

Stress sheet
DrugControl COC Test
008Q114



Accelerated Stability

Accelerated Stability of the ulti med DrugControl COC Cassette was evaluated using samples from three different batches. These were placed in an incubator with the temperature calibrated at 45° C and 55° C, and relative humidity (RH) calibrated at 60%. A series of stability tests were performed at 7, 14, 21, 28, 35, 42, 56, 77, 84 days. Tests were assayed using each test concentration at drug free urine, -50% Cut-off and +50% Cut-off urine specimens. Testing at each specific time interval consisted of triplicates for each specimen. The tests were performed according to the package insert. Results are presented in tables below.

Table: Timeline for Accelerate Stability Study

Day Temp.	0 day	7 days	14 days	21 days	28 days	35 days	42 days	56 days	77 days	84 days
45°C	√	√	√	√	√	√	√	√	√	√
55°C	√	√	√	√	√	√	√	X	X	X

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Table: Accelerated Stability Summary

Accelerated Stability Study Results at 45°C					
Product	Day	Specimen	Batch No.		
			Lot 1	Lot 2	Lot 3
COC 300	0	Drug free urine	-,-,-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-,-,-
		-50% Cut-off	-,-,-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-,-,-
		+50% Cut-off	+,+,+,+,+,+,+,+,+,+	+,+,+,+,+,+,+,+,+,+	+,+,+,+,+,+,+,+,+,+
	7	Drug free urine	-,-,-	-,-,-	-,-,-
		-50% Cut-off	-,-,-	-,-,-	-,-,-
		+50% Cut-off	+,+,+	+,+,+	+,+,+
	14	Drug free urine	-,-,-	-,-,-	-,-,-
		-50% Cut-off	-,-,-	-,-,-	-,-,-
		+50% Cut-off	+,+,+	+,+,+	+,+,+
	21	Drug free urine	-,-,-	-,-,-	-,-,-
		-50% Cut-off	-,-,-	-,-,-	-,-,-
		+50% Cut-off	+,+,+	+,+,+	+,+,+
	28	Drug free urine	-,-,-	-,-,-	-,-,-
		-50% Cut-off	-,-,-	-,-,-	-,-,-
		+50% Cut-off	+,+,+	+,+,+	+,+,+
	35	Drug free urine	-,-,-	-,-,-	-,-,-
		-50% Cut-off	-,-,-	-,-,-	-,-,-
		+50% Cut-off	+,+,+	+,+,+	+,+,+
	42	Drug free urine	-,-,-	-,-,-	-,-,-

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		-50% Cut-off	-,-,-	-,-,-	-,-,-
		+50% Cut-off	+,+,+	+,+,+	+,+,+
	56	Drug free urine	-,-,-	-,-,-	-,-,-
		-50% Cut-off	-,-,-	-,-,-	-,-,-
		+50% Cut-off	+,+,+	+,+,+	+,+,+
	77	Drug free urine	-,-,-	-,-,-	-,-,-
		-50% Cut-off	-,-,-	-,-,-	-,-,-
		+50% Cut-off	+,+,+	+,+,+	+,+,+
	84	Drug free urine	-,-,-	-,-,-	-,-,-
		-50% Cut-off	-,-,-	-,-,-	-,-,-
		+50% Cut-off	+,+,+	+,+,+	+,+,+

Accelerated Stability Study Results at 55°C

Product	Day	Specimen	Batch No.		
			Lot 1	Lot 2	Lot 3
COC 300	0	Drug free urine	-,-,-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-,-,-
		-50% Cut-off	-,-,-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-,-,-	-,-,-,-,-,-,-,-,-,-
		+50% Cut-off	+,+,+,+,+,+,+,+,+	+,+,+,+,+,+,+,+,+	+,+,+,+,+,+,+,+,+
	7	Drug free urine	-,-,-	-,-,-	-,-,-
		-50% Cut-off	-,-,-	-,-,-	-,-,-
		+50% Cut-off	+,+,+	+,+,+	+,+,+
	14	Drug free urine	-,-,-	-,-,-	-,-,-
		-50% Cut-off	-,-,-	-,-,-	-,-,-
		+50% Cut-off	+,+,+	+,+,+	+,+,+

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	21	Drug free urine	-,-,-	-,-,-	-,-,-
		-50% Cut-off	-,-,-	-,-,-	-,-,-
		+50% Cut-off	+,+,+	+,+,+	+,+,+
	28	Drug free urine	-,-,-	-,-,-	-,-,-
		-50% Cut-off	-,-,-	-,-,-	-,-,-
		+50% Cut-off	+,+,+	+,+,+	+,+,+
	35	Drug free urine	-,-,-	-,-,-	-,-,-
		-50% Cut-off	-,-,-	-,-,-	-,-,-
		+50% Cut-off	+,+,+	+,+,+	+,+,+
	42	Drug free urine	-,-,-	-,-,-	-,-,-
		-50% Cut-off	-,-,-	-,-,-	-,-,-
		+50% Cut-off	+,+,+	+,+,+	+,+,+

Conclusion: The **ulti med DrugControl COC Test** is stable at 45°C for 84 days or 55°C for 42 days. These data were plotted on an Arrhenius Plot and the shelf life of this product was determined to be at least 27 months from the data of manufacture.

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