 2 to the Request for proposal

Case ZO-06-2019

**DECLARATION ON MEETING PARTICIPATION CRITERIA**

**FOR THE PROCEEDINGS AND NO GROUNDS FOR EXCLUSION**

**DUE TO A CONFLICT OF INTEREST**

On submission of the tender for **MICRONIZATION OF EC313 COMPOUND**, I declare that the Contractor:

…............................................................................................................................................................

(CONTRACTOR'S NAME AND SURNAME/FULL NAME)

seated in / residence address \*\*…........................................................................................................

(RESIDENCE ADDRESS / SEAT ADDRESS)

…............................................................................................................................................................

(PHONE, FAX, E-MAIL)

**meets** the conditions for participation in respect of knowledge and experience, financial status, and technical and human potential;

**is not affiliated** to the Contracting Entity, personally or in terms of equity, by mutual relations between the beneficiary and individuals authorised to bind the beneficiary or individuals performing on behalf of the beneficiary actions related to preparation and running the proceedings for choosing a contractor and the contractor, which in particular includes:

1. being a partner to a civil partnership or another partnership
2. holding at least 10% of shares,
3. acting as member of a supervisory or management board, proxy, attorney
4. being married, in consanguinity or affinity in a straight line, in second degree of kinship or affinity of the second degree in collateral line or by adoption, guardianship or custody

….....................................................................................

signature and personal stamp of the authorised signatory

\*\* - delete not applicable

Attachment no. 3 to the Request for proposal

Case ZO-06-2019

**PRICE CALCULATION / SCOPE OF THE ORDER**

**Task 1 – Micronization 100g**

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| --- | --- | --- | --- | --- | --- | --- |
| No. | Study | Requirements (including standard) | Turnover (time) | Net price | Vat  rate | Gross  price |
| 1. | **EC313 not micronized**   * Analytical part | * X-Ray Powder Diffractometry (XRPD) analysis * Differential Scanning Calorimetry (DSC) analysis * **The price should include any other mandatory costs required to perform the study (if not indicated otherwise in the description) also report preparation** |  |  |  |  |
| 2. | **EC313 micronized**   * Analytical part   according to cGMP | * X-Ray Powder Diffractometry (XRPD) analysis * Differential Scanning Calorimetry (DSC) analysis * Comparison of XRPD analyses for both micronized and not micronized EC313 * Comparison of DSC analyses for both micronized and not micronized EC313 * Target values: d1o≤1µm; d5o≤4µm; d90≤8µm; * The offer should include the price for micronization of following quantity of not micronized material :   + 100g * **The price should include any other mandatory costs required to perform the micronization (if not indicated otherwise in the description) also report preparation, costs of milled material delivery to customer (please include options for delivery to Poland)** |  |  |  |  |
| 3 | Shipment | Delivery to Poland | |  |  |  |

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signature of authorised person

**Task 2 – Micronization 250g**

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| No. | Study | Requirements (including standard) | Turnover (time) | Net price | Vat  rate | Gross  price |
| 1 | **EC313 micronized**   * Analytical part   according to cGMP | * X-Ray Powder Diffractometry (XRPD) analysis * Differential Scanning Calorimetry (DSC) analysis * Comparison of XRPD analyses for both micronized and not micronized EC313 * Comparison of DSC analyses for both micronized and not micronized EC313 * Target values: d1o≤1µm; d5o≤4µm; d90≤8µm; * The offer should include the price for micronization of following quantity of not micronized material :   + 250g * **The price should include any other mandatory costs required to perform the micronization (if not indicated otherwise in the description) also report preparation, costs of milled material delivery to customer (please include options for delivery to Poland)** |  |  |  |  |
| 2 | Shipment | Delivery to Poland | |  |  |  |

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signature of authorised person

