



Bioanalytical Methods



Highlights

- Spacious analytical lab spread over 5000 sq. mts. area
- 30 LC/MS/MS Instruments
- Over 246 validated methods
- About 9 methods under development and validation
- SDMS for Online chromatograms review, audit and archival



Part A

List of Premium Validated Methods



PREMIUM METHODS

Sr. No.	Drug Name	Instrument	Matrix	Range	Anticoagulant	Dose
1	Alendronate	LC-MS/MS (API 4000)	Human Urine	2 to 600 ng / mL	NA	70 mg
2	Alendronate	LC-MS/MS (API 4000)	Human Plasma	3 to 120 ng / mL	K ₂ EDTA	70 mg
3	Bicalutamide (R & S)	LC-MS/MS (Waters)	Human Plasma	5 to 1000 ng / mL	K ₂ EDTA	50 mg
4	S-citalopram	LC-MS/MS (Waters)	Human Plasma	0.25 to 25 ng / mL	Heparin	20 mg
	R-citalopram	LC-MS/MS (Waters)	Human Plasma	0.25 to 25 ng / mL	Heparin	20 mg
	S- desmethyl citalopram	LC-MS/MS (Waters)	Human Plasma	0.25 to 15 ng / mL	Heparin	-
5	Carvedilol	LC-MS/MS (Waters)	Human Plasma	0.1 to 50 ng / mL	K ₂ EDTA	40 mg
	4-Hydroxy Phenyl Carvedilol	LC-MS/MS (Waters)	Human Plasma	0.05 to 5 ng / mL	K ₂ EDTA	-
6	Capecitabine	LC-MS/MS (Thermo)	Human Plasma	10 to 5000 ng / mL	K ₂ EDTA	500 mg (multiple dosing)
	5-fluorouracil	LC-MS/MS (Thermo)	Human Plasma	5 to 740 ng / mL	K ₂ EDTA	-
7	Capecitabine	LC-MS/MS (API 4000)	Human Plasma	10 to 8000 ng / mL	K ₂ EDTA	500 mg (multiple dosing)
	5-Deoxy-5-Fluorocytidine	LC-MS/MS (API 4000)	Human Plasma	10 to 8000 ng / mL	K ₂ EDTA	-
8	Carprofen	LC-MS/MS (API 3200)	Beagle Dog Plasma	0.5 to 100 µg / mL	K ₂ EDTA	100 mg
9	17-Desacetyl Norgestimate	LC-MS/MS (API 4000)	Human Plasma	0.05 to 7.5 ng / mL	K ₂ EDTA	0.5 mg
10	Ethinyl estradiol	LC-MS/MS (Thermo)	Human Plasma	2 to 400 pg / mL	K ₂ EDTA	0.07 mg
11	Ethinyl estradiol	LC-MS/MS (Thermo)	Human Plasma	2 to 150 pg / mL	K ₂ EDTA	0.035 mg
12	Ibandronate	LC-MS/MS (Thermo)	Human Plasma	0.1 to 100 ng / mL	Heparin	50 mg
13	Ibandronate	LC-MS/MS (API 4000)	Human Plasma	0.75 to 300 ng / mL	Heparin	150 mg
14	Ibuprofen (R & S)	LC-MS/MS (Waters)	Human Plasma	0.1 to 25 µg/ mL	Heparin	200 mg



