



CONFIRM: \_\_\_\_\_  
 JSC "Olainfarm" Chairman of the Board  
 Lauris Macijeviskis  
 Olaine, October 15<sup>th</sup> 2019

**Description of the Procurement Subject**

**1. General information about the customer:**

Name of the company: JSC "Olainfarm"

Registration number: 40003007246

Address: 5 Rupnicu street, Olaine, LV-2114, Latvia

Contact person: Alexandr Bolotin, Head of API analytical laboratory, phone: +371 67013733, e-mail: alexandr.bolotin@olainfarm.com

**2. Procurement subject:**

**API Phenibut related substance acetone cyanohydrin determination method development and validation**

	Job assignment	1. Method development for acetone cyanohydrin determination, with the specification limit being of 0.10 % to API; 2. Acetone cyanohydrin determination method validation. 3. Analysis of 6 batches of customer's Phenibut API for the content of Acetone cyanohydrin under GxP conditions. CoA issuing for the test results.
1.	Acetone cyanohydrin determination method development	Describe selected method conditions in the development report.
2.	Acetone cyanohydrin determination method validation	Perform method validation according to ICH Q2(R1) requirements. Parameters to be tested: - Specificity - Linearity - Range - Accuracy - Precision (repeatability and intermediate precision) - LOQ/LOD - Testing solution stability - Robustness
3.	Analysis of 6 batches of customer's Phenibut API for the content of acetone cyanohydrin under GxP conditions. CoA issuing for the test results.	Test Phenibut API batches provided by a customer for the content of Acetone cyanohydrin under GLP(GMP) conditions. On test performing issue CoAs for the batches tested showing the results of acetone cyanohydrin content.

### 3. Criteria for selection of offers:

1.	Applicant's experience:	At least 3 year experience in the development of analytical methods for quantitative determination of impurities in APIs and/or final dosage formulations.
2.	Applicant's resource:	1. An applicant has appropriate staff. 2. Applicant has the necessary technical equipment to carry out the studies (method development and validation) in accordance with the requirements of the present procurement subject.
3.	Offer expires:	31.12.2019.
4.	Delivery terms:	Development and validation reports must be prepared in English language and must be delivered (electronically and in paper) to the customer according to deadline for the execution of work.
5.	Deadline for the execution of work:	Not later than 30.06.2020.
6.	Scope of the offer:	The offer has to be submitted for all the procurement tasks.
7.	Compliance:	In case of possible equivalent for requirements listed in the description of procurement subject, unforeseen by the customer, the applicant can submit equivalent offer in conformity with requirements. The applicant can also submit the offer, which corresponds to higher (better) requirements.
8.	Price:	Price shall be specified in EUR (without VAT)
9.	Payment terms:	The applicant agrees that the payment terms are defined in the agreement. The maximum allowed advance payment is 25 %. The final payment is not less than 20 %.
10.	Applicable documents to the offer:	1. Copies of documents verifying the applicant's legal status. 2. The list of the inspections performed by EMA and/or by EU member state Regulatory Authority over the last five (5) years (indicating the date of inspection, the name of inspection authority, area of inspection (GMP and/or GLP) and critical findings (Yes/No). 3. A copy of GxP certificates.
11.	Requirements for offer preparation:	1. Offer shall be submitted in accordance with the described in Procurement subject. 2. Offer shall be submitted in two (2) original, typed either in the English language. 3. Offer preparation date, place and number, as well as the signature and printed name of signature shall be indicated. 4. Offer should be sent via post or delivered personally to the following address: Ansis Pekss, Deputy Head of Development Project unit, JSC "Olainfarm" 5 Rupnicu Street, Olaine, LV-2114, Latvia. 5. The signed and scanned offer should be sent to Ansis Pekss, e-mail address: <a href="mailto:apekss@olainfarm.lv">apekss@olainfarm.lv</a>