

## Certificate of analysis

<b>Work Order</b>	: <b>FP1311512</b>	<b>Issue Date</b>	: 30-AUG-2013
<b>Client</b>	: <b>ALS Czech Republic, s.r.o.</b>	<b>Laboratory</b>	: ALS Czech Republic, s.r.o.
<b>Contact</b>	: Kristína Jánosová	<b>Contact</b>	: F&P Client Service
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<b>Project</b>	: Zkusební zakázka	<b>Page</b>	: 1 of 3
<b>Order number</b>	: ----	<b>Date of test</b>	: 29-AUG-2013 - 30-AUG-2013
<b>C-O-C number</b>	: ----	<b>Quote number</b>	: PR2008ALSCR-CZ0020
<b>Site</b>	: ----		
<b>Sampled by</b>	: ----		

### General Comments

This report shall not be reproduced except in full, without prior written approval from the laboratory.  
The laboratory declares that the test results relate only to the listed samples.

### Responsible person

Responsible for accuracy of reported results are persons listed below. The results were approved and authorized for reporting according to the procedures specified in the document CZ\_SOP\_D06\_GMP\_04 Approval and authorization of results which is in accordance with the procedures specified in FDA document CFR Title 21, Part 11.

Name	Position	Authorization date
Jan Vanek	Metals coordinator	30-AUG-2013
Vendula Prokoratova	Pharmaceutical Section Supervisor	29-AUG-2013





## Analytical Results

### Aqua Purificata

Sub-Matrix: PHARMACEUTICAL		Client sample ID	Vzorek	Aqua Purificata			
		Laboratory sample ID	FP1311512001				
		Client sampling date / time	29-AUG-2013 00:00				
Parameter	Method	Unit	Result	Low	High	Unit	Evaluation
<b>Chemical Parameters</b>							
Electrical Conductivity @ 20°C	P-CON-ELE01	µS/cm	1	----	4.3	µS/cm	Pass
<b>Total Metals / Major Cations</b>							
Mercury	P-HG-AMAT	mg/kg	<0.003	----	----	----	----

### Ad-hoc Guideline

Sub-Matrix: PHARMACEUTICAL		Client sample ID	Vzorek	Ad-hoc_FP1311512001_PHARMACEUTIC AL/VET			
		Laboratory sample ID	FP1311512001				
		Client sampling date / time	29-AUG-2013 00:00				
Parameter	Method	Unit	Result	Low	High	Unit	Evaluation
<b>Chemical Parameters</b>							
Electrical Conductivity @ 20°C	P-CON-ELE01	µS/cm	1	----	----	----	----
<b>Total Metals / Major Cations</b>							
Mercury	P-HG-AMAT	mg/kg	<0.003	----	20	mg/kg	Pass

## Descriptive Results

Sub-Matrix: PHARMACEUTICAL

Sub-Matrix: PHARMACEUTICAL		Client sample ID	Vzorek		
		Laboratory sample ID	FP1311512001		
		Client sampling date / time	29-AUG-2013 00:00		
Compound	Method	Result	Limit	Evaluation	
<b>Chemical Parameters</b>					
Acid or Alcalic Substances	P-AAS-VIS01	solution 1 is not red, solution 2 is not blue	solution 1 is not red, solution 2 is not blue	pass	
Calcium and Magnesium	P-CAMG-VIS01	brightly blue colour	brightly blue colour	pass	
Chloride	P-CL-VIS02	without turbidity	without turbidity	pass	
Heavy Metals	P-HMET-VIS01	<0.1 µg/g	<0.1 µg/g	pass	
Ammonia and ammonium ions	P-NH4-VIS01	<0.2 µg/g	<0.2 µg/g	pass	
Nitrates	P-NO3-VIS02	<0.2 µg/g	<0.2 µg/g	pass	
Oxidising Substances	P-OXS-VIS01	solution colour is light pink	solution colour is light pink	pass	
Residue after vaporization	P-RES-GR01	<1 mg (100 mL)	<1 mg (100 mL)	pass	
Sulfate	P-SO4-VIS02	without turbidity	without turbidity	pass	

If the client does not specify the date and time of sample collection, the laboratory will specify the date on sample delivery in parentheses, instead. If the time of sample collection is specified as 0:00 it means that the client did specify the date but not the time.

**The end of result part of the certificate of analysis**

## Brief Method Summaries

Analytical Methods	Method Descriptions
Location of test performance: Na Harfe 336/9 Prague 9 - Vysocany Czech Republic 190 00	
P-AAS-VIS01	Czech Pharmacopoeia / European Pharmacopoeia; Determination of Acid or Alcalic Substances in Aqua Dialysi, Aqua Purificata and Aqua pro Injectione

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<i>Analytical Methods</i>	<i>Method Descriptions</i>
P-CAMG-VIS01	Czech Pharmacopoeia / European Pharmacopoeia; Determination of Calcium and Magnesium in Aqua Purificata and Aqua pro Injctione
P-CL-VIS02	Czech Pharmacopoeia / European Pharmacopoeia; Determination of Chlorides in Aqua Purificata and Aqua pro Injctione
P-CON-ELE01	Czech Pharmacopoeia / European Pharmacopoeia; Determination of Electrical Conductivity at 20°C - Aqua Purificata, Aqua pro Injctione
P-HG-AMAT	CZ_SOP_D06_02_003 (CSN 46 5735, CSN 75 7440, samples prepared as per CZ_SOP_D06_02_J02 chap. 10.1 to 10.17.14) Determination of Hg by Atomic Absorption Spectrometry. Method in accordance with Czech Pharmacopoeia / European Pharmacopoeia chapter 2.2.23.
P-HMET-VIS01	Czech Pharmacopoeia / European Pharmacopoeia; Determination of Heavy Metals in Aqua Dialysi, Aqua Purificata and Aqua pro Injctione
P-NH4-VIS01	Czech Pharmacopoeia / European Pharmacopoeia; Determination of Ammonia in Aqua Dialysi, Aqua Purificata and Aqua pro Injctione
P-NO3-VIS02	Czech Pharmacopoeia / European Pharmacopoeia; Determination of Nitrates in Aqua Purificata and Aqua pro Injctione
P-OXS-VIS01	Czech Pharmacopoeia / European Pharmacopoeia; Determination of Oxidable Substances in Aqua Dialysi, Aqua Purificata and Aqua pro Injctione
P-RES-GR01	Czech Pharmacopoeia / European Pharmacopoeia; Determination of Residue after Vaporization in Aqua Purificata and Aqua pro Injctione
P-SO4-VIS02	Czech Pharmacopoeia / European Pharmacopoeia; Determination of Sulfates in Aqua Purificata and Aqua pro Injctione