PREMIUM METHODS

Sr. No.	Drug Name	Instrument	Matrix	Range	Anticoagulant	Dose
15	R-Fluvastatin	LC-MS/MS (API 4000)	Human Plasma	0.5 to 200 ng / mL	Heparin	40 mg
	S- Fluvastatin	LC-MS/MS (API 4000)	Human Plasma	0.5 to 200 ng / mL	Heparin	-
16	6-Mercaptopurine	LC-MS/MS (Waters)	Human Plasma	0.75 to 500 ng / mL	K ₂ EDTA	100 mg
17	Mifepristone	LC-MS/MS (Thermo)	Human Plasma	25 to 5000 ng / mL	Heparin	200 mg
	N-desmethyl Mifepristone	LC-MS/MS (Thermo)	Human Plasma	50 to 5000 ng / mL	Heparin	-
	N,N-didesmethyl mifepristone	LC-MS/MS (Thermo)	Human Plasma	10 to 2000 ng / mL	Heparin	-
	Hydroxy mifepristone	LC-MS/MS (Thermo)	Human Plasma	10 to 1000 ng / mL	Heparin	-
18	Misoprostol Acid	LC-MS/MS (API 4000)	Human Plasma	0.015 to 1 ng / mL	K ₂ EDTA	0.2 mg
19	Montelukast	LC-MS/MS (API 3200)	Human Plasma	5 to 1000 ng / mL	Heparin	10 mg
20	Montelukast	LC-MS/MS (API 3200)	Human Plasma	5 to 500 ng / mL	Heparin	5 mg
21	Mycophenolate mofetil	LC-MS/MS (Waters)	Human Plasma	0.1 to 10 ng / mL	K ₂ EDTA	250 mg
	Mycophenolic acid	LC-MS/MS (Waters)	Human Plasma	25 to 15000 ng / mL	K ₂ EDTA	-
22	Mycophenolate mofetil	LC-MS/MS (Waters)	Human Plasma	0.1 to 10 ng / mL	K ₂ EDTA	500 mg
	Mycophenolic acid	LC-MS/MS (Waters)	Human Plasma	75 to 25000 ng / mL	K ₂ EDTA	-
23	Lercanidipine (R & S)	LC-MS/MS (Waters)	Human Plasma	0.02 to 4 ng / mL	Heparin	10 mg



PREMIUM METHODS

Sr. No.	Drug Name	Instrument	Matrix	Range	Anticoagulant	Dose
24	Lercanidipine (R & S)	LC-MS/MS (Waters)	Human Plasma	0.5 to 12 ng / mL	Heparin	20 mg
25	Levonorgestrel	LC-MS/MS (API 4000)	Human Plasma	0.05 to 15 ng / mL	K ₂ EDTA	0.15 mg
26	Raloxifene	LC-MS/MS (Thermo)	Human Plasma	20 to 1000 pg / mL	K ₂ EDTA	60 mg
	Raloxifene 4-glucuronide	LC-MS/MS (Thermo)	Human Plasma	0.6 to 400 ng / mL	K ₂ EDTA	-
	Raloxifene 6-glucuronide	LC-MS/MS (Thermo)	Human Plasma	0.35 to 100 ng / mL	K ₂ EDTA	-
27	Quetiapine	LC-MS/MS (API 2000)	Human Plasma	20 to 2000 ng / mL	K ₂ EDTA	300 /400 mg
	N-Des Alkylated Quetiapine	LC-MS/MS (API 2000)	Human Plasma	2 to 500 ng / mL	K ₂ EDTA	-
28	Temozolomide	LC-MS/MS (Waters)	Human Plasma	100 to 20000 ng / mL	Heparin	250 mg
29	Temozolomide Metabolite (MTIC)	LC-MS/MS (Waters)	Human Plasma	3 to 600 ng /mL	Heparin	250 mg



