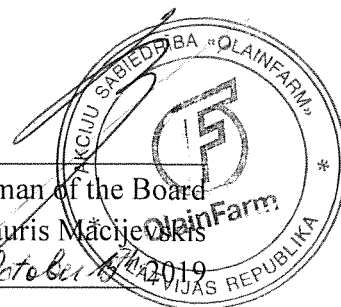


CONFIRM:
JSC "Olainfarm" Chairman of the Board
Lauris Mācijs
Olaine, *October 16, 2019*



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:

Method validation for 2,4,6,8-Tetramethyl-2,4,6,8-tetraazobicyclo[3.3.0]octane-3,7,-dione related substance determination

Job assignment	<p>1) Method validation (HPLC-UV) To validate a method for related substance content determination in 2,4,6,8-Tetramethyl-2,4,6,8-tetraazobicyclo[3.3.0]octane-3,7,-dione API. Specification limits:</p> <ul style="list-style-type: none">- impurity A NMT 0.4 %- impurity B NMT 0.3 %- any unidentified impurity NMT 0.4 %- total impurities NMT 1.0 % <p>Method validation to be performed according to ICH Q2(R1) requirements.</p> <p>Parameters to be tested and minima acceptance criteria:</p> <ul style="list-style-type: none">- Specificity Resolution ≥ 1.5 between a critical pair of peaks- Linearity and range $n \geq 6$, $R > 0.990$, Residual standard deviation ≤ 5 % Range from LOQ to at least 120 % of specification- Accuracy At least $n = 9$ (at least three concentration levels covering the specified range) Mean recovery is within 95-105 %, RSD of mean recovery ≤ 5 % Recovery at the LOQ level is within 90-110%
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	<p>- Precision <i>Repeatability:</i> to be assessed at the LOQ level (RSD ≤ 10 %) and the level of 100 % (RSD ≤ 5 %) to the specification limit or a minimum of 9 determinations covering the specified range (RSD to be defined)</p> <p><i>Intermediate precision</i> RSD is not more than doubled value for repeatability</p> <p>- LOQ/LOD LOD: peak signal/noise ratio ≥ 3:1 LOQ: peak signal/noise ratio ≥ 10:1</p> <p>- Testing solution stability Changes between the values of responses at initial time and those at each tested point NMT 10.0 % within stability period. Confirmation of SST acceptance criteria at each tested time point.</p> <p>- Robustness Check effects of at least mobile phase, flow rate, column temperature and injection volume changes, as well as different lot of columns. Deviations of impurity content NMT 10%. Confirmation of SST acceptance criteria for each variation of the factors.</p> <p>2) Method transfer to a customer QC laboratory. Optional; in case if the method changes as compared to initial method project To transfer a validated method using a spike solution technique: - substance solutions spiked with known impurities; - at least three concentration levels covering the specified range. Acceptance criteria: Difference between results of two laboratories NMT 10.0 % (30 % if at LOQ level).</p>
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3. Criteria for selection of offers:

1.	Applicant's experience:	At least 3 year experience in the development and validation 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 30.04.2020.
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:	<ol style="list-style-type: none"> 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:	<ol style="list-style-type: none"> 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: apekss@olainfarm.lv

Sagatavoja:

Saskaņoja: