

QUANTISAL® ORAL FLUID COLLECTION DEVICE

Storage and Transportation of Drugs in Oral Fluid

Storage

- Drug-free oral fluid specimens were fortified with drugs at two concentrations: -50% and +50% of cutoff
- The specimens were stored under two conditions: room temperature (23°C) in the dark and refrigerated (4°C)
- Duplicate aliquots were analyzed using validated LC-MS/MS procedures: after 7, 14, and 30 days of storage

Results 1 of 2

Room temperature (23°C):

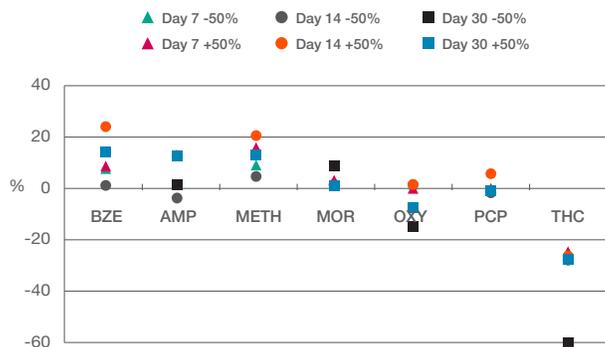
-50% of cutoff concentration

Drug Class	Target Concentration (ng/mL)	Day 0		Day 7		Day 14		Day 30	
		ng/mL	% Loss	ng/mL	% Loss	ng/mL	% Loss	ng/mL	% Loss
Benzoylcegonine	7.5	8	0	8	0	8.5	+6	8.5	+6
Amphetamine	25	25	0	25.5	+2	24.5	-2	25.5	+2
Methamphetamine	25	25	0	27	+8	26	+4	28.5	+14
Morphine	15	15	0	15	0	15	0	16.5	+10
Oxycodone	15	15	0	15	0	15	0	13	-13
PCP	5	5	0	5	0	5	0	5	0
THC	2	2	0	1.4	-30	1.4	-30	0.8	-60

Room temperature (23°C):

+50% of cutoff concentration

Drug Class	Target Concentration (ng/mL)	Day 0		Day 7		Day 14		Day 30	
		ng/mL	% Loss	ng/mL	% Loss	ng/mL	% Loss	ng/mL	% Loss
Benzoylcegonine	22.5	23	0	24.5	+7	28.5	+24	26	+13
Amphetamine	75	76	0	84	+11	84.5	+11	85	+12
Methamphetamine	75	75	0	86	+15	91	+21	85	+13
Morphine	45	45	0	47	+4	45.5	+1	46	+2
Oxycodone	45	45	0	45	0	46.5	+3	42	-7
PCP	15	15	0	16	+7	16	+7	15	0
THC	6	6	0	4.5	-25	4.4	-27	4.2	-30



Summary

- ±20% considered to be within analytical range
- THC shows significant loss at room temperature after 7 days; other drugs remain stable
- Higher concentrations demonstrate extended stability

Storage and transportation of drugs in oral fluid

Storage (cont'd)

Results 2 of 2

Refrigerated (4°C):

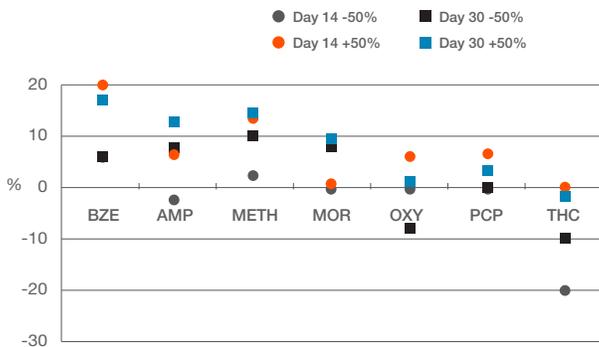
-50% of cutoff concentration

Drug Class	Target Concentration (ng/mL)	Day 0		Day 14		Day 30	
		ng/mL	% Loss	ng/mL	% Loss	ng/mL	% Loss
Benzoylcegonine	7.5	8	0	8.5	+6	8.5	+6
Amphetamine	25	25	0	24	-4	27	+8
Methamphetamine	25	25	0	25.5	+2	27.5	+10
Morphine	15	15	0	15	0	16	+7
Oxycodone	15	15	0	15	0	14	-7
PCP	5	5	0	5	0	5	0
THC	2	2	0	1.6	-20	1.8	-10

Refrigerated (4°C):

+50% of cutoff concentration

Drug Class	Target Concentration (ng/mL)	Day 0		Day 14		Day 30	
		ng/mL	% Loss	ng/mL	% Loss	ng/mL	% Loss
Benzoylcegonine	22.5	23	0	27.5	+20	27	+17
Amphetamine	75	76	0	81.5	+7	86	+13
Methamphetamine	75	75	0	85.5	+14	86	+15
Morphine	45	45	0	45.5	+1	49	+9
Oxycodone	45	45	0	47.5	+6	45.5	+1
PCP	15	15	0	16	+7	15.5	+3
THC	6	6	0	6	0	5.9	-2



Summary

- Refrigerated specimens show minor degradation (within analytical range)
- THC losses are minimized at both concentrations
- Higher concentrations demonstrate extended stability

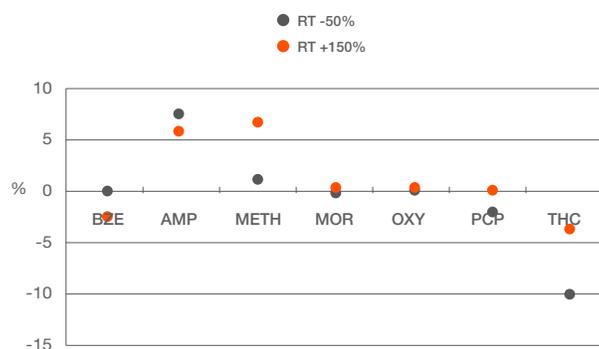
Transportation

- Drug free oral fluid specimens were fortified with drugs at two concentrations: -50% and +50% of cutoff.
- The specimens were shipped roundtrip from the west to east coast of the continental USA using overnight shipping method both ways. The specimens were shipped in regulation packages with no additional cooling mechanisms.
- Duplicate aliquots were analyzed using validated LC-MS/MS procedures after shipment returned.

Results

-50% and +50% of cutoff concentration

Drug Class	Original Concentration (ng/mL)		No Cold Packs (roundtrip) Temperature: 58.7 – 86.3°C / Humidity: 37.6 – 63.6%			
	-50%	+50%	-50% of cutoff (ng/mL)	% Loss or Gain	+50% of cutoff (ng/mL)	% Loss or Gain
Benzoyllecgonine	7.5	23	8	0	22.5	-2
Amphetamine	25	76	27	8	80.5	5
Methamphetamine	25	75	25	0	80.5	7
Morphine	15	45	15	0	45.5	1
Oxycodone	15	45	15	0	45	0
PCP	5	15	4.9	-2	15	0
THC	2	6	1.8	-10	5.8	-3



Summary

- No significant drug loss in transportation using standard shipping methods
- Minor loss of THC (10%) at the -50% concentration

Conclusion

- Drugs are stable in the Quantisal® collection system for 30 days at room temperature with the exception of THC which shows significant loss after 7 days (25–30%).
- All drugs, including THC, are stable in the Quantisal collection system for at least 30 days (< 20%) in refrigerated conditions.
- All drugs including THC are stable in the Quantisal collection system during shipping, using standard protocols, without additional refrigerated packaging.

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888.664.8378