Part B

List of Validated Methods



Sr. No.	Drug Name	Instrument	Matrix	Range	Anticoagulant	Dose
1	Aceclofenac	HPLC-UV	Human Plasma	0.2 to 15 µg / mL	Heparin	100 mg
2	Acetyl salicylic acid	HPLC-UV	Human Plasma	0.05 to 8 µg / mL	K ₂ EDTA / Heparin	650 mg
	Salicylic acid	HPLC-UV	Human Plasma	0.4 to 40 µg / mL	K ₂ EDTA / Heparin	-
3	Acetyl salicylic acid	LC-MS/MS (API 4000)	Human Plasma	2.5 to 500 ng/ mL	K ₂ EDTA	25 mg
	Salicylic acid	LC-MS/MS (API 4000)	Human Plasma	100 to 6000 ng / mL	K ₂ EDTA	-
4	Alendronate	LC-MS/MS (Thermo)	Human Plasma	0.05 to 20 ng / mL	K ₂ EDTA	10 mg
5	Allopurinol	LC-MS/MS (API 3200)	Human Plasma	10 to 5000 ng / mL	K ₂ EDTA	300 mg
6	Amlodipine	LC-MS/MS (API 2000)	Human Plasma	0.2 to 10 ng / mL	Heparin	10 mg
7	Amiloride	LC-MS/MS (Waters)	Human Plasma	0.15 to 20 ng / mL	K ₂ EDTA	5 mg
8	Amiodarone	LC-MS/MS (Waters)	Human Plasma	1 to 300 ng / mL	K ₂ EDTA	200 mg
9	Amitriptyline	LC-MS/MS (Waters)	Human Plasma	0.1 to 30 ng / mL	K ₂ EDTA	25 mg
	Nortriptyline	LC-MS/MS (Waters)	Human Plasma	0.2 to 15 ng / mL	K ₂ EDTA	-
10	Amoxicillin	HPLC-UV	Human Plasma	0.5 to 15 µg / mL	K ₂ EDTA / Heparin	500 mg
11	Amphotericin B	HPLC-UV	Human Plasma	0.25 to 10 µg / mL	K ₂ EDTA	2 mg
12	Anastrozole	LC-MS/MS (API 3200)	Human Plasma	0.25 to 25 ng / mL	Heparin	1 mg
13	Aripiprazole	LC-MS/MS (Waters)	Human Plasma	0.1 to 50 ng / mL	K ₂ EDTA	5 mg
	Dehydro aripiprazole	LC-MS/MS (Waters)	Human Plasma	0.1 to 50 ng / mL	K ₂ EDTA	-
14	Aripiprazole	LC-MS/MS (Waters)	Human Plasma	0.5 to 150 ng / mL	K ₂ EDTA	10 mg
15	Atenolol	HPLC - Fluorescence	Human Plasma	10 to 800 ng / mL	K ₂ EDTA / Heparin	100 mg



Sr. No.	Drug Name	Instrument	Matrix	Range	Anticoagulant	Dose
16	Atorvastatin	LC-MS/MS (API 4000)	Human Plasma	0.5 to 100 ng / mL	Heparin	80 mg
	O-Hydroxy Atorvastatin	LC-MS/MS (API 4000)	Human Plasma	0.5 to 100 ng / mL	Heparin	-
	P-Hydroxy Atorvastatin	LC-MS/MS (API 4000)	Human Plasma	0.1 to 12 ng / mL	Heparin	-
17	Azithromycin	LC-MS/MS (API 2000)	Human Plasma	30 to 3000 ng /mL	Heparin	2 g / 60 mL
18	Benazepril	LC-MS/MS (API 2000)	Human Plasma	2 to 1200 ng / mL	K ₂ EDTA	40 mg
	Benazeprilat	LC-MS/MS (API 2000)	Human Plasma	3 to 1200 ng / mL	K ₂ EDTA	-
19	Bicalutamide	LC-MS/MS (API 2000)	Human Plasma	10 to to 1000 ng / mL	Heparin	25 mg
20	Bicalutamide	LC-MS/MS (API 2000)	Human Plasma	50 to to 2000 ng / mL	K ₂ EDTA / Heparin	50 mg
21	Bicalutamide	LC-MS/MS (API 2000)	Human Plasma	100 to 5000 ng / mL	K ₂ EDTA	150 mg
22	Bisoprolol	LC-MS/MS (API 3200)	Human Plasma	0.5 to 80 ng / mL	K ₂ EDTA	10 mg
23	Bupropion	LC-MS/MS (Waters)	Human Plasma	0.5 to 250 ng / mL	K ₂ EDTA	150 mg
	Hydroxybupropion	LC-MS/MS (Waters)	Human Plasma	2 to 1000 ng / mL	K ₂ EDTA	-
24	Candesartan	LC-MS/MS (Waters)	Human Plasma	4 to 700 ng / mL	K ₂ EDTA	32 mg
25	Candesartan	LC-MS/MS (Waters)	Human Plasma	1 to 350 ng / mL	K ₂ EDTA	16 mg
26	Candesartan	LC-MS/MS (Waters)	Human Plasma	0.4 to 160 ng / mL	K ₂ EDTA	8 mg
27	Carbamazepine	LC-MS/MS (API 2000)	Human Plasma	50 to 7000 ng / mL	K ₂ EDTA	300 / 400 mg
28	Carbamazepine	LC-MS/MS (API 2000)	Human Plasma	0.5 to 20 µg / mL	K ₂ EDTA	400 mg (steady state)
29	Carbamazepine	LC-MS/MS (API 2000)	Human Plasma	100 to 7000 ng / mL	K ₂ EDTA	300 / 400 mg
	C 10, 11- Epoxide Metabolite	LC-MS/MS (API 2000)	Human Plasma	5 to 500 ng /mL	K ₂ EDTA	-
30	Cefaclor	HPLC-UV	Human Plasma	0.2 to 25 µg / mL	Heparin	500 mg



