



Pharmaceutical (PHARMASSURE) PH0427 - Scientific Centre of Drug and Medical Technology Expertise JSC Individual Report

Round: 61

Issue Number 1

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Sample Details

Samples were despatched on 5 June 2017
The reporting deadline was 3 July 2017

The following samples were distributed in Pharmassure round 61:

Basic Chemical Testing

- 1A: 1 x 60mL buffer solution for determination of pH.
- 1B: 1 x 60mL acid solution for acid/base titration.
- 1C: 1 x 60mL sodium bicarbonate solution for methyl orange titration.
- 1D: 1 x 60mL olive oil sample for determination of density.
- 1E: 1 x 60mL sugar solution for determination of refractive index.
- 1F: 1 x 2g sample of succinic acid for determination of melting point.

Advanced Chemical Testing

- 2B Trace elements: 1 x 5g of sample for trace elements determination in caffeine and 1 x 1g of caffeine for matrix recovery/matching.
- 6A Gas chromatography (GC): 1 x 0.1g methyl behenate, 1 x 1ml bupivacaine HCl reference standard, 8ml Sample A.
- 6B UV: 1 x 1ml Hydrocortisone acetate.
- 6C Viscosity: 1 x 250ml test solution.
- 7A Dissolution testing: 16 ibuprofen tablets, 1 x 0.2g ibuprofen reference standard.

Microbiological testing

- 3:1 x freeze-dried vial resuscitated in 100ml diluent containing *Enterobacter aerogenes*.
- 5: 5 x Freeze-dried vial resuscitated in 100ml diluent. Samples B and C were sterile and samples A, D and E contained low-levels (<50 cfu per 100ml) of *Candida albicans*.

Further information regarding assigned values, performance assessment and technical comments can be found under the individual sample and analyte results.

Individual Report

This individual report contains a summary of all the results submitted and the performance assessments for your laboratory and your individual analysts. Please note that nominated laboratory results are represented by a blue highlight in the analyst box.

Data statistics given in the individual report are for the method you have used for each analyte. Further detail can be obtained from the main report.

Full details of the scheme, sample types, analytes and data analysis can be found in the corresponding Main Report, along with any technical comments, if applicable. The Main Report is the definitive version.

If you have any questions regarding your results which are not answered in the Main Report, please contact us using the details on the front of the report. If you would like to order any samples for re-test, please contact our customer service department or your local office.

Results Summary

Sample	Results Reported	Satisfactory Results	Questionable Results	Unsatisfactory Results	Not Assessed [^]
6A - Gas Chromatography (GC)	1	1	0	0	0
7A - Dissolution testing	2	2	0	0	0
Round Total	3	3	0	0	0

[^] Results which are Not Assessed should be reviewed by comparing them with the assigned value and other relevant statistics given in the main report. Participants, according to their internal quality criteria, may consider Not Assessed results to be satisfactory, questionable or unsatisfactory. Further information regarding why results may not be assessed is given in the Scheme Information section of the main report.

Please note surplus PT samples are available as QC materials once the round has closed. These samples can be purchased at a reduced rate if you have taken this sample during the main round.

No unsatisfactory results in this round

No questionable results in this round

6A - Gas Chromatography (GC)

Analyte	Analyst	Method	Result	Ux	Units	z score (** z' score)	Assigned Value	Ux AV	SDPA	Exp.SDPA	No of results	Median	Mean	Robust SD	SD
Bupivacaine hydrochloride	Lab Result	Other	13.75	0.13	mg/ml	0.00 **	13.75	1.10	2.922	3.122	2	14.40	14.40	0.957	0.912

7A - Dissolution testing#

Analyte	Analyst	Method	Result	Ux	Units	z score (** z' score)	Assigned Value	Ux AV	SDPA	Exp.SDPA	No of results	Median	Mean	Robust SD	SD
Ibuprofen in acetate buffer, pH 4.5#	Lab Result	Other	50.92	0.82	%	0.12	50.57	0.74	2.847	N/A	4	49.83	49.79	2.788	2.413
Ibuprofen in phosphate buffer, pH 6.8#	Lab Result	Other	100.24	1.73	%	0.16	99.85	0.62	2.491	N/A	4	100.07	100.16	0.549	0.638

** Please note, participant performance for this analyte has been assessed using a z' score, rather than a z score, in order to account for the measurement uncertainty of the assigned value which is not negligible when compared to the SDPA.

