

CADILA PHARMACEUTICALS LTD. - CRO

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**LIST OF VALIDATED METHODS****HUMAN PLASMA**

<u>SR. NO.</u>	<u>ANALYTE</u>	<u>INSTRUMENT</u>	<u>LINEARITY RANGE</u>	<u>LLOQ</u>
1	Acyclovir	LC-MS/MS	5.00 to 4999.56 ng/ml	5.00 ng/ml
2	Alverine +	LC-MS/MS	0.060 to 10.051 ng/ml	0.060ng/ml
	10-OH Alverine	LC-MS/MS	0.059 to 10.017 ng/ml	0.059 ng/ml
3	Amlodipine	LC-MS/MS	0.10 to 20.13 ng/ml	0.10 µg/ml
4	Amiodarone	LC-MS/MS	52.00 to 3000.07 ng/ml	52.00 ng/ml
5	Amoxicillin	HPLC	0.51 to 30.06 µg/ml	0.51 µg/ml
		UPLC	0.5 µg/ml to 50 µg/ml	0.5 µg/ml
6	Ampicillin	HPLC	0.20 to 9.00 µg/ml	0.20 µg/ml
7	Asprin	UPLC	30.09 to 1805.39 ng/ml	30.09 ng/ml
8	Atenolol	LC-MS/MS	0.300 to 40.00 ng/ml	0.300 ng/ml
			2.00 ng/ml to 1000 ng/ml	2 ng/ml
9	Atorvastain	LC-MS/MS	1.00 to 320.64 ng/ml	1.00 ng/ml
10	Atorvastatin	LC-MS/MS	0.512 to 51.251 ng/ml	0.512 ng/ml
	o-Hydroxy Atrovastatin	LC-MS/MS	0.513 to 51.302 ng/ml	0.513 ng/ml
	p-Hydroxy Atorvastatin	LC-MS/MS	0.513 to 51.282 ng/ml	0.513 ng/ml
11	Azithromycin	LC-MS/MS	0.95ng/ml to 951.63 ng/ml	0.95 ng/ml
12	Candesartan	UPLC	25.00 to 1499.00 ng/ml	25.00 ng/ml

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13	Captopril	LC-MS/MS	10.07 to 3525.20 ng/ml	10.07 ng/ml
14	Carbamazepine +	LC-MS/MS	49.77 ng/ml to 7905.49 ng/ml	49.77 ng/ml
15	Carpamazepine 10 – 11 Epoxide	LC-MS/MS	5.64 ng/ml to 1723.24 ng/ml	5.64 ng/ml
16	Cephalexin	HPLC	1.04 to 55.00 µg/ml	1.04 µg/ml
17	Cilastozole	HPLC	59.02 to 1210.56 ng/ml	59.02 ng/ml
18	Ciprofibrate	HPLC	0.40 to 109.35 ng/ml	0.40 ng/ml
19	Clarithromycine +	LC-MS/MS	10.00 to 3000.60 ng/ml	10.00 ng/ml
20	14-OH Clarithromycine	LC-MS/MS	10.00 to 2999.40 ng/ml	10.00 ng/ml
21	Clonidine	LC-MS/MS	0.49 to 73.98 ng/ml	0.49 ng/ml
22	Dicyclomine	LC-MS/MS	2.87 to 117.53 ng/ml	2.87 ng/ml
23	Docosahexanoic Acid (DHA)	LC-MS/MS	50.00 ng/ml to 7500.00 ng/ml	50.00 ng/ml
	Ecosapentanoic Acid (EPA)	LC-MS/MS	50.00 ng/ml to 7500.00 ng/ml	50.00 ng/ml
24	Doxycycline	HPLC	0.30 to 11.98 µg/ml	0.30 µg/ml
25	Enalpril	LC-MS/MS	1.02 to 500.16 ng/ml	1.02 ng/ml
26	Enalprilat	LC-MS/MS	3.08 to 410.20 ng/ml	3.08 ng/ml
27	Erdosteine	LC-MS/MS	50.00 to 3004.00 ng/ml	50.00 ng/ml
28	Ethambutol	LC-MS/MS	50.00 to 5000.12 ng/ml	50.00 ng/ml
29	Famotidine	HPLC	10.00 to 700.00 ng/ml	10.00 ng/ml
30	Fexofenadine	HPLC	28.42 to 1206.44 ng/ml	28.42 ng/ml
31	Fexofenadine	UPLC	30.09 to 1805.39 ng/ml	30.09 ng/ml
32	Fluoxetine +	LC-MS/MS	0.50 to 49.95 ng/ml	0.50 ng/ml
	Norfluoxetine	LC-MS/MS	0.50 to 49.85 ng/ml	0.50 ng/ml
33	Glibenclamide	LC-MS/MS	10.00 to 1000.50 ng/ml	10.00 ng/ml