Sr. No.	Drug Name	Instrument	Matrix	Range	Anticoagulant	Dose
31	Cefadroxil	HPLC-UV	Human Plasma	0.5 to 50 µg / mL	Heparin	500 mg
32	Cefdinir	HPLC-UV	Human Plasma	0.035 to 5 ng / mL	Heparin	250 mg
33	Cefixime	HPLC-UV	Human Plasma	0.05 to 8 µg / mL	K ₂ EDTA / Heparin	400 mg
34	Ceftazidime	HPLC-UV	Human Plasma	0.3 to 60 µg / mL	Heparin	1 g injection
35	Cefuroxime	HPLC-UV	Human Plasma	0.3 to 35 µg / mL	Heparin	750 mg injection
36	Cefuroxime	HPLC-UV	Human Plasma	0.075 to 13 µg / mL	Heparin	500 mg
37	Celecoxib	LC-MS/MS (Waters)	Human Plasma	10 to 2000 ng / mL	Heparin	200 mg
38	Cephalexin	HPLC-UV	Human Plasma	0.3 to 40 µg / mL	Heparin	500 mg
39	Cetirizine	LC-MS/MS (API 3200)	Human Plasma	5 to 500 ng / mL	Heparin	10 mg
40	Chlorthalidone	HPLC-UV	Human Plasma	10 to 500 ng / mL	CPD	25 mg
41	Chlorthalidone	HPLC-UV	Human Plasma	50 to 3000 ng / mL	CPD	200 mg
42	Ciprofloxacin	HPLC - Fluorescence	Human Plasma	0.05 to 4 µg / mL	K ₂ EDTA	750 mg
43	Cimetidine	LC-MS/MS (Waters)	Human Plasma	5 to 1000 ng / mL	Heparin	200 mg
44	Cimetidine	LC-MS/MS (Waters)	Human Plasma	15 to 6000 ng / mL	Heparin	800 mg
45	Citalopram	HPLC - Fluorescence	Human Plasma	2 to 80 ng / mL	Heparin	40 mg
46	S-citalopram	LC-MS/MS (API 3200)	Human Plasma	0.25 to 50 ng / mL	K ₂ EDTA	20 mg
	S-desmethyl citalopram	LC-MS/MS (API 3200)	Human Plasma	0.125 to 25 ng / mL	K ₂ EDTA	-
47	Clavulanic acid	HPLC-UV	Human Plasma	0.05 to 4 µg / mL	K ₂ EDTA / Heparin	125 mg
48	Clopidogrel	LC-MS/MS (API 4000)	Human Plasma	20 to 4000 pg / mL	Heparin	75 mg



