



**CPAchem Ltd.**  
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## **Invitation for participation in proficiency testing (PT)**

**Field: Pharmaceuticals**

**Identification: Impurities**

### **Purpose:**

- Evaluation of performance of participating laboratories;
- Establishment of effectiveness and comparability of testing or measurement methods;
- Establishment of equivalence and comparability of results in measurement of impurities.

**PT scheme coordinator:** Dimka Ivanova

**Характеристики, обект на измерване и обхват на величината**

**Description of object/sample for comparison, measurand and range:**

1 x 100 ml solution of sodium hydroxide

Measurands, range:

Chlorides	(20 – 100) ppm
Sulphates	(20 – 100) ppm
Iron	(20 – 100) ppm
Heavy metals (as Pb)	(20 – 100) ppm

**Homogeneity and stability test:** Homogeneity and stability tests are performed by following the procedure, described in ISO/IEC 13528: Statistical methods for use in Proficiency Testing by Interlaboratory Comparisons and/ or interlaboratory procedures MQP 5.13.1 and MQP 5.14.1

**Method for characterization and assigning value of characteristic/characteristics:** certified value, obtained by characterization in ASPL

**Information for the methods which can be used for sample preparation and testing of participating laboratories:** Participants use routine testing methods

**Expected number of participants:**30

**Participation fee:** 176 EUR

**Technical protocol:** The technical protocol is provided to the participants before the beginning of comparison.

**Transportation of sample, subject to proficiency testing:**



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Samples, subject to PT are sent in proper packaging and as per terms, guaranteeing the integrity of material during transportation. After the material is delivered, CPAChem does not take any responsibility if the material was not handed to the respective specialist or if it wasn't stored as per the recommended conditions. Participant's are obliged to check the contents if the shipment in the moment of delivery and contact the PT Coordinator in case of any problems connected with material's condition or the accompanying documents. If the package was received damaged, the participant should send a picture, if possible. If a return of the PT sample is necessary, the participant shall receive instructions.

**Evaluation of results:** Results of participants will be evaluated as per  $z$  – score and “ $\zeta$  -zeta” criteria (for laboratories, presenting results with associated uncertainty).

**Accreditation:** According to ISO/IEC 17043 № AP2024 ANSI-ASQ National Accreditation Board

**Declaration of confidentiality:** ASPL will preserve strictly the information for all the participating laboratories and also for the obtained results via an identification code for every participant. The identification code will be provided by the coordinator to the participant together with the technical protocol.

**Time of conducting:**

Beginning 07.11.2016

End 09.12.2016

**Terms for participation**

- The participation fees in the PT are paid after registration confirmation;
- If the results are insufficient, the paid fees are not paid back;
- The participants can object against the evaluation of their results. The objections are submitted in free written form to the ASPL Manager. The PT scheme coordinator responds in 10-days.

**Date: 25.01.2016**

**PT scheme coordinator: Dimka Ivanova**

**ASPL Manager: Krassimira Taralova**