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34	Gliclazide	HPLC	0.39 to 8.15 µg/ml	0.39 ng/ml
35	Glimepiride	HPLC	15.03 to 901.59 ng/ml	15.03 ng/ml
36	Hydrochlorothazide	LC-MS/MS	1.50 to 5.00 ng/ml	1.500 ng/ml
37	Indinavir	HPLC	144.23 to 9606.02 ng/ml	144.23 ng/ml
38	Indinavir	LC-MS/MS	10.00 to 12000.00 ng/ml	10.00 ng/mL
39	Indomethacine	HPLC	99.96 to 2998.77 ng/ml	99.96 ng/ml
40	Isoniazide	HPLC	0.10 to 17.92 µg/ml	0.10 µg/ml
41	ISMN	HPLC	37.71 to 1000.45 ng/ml	37.71 ng/ml
42	Itopride	HPLC	14.84 to 850.63 ng/ml	14.84 ng/ml
43	Ketorolac	HPLC	51.38 to 3044.77 ng/ml	51.38 ng/ml
44	Lacidine	LC-MS/MS	0.10 to 20.00 ng/ml	0.10 ng/ml
45	Lacidipine	LC-MS/MS	0.05 to 20.00 ng/ml	0.05 ng/ml
46	Lafutidine	LC-MS/MS	1.00 to 1000.00 ng/ml	1.00 ng/ml
47	Lamivudine	LC-MS/MS	30.00 to 3000.00 ng/ml	30.00 ng/ml
48	Levofloxacin	LC-MS/MS	25.00 to 10000 ng/ml	25.00 ng/mL
49	Losartan +	LC-MS/MS	5.00 to 1501.00 ng/ml	5.00 ng/ml
	Losartan Carboxylic Acid	LC-MS/MS	5.00 to 1500.50 ng/ml	5.00 ng/ml
50	Meloxicam	HPLC	0.10 to 9.00 µg/ml	0.10 µg/ml
51	Metformin	LC-MS/MS	30.00 to 5003.20 ng/ml	30.00 ng/ml
52	Metformin	HPLC	76.70 to 4843.98 ng/ml	76.70 ng/ml
53	Methocarbamol	HPLC	0.77 to 76.22 µg/ml	0.77 µg/ml
54	Metronidazole	HPLC	0.30 to 10.08 µg/ml	0.30 µg/ml
55	Nebivolol	LC-MS/MS	0.051 to 8.728 ng/ml	0.051 ng/ml
56	Nelfinavir	HPLC	48.21 to 3296.69 ng/ml	48.21 ng/ml