Sr. No.	Drug Name	Instrument	Matrix	Range	Anticoagulant	Dose
49	Clopidogrel	LC-MS/MS (API 2000)	Human Plasma	0.1 to 20 ng / mL	Heparin	300 mg
50	Clopidogrel Carboxy acid	LC-MS/MS (API 2000)	Human Plasma	30 to 5000 ng / mL	Heparin	75 mg
51	Clozapine	LC-MS/MS (Waters)	Human Plasma	2 to 750 ng / mL	K ₂ EDTA	200 mg multiple dose
52	Diclofenac sodium	LC-MS/MS (API 2000)	Human Plasma	5 to 2000 ng / mL	Heparin	75 mg / 100 mg
53	Diltiazem	LC-MS/MS (Waters)	Human Plasma	1 to 250 ng / mL	K ₂ EDTA	240 mg
	N-Des Methyl Diltiazem	LC-MS/MS (Waters)	Human Plasma	0.25 to 64 ng / mL	K ₂ EDTA	-
	Des Acetyl Diltiazem	LC-MS/MS (Waters)	Human Plasma	0.15 to 40 ng / mL	K ₂ EDTA	-
54	Dipyridamole	LC-MS/MS (API 2000)	Human Plasma	20 to 5000 ng / mL	K ₂ EDTA	200 mg
55	Docetaxel	LC-MS/MS (Waters)	Human Plasma	10 to 5000 ng / mL	K ₂ EDTA	20 mg / 0.5 mL injection
56	Docetaxel	LC-MS/MS (Waters)	Beagle Dog Plasma	10 to 4000 ng / mL	K ₂ EDTA	80mg / 2mL
57	Donepezil	LC-MS/MS (API 3200)	Human Plasma	0.4 to 30 ng / mL	K ₂ EDTA	10 mg
58	Duloxetine	LC-MS/MS (API 3200)	Human Plasma	0.5 to 100 ng / mL	Heparin	60 mg
59	Endoxifen	LC-MS/MS (Thermo)	Human Plasma	25 to 10000 ng /mL	K ₂ EDTA	0.5mg to 4.0 mg (Multiple dosing)
60	Entacapone	LC-MS/MS (API 3200)	Human Plasma	25 to 2500 ng / mL	Heparin	200 mg
61	Eplerenone	LC-MS/MS (Waters)	Human Plasma	5 to 1505 ng / mL	Heparin	50 mg
62	Eprosartan	LC-MS/MS (API 2000)	Human Plasma	10 to 5000 ng / mL	Heparin	300 mg
63	Esomeprazole	LC-MS/MS (Waters)	Human Plasma	20 to 3000 ng / mL	K ₂ EDTA	40 mg
64	Exemestane	LC-MS/MS (Waters)	Human Plasma	0.2 to 50 ng / mL	Heparin	25 mg
65	Ezetimibe (Total)	LC-MS/MS (Waters)	Human Plasma	0.5 to 250 ng / mL	Heparin	10 mg



Sr. No.	Drug Name	Instrument	Matrix	Range	Anticoagulant	Dose
66	Ezetimibe (Unconjugated)	LC-MS/MS (API 4000)	Human Plasma	0.075 to 15 ng / mL	Heparin	10 mg
67	Finasteride	LC-MS/MS (Waters)	Human Plasma	0.2 to 50 ng / mL	Heparin	5 mg
68	Finasteride	LC-MS/MS (Waters)	Human Plasma	0.2 to 30 ng / mL	Heparin	1 mg
69	Flucloxacilin	HPLC-UV	Human Serum	0.3 to 20 µg / mL	NA	500 mg
70	Fluconazole	LC-MS/MS (API 2000)	Human Plasma	50 to 10000 ng / mL	K ₂ EDTA	150 mg
71	Fluoxetine	LC-MS/MS (API 4000)	Human Plasma	0.25 to 25 ng /mL	K ₂ EDTA	20 mg
	Norfluoxetine	LC-MS/MS (API 4000)	Human Plasma	0.25 to 25 ng / mL	K ₂ EDTA	-
72	Fluoxetine	LC-MS/MS (API 3200)	Human Plasma	2.5 to 50 ng /mL	K ₂ EDTA	40 mg
73	Fluvastatin	LC-MS/MS (API 4000)	Human Plasma	1 to 500 ng / mL	Heparin	80 mg
74	Fluvastatin	LC-MS/MS (API 4000)	Human Plasma	0.5 to 200 ng / mL	Heparin	40 mg
75	Fulvestrant	LC-MS/MS (Waters)	Human Plasma	0.2 to 20 ng /mL	K ₂ EDTA	250 mg
76	Gabapentin	LC-MS/MS (API 2000)	Human Plasma	50 to 5000 ng / mL	K ₂ EDTA	400 mg
77	Gabapentin	LC-MS/MS (API 2000)	Human Plasma	150 to 10000 ng / mL	K ₂ EDTA	1200 / 800 mg
78	Glicazide	LC-MS/MS (API 3200)	Human Plasma	0.1 to 10 µg/mL	K ₂ EDTA	80 mg
79	Glimepiride	LC-MS/MS (API 2000)	Human Plasma	3 to 600 ng / mL	Heparin	4 mg
80	Hydrochlorothiazide	LC-MS/MS (API 4000)	Human Plasma	1 to 300 ng / mL	K ₂ EDTA	25 mg
81	Hydrochlorothiazide	LC-MS/MS (API 4000)	Human Plasma	2 to 400 ng / mL	K ₂ EDTA	50 mg
82	Ibuprofen	HPLC-UV	Human Plasma	1 to 100 µg / mL	Heparin	800 mg
83	Ibuprofen	LC-MS/MS (API 3200)	Human Plasma	0.1 to 40 µg / mL	Heparin	200 mg