**Task 3 – Micronization 500g**

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| No. | Study | Requirements (including standard) | Turnover (time) | Net price | Vat  rate | Gross  price |
| 1 | **EC313 micronized**   * Analytical part   according to cGMP | * X-Ray Powder Diffractometry (XRPD) analysis * Differential Scanning Calorimetry (DSC) analysis * Comparison of XRPD analyses for both micronized and not micronized EC313 * Comparison of DSC analyses for both micronized and not micronized EC313 * Target values: d1o≤1µm; d5o≤4µm; d90≤8µm; * The offer should include the price for micronization of following quantity of not micronized material :   + 500g * **The price should include any other mandatory costs required to perform the micronization (if not indicated otherwise in the description) also report preparation, costs of milled material delivery to customer (please include options for delivery to Poland)** |  |  |  |  |
| 2 | Shipment | Delivery to Poland | |  |  |  |

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siganture of authorised person

**Task 4– Micronization 1000g**

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| No. | Study | Requirements (including standard) | Turnover (time) | Net price | Vat  rate | Gross  price |
| 1. | **EC313 micronized**   * Analytical part   according to cGMP | * X-Ray Powder Diffractometry (XRPD) analysis * Differential Scanning Calorimetry (DSC) analysis * Comparison of XRPD analyses for both micronized and not micronized EC313 * Comparison of DSC analyses for both micronized and not micronized EC313 * Target values: d1o≤1µm; d5o≤4µm; d90≤8µm; * The offer should include the price for micronization of following quantity of not micronized material :   + 1000g * **The price should include any other mandatory costs required to perform the micronization (if not indicated otherwise in the description) also report preparation, costs of milled material delivery to customer (please include options for delivery to Poland)** |  |  |  |  |
| 2 | Shipment | Delivery to Poland | |  |  |  |

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signature of authorised person

**Task 5 – Micronization 1500g**

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| No. | Study | Requirements (including standard) | Turnover (time) | Net price | Vat  rate | Gross  price |
| 1. | **EC313 micronized**   * Analytical part   according to cGMP | * X-Ray Powder Diffractometry (XRPD) analysis * Differential Scanning Calorimetry (DSC) analysis * Comparison of XRPD analyses for both micronized and not micronized EC313 * Comparison of DSC analyses for both micronized and not micronized EC313 * Target values: d1o≤1µm; d5o≤4µm; d90≤8µm; * The offer should include the price for micronization of following quantity of not micronized material :   + 1500g * **The price should include any other mandatory costs required to perform the micronization (if not indicated otherwise in the description) also report preparation, costs of milled material delivery to customer (please include options for delivery to Poland)** |  |  |  |  |
| 2 | Shipment | Delivery to Poland | |  |  |  |

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signature of authorised person

**Task 6 - Micronization 2000g**

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| No. | Study | Requirements (including standard) | Turnover (time) | Net price | Vat  rate | Gross  price |
| 1. | **EC313 micronized**   * Analytical part   according to cGMP | * X-Ray Powder Diffractometry (XRPD) analysis * Differential Scanning Calorimetry (DSC) analysis * Comparison of XRPD analyses for both micronized and not micronized EC313 * Comparison of DSC analyses for both micronized and not micronized EC313 * Target values: d1o≤1µm; d5o≤4µm; d90≤8µm; * The offer should include the price for micronization of following quantity of not micronized material :   + 2kg * **The price should include any other mandatory costs required to perform the micronization (if not indicated otherwise in the description) also report preparation, costs of milled material delivery to customer (please include options for delivery to Poland)** |  |  |  |  |
| 2 | Shipment | Delivery to Poland | |  |  |  |

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signature of authorised person

**Task 7 – Micronization 3000g**

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| No. | Study | Requirements (including standard) | Turnover (time) | Net price | Vat  rate | Gross  price |
| 1. | **EC313 micronized**   * Analytical part   according to cGMP | * X-Ray Powder Diffractometry (XRPD) analysis * Differential Scanning Calorimetry (DSC) analysis * Comparison of XRPD analyses for both micronized and not micronized EC313 * Comparison of DSC analyses for both micronized and not micronized EC313 * Target values: d1o≤1µm; d5o≤4µm; d90≤8µm; * The offer should include the price for micronization of following quantity of not micronized material :   + 3kg * **The price should include any other mandatory costs required to perform the micronization (if not indicated otherwise in the description) also report preparation, costs of milled material delivery to customer (please include options for delivery to Poland)** |  |  |  |  |
| 2 | Shipment | Delivery to Poland | |  |  |  |

