



Verification of Calibration Curve

Analyte	Phencyclidine (PCP)
Units of Measure	ng/mL
Analyst Performing Verification Studies	Tanuja Sathiraj
Responsible Supervisor	Dayong Lee
Start Date	October 26, 2018
Completion Date	November 14, 2018
Primary Matrix	Blood
Secondary Matrix	N/A
Low Calibrator Concentration	5
Highest Calibrator Concentration	100
Equipment/Instrument	GCMS-4
Instrument Serial Number	CN10937043
Method	PCP.M

Verification Approval

Analyst: _____ 11/14/2018
Date

Responsible Supervisor: _____
Date

Verification

Analyte: Phencyclidine
Units: ng/mL

New Lots of Calibration Solutions

Current Lot: 110617C-C-0.1, 110617C-C-1
New Lot: 181017C-C-0.1, 181017C-C-1

Calibration

Calibrator	Target Conc.	Current Cals (x)*	New Cals (y)*	% Difference
5CAL	5.00	4.54	4.25	-6.60
10CAL	10.00	10.18	8.38	-19.40
25CAL	25.00	27.12	21.50	-23.12
50CAL	50.00	50.67	42.94	-16.52
75CAL	75.00	74.74	64.16	-15.23
100CAL	100.00	97.72	84.52	-14.49

*Calculated concentrations using current calibration lot

Slope	0.8670
Std err in slope	0.0107
Confidence level	95%
95% CI Range	0.8373 - 0.8967

REVIEW

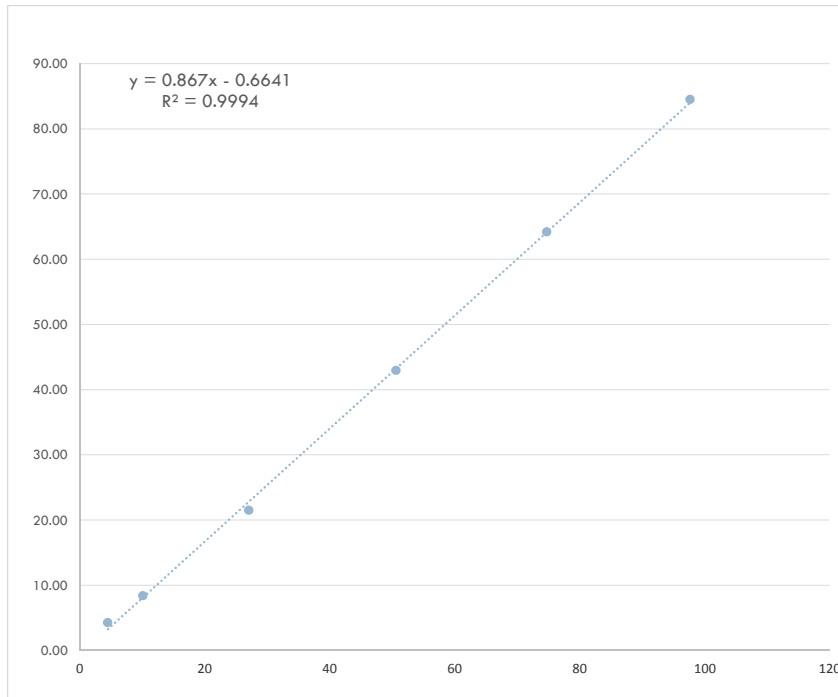
Intercept	-0.66405
Std err in Intercept	0.59527
Confidence Level	95%
95% CI Range	-2.3168 - 0.9887

PASS

New Calibrator Lot

Sample	Nominal Conc.	Concentration	% of Nominal	
New 5CAL	5.00	5.00	0.00	PASS
New 10CAL	10.00	9.84	-1.60	PASS
New 25CAL	25.00	25.24	0.96	PASS
New 50CAL	50.00	50.39	0.78	PASS
New 75CAL	75.00	75.3	0.40	PASS
New 100CAL	100.00	99.19	-0.81	PASS

*Calculated concentrations using new calibration lot



Pass/Review

Review

Comments:

When the new calibrators are plotted against the current calibrators, the 95% CI of slope does not include 1. On page 2, the percent differences between the target concentrations and the control concentrations quantified against the new calibrators (*) shows positive bias ranging from 2% to 19%. The percent differences between the target concentrations and the control concentrations (**) quantified against the current calibrators are small (<1%). The current calibrators and current controls were prepared using the VWR pipettes that are currently not in service. When external calibration certificate of VWR pipette 3266 (the pipette used to make the current calibrator) was compared with the Thermo Fisher Scientific pipette 8937 (the pipette used to prepare the current calibrator), the percent bias was less than 2% (see external calibration sheet). However, when an inhouse pipette performance check was performed using the VWR 3266 pipette there was a 13% positive bias and less than 2% negative bias using Thermo Fisher Scientific pipette 8937 at the target volume of 25 μ L, which is the volume used to prepare the new calibrators (See in-house pipette check sheet). Therefore, the positive bias on page 2 (*) could be due to using pipettes from different manufacturers to prepare the current and new calibrators. The new calibrators are deemed acceptable because the controls are within +/- 20% of the target value.

Approved?

Yes

Verification

Analyte: Phencyclidine
Units: ng/mL

New Lots of Calibration Solutions

Current Lot #: 110617C-C-0.1, 110617C-C-1
New Lot #: 181017C-C-0.1, 181017C-C-1

New Calibrators

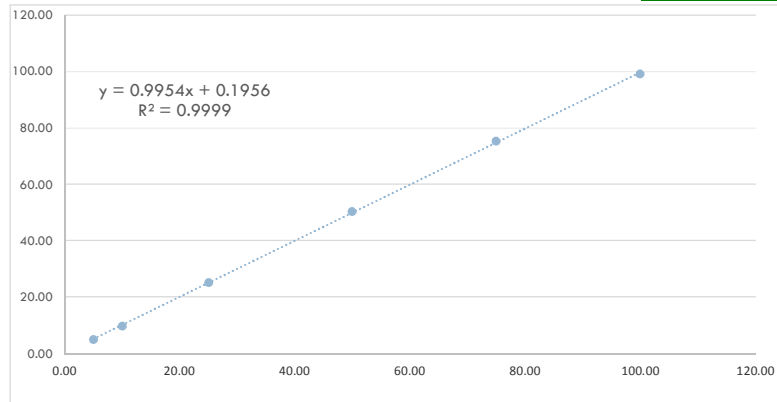
Calibrator	Target Conc.(x)	New calcs (y)	% Difference
5CAL	5.00	5.00	0.00%
10CAL	10.00	9.84	-1.60%
25CAL	25.00	25.24	0.96%
50CAL	50.00	50.39	0.78%
75CAL	75.00	75.30	0.40%
100CAL	100.00	99.19	-0.81%

Slope	0.9954
Std err in slope	0.0054
Confidence level	95%
95% CI Range	0.9803 - 1.0105
PASS	

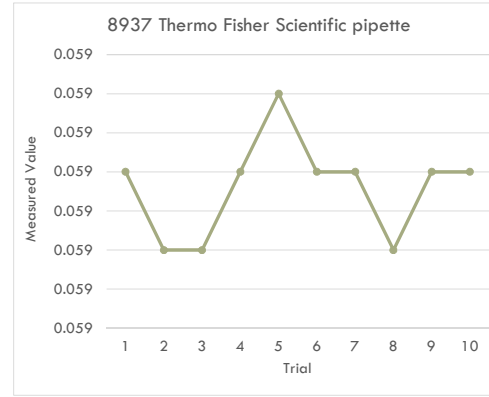
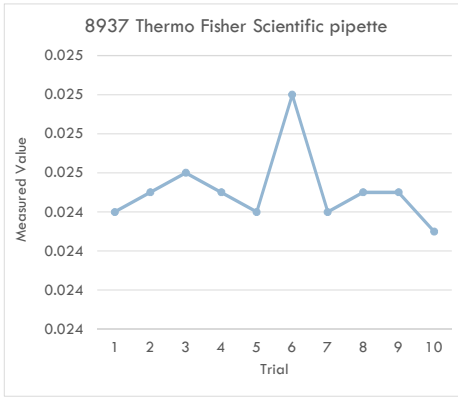
Intercept	
Std err in Intercept	0.19556
Confidence Level	0.30405
95% CI Range	95%
	-0.6486 - 1.0397
PASS	