Sr. No.	Drug Name	Instrument	Matrix	Range	Anticoagulant	Dose
84	Ibuprofen	LC-MS/MS (API 3200)	Human Plasma	0.1 to 90 µg / mL	K ₂ EDTA / Heparin	400 mg
85	Imatinib	LC-MS/MS (Waters)	Human Plasma	2 to 800 ng / mL	K ₂ EDTA	100 mg
	N-Desmethyl Imatinib	LC-MS/MS (Waters)	Human Plasma	0.5 to 125 ng / mL	K ₂ EDTA	-
86	Irbesartan	LC-MS/MS (API 2000)	Human Plasma	50 to 4500 ng / mL	Heparin	300 mg
87	Itraconazole	HPLC - Fluorescence	Human Plasma	5 to 500 ng / mL	CPD	100 mg
	OH-Itraconazole	HPLC - Fluorescence	Human Plasma	5 to 500 ng / mL	CPD	-
88	Itraconazole	LC-MS/MS (Waters)	Human Plasma	5 to 500 ng / mL	Heparin	100 mg
	OH-Itraconazole	LC-MS/MS (Waters)	Human Plasma	5 to 500 ng / mL	Heparin	-
89	3-Ketodesogestrel	LC-MS/MS (Thermo)	Human Plasma	40 to 5000 pg / mL	K ₂ EDTA	0.3 mg
90	Ketoconazole	HPLC - Fluorescence	Human Plasma	0.05 to 5 µg / mL	CPD	200 mg
91	Lamivudine	LC-MS/MS (API 2000)	Human Plasma	25 to 3000 ng / mL	Heparin	150 mg
92	Lacidipine	LC-MS/MS (API 4000)	Human Plasma	0.025 to 8 ng / mL	K ₂ EDTA	4 mg
93	Lansoprazole	LC-MS/MS (API 3200)	Human Plasma	10 to 2000 ng / mL	Heparin	30 mg
94	Lapatinib	LC-MS/MS (API 2000)	Human Plasma	15 to 6000 ng / mL	K ₂ EDTA	1250 mg
95	Lercanidipine	LC-MS/MS (API 3200)	Human Plasma	0.025 to 12 ng / mL	Heparin	20 mg
96	Letrozole	LC-MS/MS (API 3200)	Human Plasma	0.5 to 50 ng / mL	Heparin	2.5 mg
97	Levetiracetam	LC-MS/MS (API 3200)	Human Plasma	0.25 to 40 µg / mL	Heparin	1000 mg
98	Levocetirizine	LC-MS/MS (Waters)	Human Plasma	0.5 to 500 ng / mL	K ₂ EDTA	5 mg