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57	Nevirapine	LC-MS/MS	10.00 ng/ml to 5000.00 ng/ml	10.00ng/ml
58	Nortriptyline +	LC-MS/MS	0.240 to 100.20 ng/ml	0.240 ng/ml
	10-OH Nortriptyline	LC-MS/MS	0.240 to 99.60 ng/ml	0.240 ng/ml
59	Nortryptiline +	LC-MS/MS	0.240 to 100.200 ng/ml	0.240 ng/ml
	10-OH Nortriptyline	LC-MS/MS	0.240 to 99.600 ng/ml	0.240 ng/ml
60	Ofloxacin	LC-MS/MS	24.72 to 9971.60 ng/ml	24.72 ng/ml
61	Olanzapine	LC-MS/MS	2.00 to 198.00 ng/ml	2.00 ng/ml
62	Omeprazole	LC-MS/MS	2.00 to 1002.40 ng/ml	2.00 ng/ml
63	Omeprazole	UPLC	20.01 to 3001.92 ng/ml	20.01 ng/ml
64	Propafenone +	LC-MS/MS	5.11 to 1000.85 ng/ml	5.11 ng/ml
	5-OH Propafenone +	LC-MS/MS	5.11 to 1001.27 ng/ml	5.11 ng/ml
	Des propyl Propafenone	LC-MS/MS	0.51 to 100.64 ng/ml	0.51 ng/ml
65	Propofol	HPLC	32.56 to 4167.24 ng/ml	32.56 ng/ml
66	Pyridostigmine	LC-MS/MS	5.00 to 499.00 ng/ml	5.00 ng/ml
67	Ramipril + Ramiprilat	LC-MS/MS	0.300 to 40.00 ng/ml	0.300 ng/ml
68	Ranitidine	HPLC	42.98 to 1989.93 ng/ml	42.98 ng/ml
69	Rifampicine	HPLC	0.99 to 39.46 ng/ml	0.99 ng/ml
70	Rifampicin	LC-MS/MS	0.051µg/ml to 25.005 µg/ml	0.051 µg/ml

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71	Rifampicin +	LC-MS/MS	0.050 to 20.070 µg/ml	0.050 µg/ml
	Des Rifampicin		0.025 to 10.080 µg/ml	0.025 µg/ml
72	Rifampicin +	HPLC	0.226 to 28.800 µg/ml	0.226 µg/ml
	Des Rifampicin		0.224 to 11.520 µg/ml	0.224 µg/ml
73	R-Ondansetron	LC-MS/MS	0.20 to 50.00 ng/ml	0.2 ng/ml
74	Sertralin	LC-MS/MS	1.03 to 443.66 ng/ml	1.03 ng/ml
75	Simvastatin +Simvastatin OH- carboxylic acid	LC-MS/MS	0.280 to 60.00 ng/ml	0.280 ng/ml
76	Stavudine	HPLC	41.66 to 1587.04 ng/ml	41.66 ng/ml
77	Tacrolimus	LC-MS/MS	0.321 to 128.00 ng/ml	0.321 ng/ml
78	Tadalafil	LC-MS/MS	4.0 ng/ml to 1000.00 ng/ml	4.0 ng/ml
79	Telmisartan	LC-MS/MS	2.0 ng/ml to 2000.00 ng/ml	2.0 ng/ml
80	Tetracycline	HPLC	7.30 to 200.76 ng/ml	7.30 ng/ml
81	UDCA +	LC-MS/MS	20.00 to 20016.00 ng/ml	20.00 ng/ml
	GDCA	LC-MS/MS	20.00 to 20025.00 ng/ml	20.00 ng/ml
82	Valsartan (Plasma)	LC-MS/MS	50.00 ng/ml to 20050.00 ng/ml	50.00 ng/ml
83	Valsartan (Serum)	LC-MS/MS	50.00 ng/ml to 20050.00 ng/ml	50.00 ng/ml
84	Zidovudine	LC-MS/MS	30.00 to 3000.00 ng/ml	30.00 ng/ml
85	Zolpidem	HPLC	5.00 to 400.48 ng/ml	5.00 ng/ml

PRE-CLINICAL

<u>SR. NO.</u>	<u>ANALYTE</u>	<u>INSTRUMENT</u>	<u>LINEARITY RANGE</u>	<u>LLOQ</u>
1	Curcumin - Rat Plasma	LC-MS/MS	1.000 to 995.200 ng/ml	1.000 ng/ml

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2	Paclitaxel - Rat Plasma	LC-MS/MS	0.5 ng/ml to 500 ng/ml	0.5 ng/ml
3	Tacrolimus - Rat Whole Blood	LC-MS/MS	0.200 to 200.592 ng/ml	0.200ng/ml