Controls

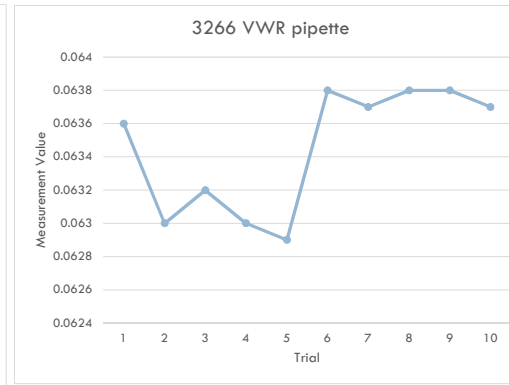
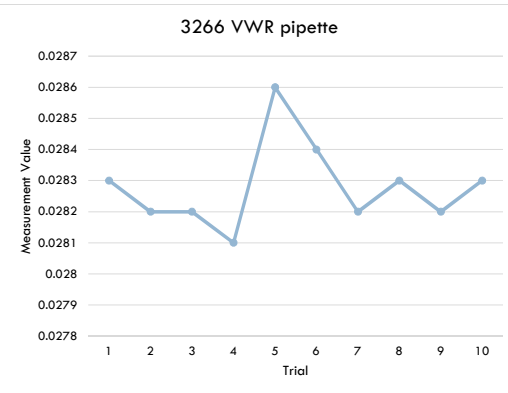
Target Conc of Controls	Controls concentration against current calibrators	% Difference (**)	Controls concentration against new calibrators	% Difference (*)
15.00	15.11	0.01	17.74	18.27%
15.00	13.12	-0.13	15.41	2.73%
45.00	44.19	-0.02	51.86	15.24%
45.00	41.45	-0.08	48.65	8.11%
45.00	43.42	-0.04	50.96	13.24%
80.00	76.06	-0.05	88.41	10.51%
80.00	75.34	-0.06	89.26	11.58%



Analyst Pipette Performance		
Pipette Lot #	8937 Thermo Fisher scientific	
Volume (mL)	0.025	0.050
	Weight (g) using DI-H2O	
1	0.0244	0.0590
2	0.0245	0.0589
3	0.0246	0.0589
4	0.0245	0.0590
5	0.0244	0.0591
6	0.0250	0.0590
7	0.0244	0.0590
8	0.0245	0.0589
9	0.0245	0.0590
10	0.0243	0.0590
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Expected (g)	0.025	0.050
Mean (g)	0.025	0.059
SD	0.000	0.000
3% Range	0.024 - 0.025	0.057 - 0.061
%Bias	-1.784	18.172
%CV	0.780	0.107



Analyst Pipette Performance		
Pipette Lot #	3266 VWR	
Volume (mL)	0.025	0.05
	Weight (g) using DI-H2O	
1	0.0283	0.0636
2	0.0282	0.0630
3	0.0282	0.0632
4	0.0281	0.0630
5	0.0286	0.0629
6	0.0284	0.0638
7	0.0282	0.0637
8	0.0283	0.0638
9	0.0282	0.0638
10	0.0283	0.0637
<hr/>		
Expected (g)	0.025	0.050
Mean (g)	0.028	0.063
SD	0.000	0.000
3% Range	0.027 - 0.029	0.062 - 0.065
%Bias	13.323	26.900
%CV	0.494	0.596



External calibration

	Thermo Fisher Scientific 8937		VWR 3266
	mg	μL	μL
	20.27	20.33	20.07
	20.26	20.32	20.10
	20.42	20.48	20.02
	20.2	20.26	19.95
	20.2	20.26	20.03
Expected (μL)		20.00	20.00
Mean (μL)		20.33	20.04
SD		0.09	0.06
% Bias		1.66	0.18
% CV		0.44	0.28