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signature of authorised person

**Task 8 – Micronization 4000g**

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| --- | --- | --- | --- | --- | --- | --- |
| No. | Study | Requirements (including standard) | Turnover (time) | Net price | Vat  rate | Gross  price |
| 1. | **EC313 micronized**   * Analytical part   according to cGMP | * X-Ray Powder Diffractometry (XRPD) analysis * Differential Scanning Calorimetry (DSC) analysis * Comparison of XRPD analyses for both micronized and not micronized EC313 * Comparison of DSC analyses for both micronized and not micronized EC313 * Target values: d1o≤1µm; d5o≤4µm; d90≤8µm; * The offer should include the price for micronization of following quantity of not micronized material :   + 4kg * **The price should include any other mandatory costs required to perform the micronization (if not indicated otherwise in the description) also report preparation, costs of milled material delivery to customer (please include options for delivery to Poland)** |  |  |  |  |
| 2 | Shipment | Delivery to Poland | |  |  |  |

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signature of authorised person

**Task 9 – Micronization 5000g**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| No. | Study | Requirements (including standard) | Turnover (time) | Net price | Vat  rate | Gross  price |
| 1. | **EC313 micronized**   * Analytical part   according to cGMP | * X-Ray Powder Diffractometry (XRPD) analysis * Differential Scanning Calorimetry (DSC) analysis * Comparison of XRPD analyses for both micronized and not micronized EC313 * Comparison of DSC analyses for both micronized and not micronized EC313 * Target values: d1o≤1µm; d5o≤4µm; d90≤8µm; * The offer should include the price for micronization of following quantity of not micronized material :   + 5kg * **The price should include any other mandatory costs required to perform the micronization (if not indicated otherwise in the description) also report preparation, costs of milled material delivery to customer (please include options for delivery to Poland)** |  |  |  |  |
| 2 | Shipment | Delivery to Poland | |  |  |  |

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signature of authorised person

**Task 10 – Micronization 7000g**

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| --- | --- | --- | --- | --- | --- | --- |
| No. | Study | Requirements (including standard) | Turnover (time) | Net price | Vat  rate | Gross  price |
| 1. | **EC313 micronized**   * Analytical part   according to cGMP | * X-Ray Powder Diffractometry (XRPD) analysis * Differential Scanning Calorimetry (DSC) analysis * Comparison of XRPD analyses for both micronized and not micronized EC313 * Comparison of DSC analyses for both micronized and not micronized EC313 * Target values: d1o≤1µm; d5o≤4µm; d90≤8µm; * The offer should include the price for micronization of following quantity of not micronized material :   + 7kg * **The price should include any other mandatory costs required to perform the micronization (if not indicated otherwise in the description) also report preparation, costs of milled material delivery to customer (please include options for delivery to Poland)** |  |  |  |  |
| 2 | Shipment | Delivery to Poland | |  |  |  |

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signature of authorised person

**Task 11 – Micronization 10000g**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| No. | Study | Requirements (including standard) | Turnover (time) | Net price | Vat  rate | Gross  price |
| 1. | **EC313 micronized**   * Analytical part   according to cGMP | * X-Ray Powder Diffractometry (XRPD) analysis * Differential Scanning Calorimetry (DSC) analysis * Comparison of XRPD analyses for both micronized and not micronized EC313 * Comparison of DSC analyses for both micronized and not micronized EC313 * Target values: d1o≤1µm; d5o≤4µm; d90≤8µm; * The offer should include the price for micronization of following quantity of not micronized material :   + 10kg * **The price should include any other mandatory costs required to perform the micronization (if not indicated otherwise in the description) also report preparation, costs of milled material delivery to customer (please include options for delivery to Poland)** |  |  |  |  |
| 2 | Shipment | Delivery to Poland | |  |  |  |

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signature of authorised person