

Table 5. Interference/Cross Reactivity - Hemolysis									
Level of Hemolysis	5%			10%			15%		
	NC pool HEMPC 11	Low ATA HEMPC 22	High ATA HEMPC 33	NC pool HEMPC 44	Low ATA HEMPC 55	High ATA HEMPC 66	NC pool HEMPC 77	Low ATA HEMPC 88	High ATA HEMPC 99
Run ID	ABC001	ABC001	ABC001	ABC001	ABC001	ABC001	ABC001	ABC001	ABC001
19ABCDEH2	0.111	0.222	0.333	0.444	0.555	0.666	0.777	0.888	0.999
Theoretical Concentration (ng/mL) % Difference from	0.00	50	100	0	50	100	0	50	100
ABCDE 8	N/A	N/A	N/A	N/A	N/A	1.0	N/A	N/A	2.0
Result	Negative	Positive	Positive	Negative	Positive	Positive	Negative	Positive	Positive

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Table 5. Interference/Cross Reactivity - Lipolysis									
Level of Lipolysis	5%			10%			15%		
	NC pool HEMPC 12	Low ATA HEMPC 23	High ATA HEMPC 34	NC pool HEMPC 45	Low ATA HEMPC 56	High ATA HEMPC 67	NC pool HEMPC 77	Low ATA HEMPC 88	High ATA HEMPC 99
Run ID	ABC001	ABC001	ABC001	ABC001	ABC001	ABC001	ABC001	ABC001	ABC001
ABCDEH192	0.111	0.222	0.333	0.444	0.555	0.666	0.777	0.888	0.999
Theoretical Concentration (ng/mL) % Difference from	0.00	50	100	0	51	100	0	50	100
ABCDE 8	N/A	N/A	N/A	N/A	N/A	1.0	N/A	N/A	2.0
Result	Negative	Positive	Positive	Negative	Positive	Positive	Negative	Positive	Positive

Real Target:
The effect of Hemolysis on the detection of ATA was evaluated in run 19ABCDEH2 by analyzing blanks (HEMPC 11, 22, and 33), low - level (HEMPC 44, 55, and 66 at 50 ng/mL).

Synthetic Target:
The effect of Lipolysis on the detection of ATA was evaluated in run ABCDEH192 by analyzing blanks (HEMPC 12, 23, and 34), low - level (HEMPC 45, 56, and 67 at 51 ng/mL).

Figure 4: Example of synthetic values created from the original table for assay validation reports. In this example, “Hemolysis” is replaced by “Lipolysis”. The synthetic value “ABCDEH192” is created by randomising the original value “19ABCDEH2”. Numerical values such as “50” have been modified to new values “51” that are close to the original values.

Sex	Group Set	Subject ID	1-7	1-8
F	1--Vehicle	Mean	-2.00	-0.01
	2--100mg/kg ABCD0001	Mean	-1.01	-0.02
	3--200mg/kg ABCD0001	Mean	-3.00	-0.03
	4--300mg/kg ABCD0001	Mean	-2.02	-0.04
M	1--Vehicle	Mean	10.01	0.05
	2--100mg/kg ABCD0001	Mean	10.03	0.06
	3--200mg/kg ABCD0001	Mean	10.04	0.07
	4--300mg/kg ABCD0001	Mean	0.01	-0.08

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Sex	Group Set	Subject ID	1-7	1-8
M	1--Vehicle	Mean	-2.02	-0.01
	2--200mg/kg ABC0001D	Mean	-1.01	-0.02
	3--300mg/kg ABC0001D	Mean	-3.15	-0.03
	4--400mg/kg ABC0001D	Mean	-2.02	-0.04
F	1--Vehicle	Mean	10.05	0.05
	2--300mg/kg ABC0001D	Mean	10.03	0.06
	3--400mg/kg ABC0001D	Mean	10.04	0.07
	4--500mg/kg ABC0001D	Mean	0.02	-0.08

Real Target:
Body weight change consisting of 1.00% loss compared to control in females at 200.0 mg/kg; Body weight change consisting of 10.00% loss compared to control in males at 300.0 mg/kg

Synthetic Target:
Body weight change consisting of 1.13% loss compared to control in males at 300.0 mg/kg; Body weight change consisting of 10.03% loss compared to control in females at 500.0 mg/kg

Figure 5: Example of synthetic values created from the original table for toxicology reports (the findings of body weight changes). In this example, the original drug name “ABCD0001” has been modified to “ABC0001D”. Dosage levels such as “200mg/kg” are replaced by other values such as “300mg/kg”. The percentages of body weight changes are also replaced by randomising the original values slightly.