Pharmacokinetic

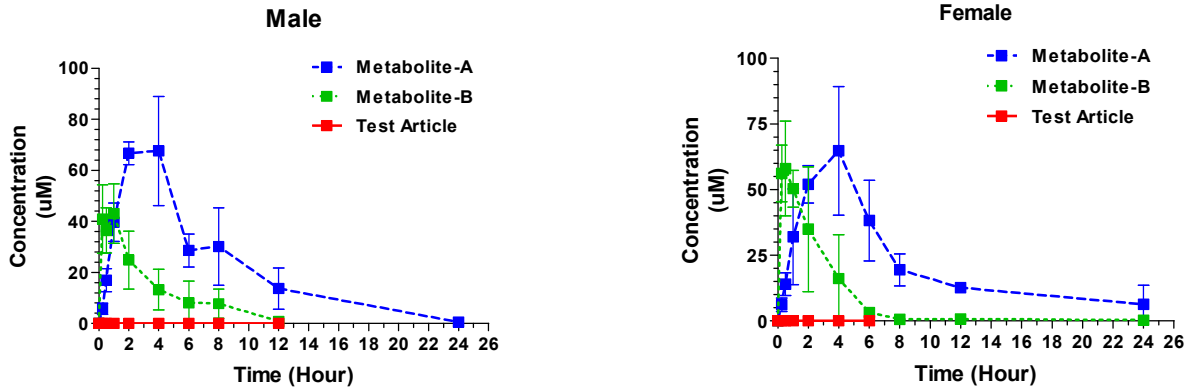
Pharmacokinetic Study in Rats

Typically in a pharmacokinetic study, blood samples are collected at different time points from test animals following a single or multiple doses. Blood samples are processed for plasma and analyzed for drug concentration. The data generated is used to calculate concentration vs. time curves and other parameters such as Cmax, Tmax, AUC, drug clearance, terminal elimination half-life, oral bioavailability and volume of distribution.

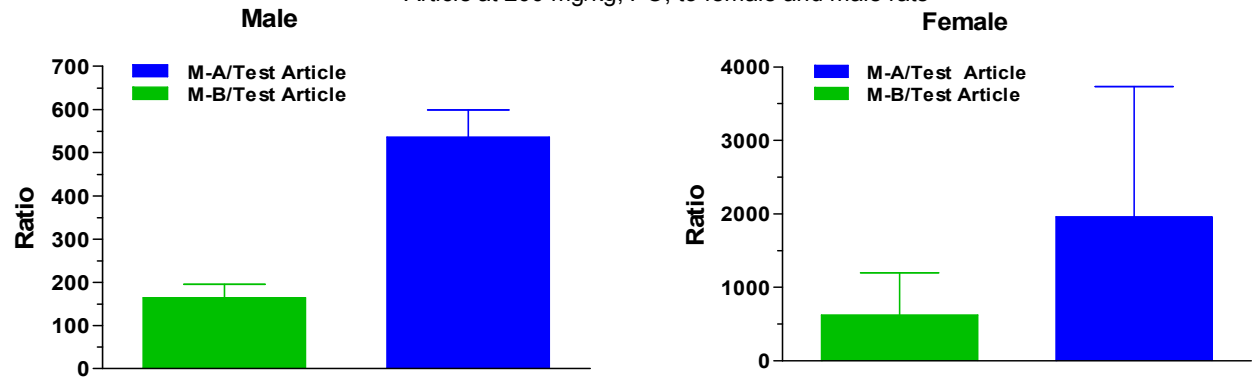
Study Design

Following acclimation, rats are randomly assigned to groups (3/group/sex) and test article is administered at 200 mg/kg, PO. Plasma samples are collected at 0, 0.25, 0.5, 1, 2, 4, 6, 8, 12, and 24 hrs and analyzed by LC/MS/MS for concentrations of drug and its metabolites.

Mean plasma concentrations of Test Article and its metabolite (μM; Mean ± SD) in male and female rats administered orally at 200 mg/kg dose.



Ratio of AUC_{inf} of Metabolite-A and B over Test Article following the administration of Test Article at 200 mg/kg, PO, to female and male rats



T_{max} (Hour, Mean ± SD), C_{max} (μM, Mean ± SD), $T_{1/2}$ (Hour, Mean ± SD), AUC_{last}, AUC_{inf}, (μM; Mean ± SD) of Test Article and its metabolite A and B following the oral administration of Test Article at 200 mg/kg to male and female rats

	Sex	T_{max} (Hour)	C_{max} (uM)	$T_{1/2}$ (Hour)	AUC_{last} (μM*Hr)	AUC_{inf} (μM*Hr)	AUC_{inf} extrapolated (%)
Test Article	Male	--	--	--	--	--	--
	Female	0.75 ± 0.35	0.08 ± 0.06	2.7 ± 0.42	0.18 ± 0.10	0.27 ± 0.14	32 ± 1.7
Metabolite-B	Male	0.75 ± 0.43	45.9 ± 8.8	1.9 ± 0.67	161 ± 34	164 ± 31	2.0 ± 2.7
	Female	0.58 ± 0.38	61.9 ± 14.2	2.5 ± 1.31	170 ± 55	172 ± 52	2.1 ± 3.1
Metabolite-A	Male	3.33 ± 1.15	73.6 ± 11.6	3.0 ± 0.42	533 ± 64	536 ± 63	0.44 ± 0.27
	Female	3.33 ± 1.15	71.3 ± 16.0	5.8 ± 3.01	473 ± 53	553 ± 124	12.9 ± 10.8

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