Sr. No.	Drug Name	Instrument	Matrix	Range	Anticoagulant	Dose
99	Levodopa	LC-MS/MS (API 4000)	Human Plasma	15 to 2000 ng / mL	K ₂ EDTA	50 mg
	Carbidopa	LC-MS/MS (API 4000)	Human Plasma	1.5 to 250 ng / mL	K ₂ EDTA	200 mg
100	Levofloxacin	HPLC-UV	Human Plasma	0.1 to 12 µg / mL	Heparin	500 mg
101	Levonorgestrel	LC-MS/MS (API 4000)	Human Plasma	0.2 to 50 ng / mL	K ₂ EDTA	1.5 mg
102	Lofepamine	LC-MS/MS (API 4000)	Human Plasma	0.1 to 40 ng / mL	Heparin	75 mg
	Desipramine	LC-MS/MS (API 4000)	Human Plasma	0.2 to 80 ng / mL	Heparin	-
103	Losartan	LC-MS/MS (API 2000)	Human Plasma	5 to 1200 ng / mL	K ₂ EDTA / Heparin	-
	Losartan carboxylic acid	LC-MS/MS (API 2000)	Human Plasma	5 to 1200 ng / mL	K ₂ EDTA / Heparin	-
104	Losartan	LC-MS/MS (API 2000)	Human Plasma	10 to 1500 ng / mL	K ₂ EDTA	100 mg
	Losartan carboxylic acid	LC-MS/MS (API 2000)	Human Plasma	25 to 2000 ng / mL	K ₂ EDTA	-
105	Meloxicam	LC-MS/MS (Waters)	Human Plasma	20 to 3000 ng / mL	K ₂ EDTA	50 mg
106	Memantine	LC-MS/MS (API 4000)	Human Plasma	0.5 to 50 ng / mL	K ₂ EDTA	10 mg
107	Mesalamine	LC-MS/MS (Waters)	Human Plasma	5 to 700 ng / mL	K ₂ EDTA	1000 mg
108	Metoprolol	LC-MS/MS (API 4000)	Human Plasma	0.3 to 50 ng / mL	Heparin	23.75 mg
109	Metoprolol	LC-MS/MS (API 3200)	Human Plasma	0.5 to 60 ng / mL	Heparin	50 mg
110	Metoprolol	LC-MS/MS (API 3200)	Human Plasma	0.75 to 175 ng / mL	Heparin	100 mg
111	Metoprolol	LC-MS/MS (API 3200)	Human Plasma	0.75 to 300 ng / mL	Heparin	200 mg
112	Minocycline	LC-MS/MS (Waters)	Human Plasma	10 to 2500 ng / mL	Heparin	90 mg
113	Minocycline	LC-MS/MS (Waters)	Human Plasma	25 to 3500 ng / mL	K ₂ EDTA	135 mg



Sr. No.	Drug Name	Instrument	Matrix	Range	Anticoagulant	Dose
114	Moexipril	LC-MS/MS (API 4000)	Human Plasma	0.5 to 150 ng / mL	K ₂ EDTA	15 mg
115	Moxifloxacin	LC-MS/MS (API 3200)	Human Plasma	30 to 6200 ng / mL	Heparin	400 mg
116	Naltrexone	LC-MS/MS (Waters)	Human Plasma	0.1 to 20 ng /mL	Heparin	50 mg
	6 beta Naltrexol	LC-MS/MS (Waters)	Human Plasma	0.5 to 200 ng / mL	Heparin	-
117	Naltrexone	LC-MS/MS (Waters)	Human Plasma	0.5 to 50 ng /mL	Heparin	100 mg
	6 beta Naltrexol	LC-MS/MS (Waters)	Human Plasma	5 to 500 ng / mL	Heparin	-
118	Naratriptan	LC-MS/MS (API 3200)	Human Plasma	0.1 to 20 ng / mL	Heparin	2.5 mg
119	Naproxen	LC-MS/MS (API 2000)	Human Plasma	500 to 50000 ng /mL	K ₂ EDTA	200 mg
120	Nevirapine	HPLC-UV	Human Plasma	100 to 4000 ng / mL	CPD	200 mg
121	Nicorandil	HPLC-UV	Human Plasma	7.5 to 300 ng / mL	K ₂ EDTA	20 mg
122	Nifedipine	LC-MS/MS (API 2000)	Human Plasma	2.5 to 250 ng / mL	K ₂ EDTA	60 mg / 90 mg
123	Nizatidine	HPLC-UV	Human Plasma	20 to 4000 ng / mL	K ₂ EDTA / Heparin	300 mg
124	19-Norethindrone	LC-MS/MS (API 4000)	Human Plasma	0.25 to 50 ng / mL	K ₂ EDTA	5 mg
125	19-Norethindrone	LC-MS/MS (Thermo)	Human Plasma	0.075 to 15 ng / mL	K ₂ EDTA	1 mg
126	Oglimilast (GRC 3886)	LC-MS/MS (API 4000)	Human Plasma	0.5 to 100 ng / mL	K ₂ EDTA	200 mg
	Oglimilast N-Oxide (GRC 3886 N-Oxide)	LC-MS/MS (API 4000)	Human Plasma	0.5 to 100 ng / mL	K ₂ EDTA	-
127	Olanzapine	LC-MS/MS (Waters)	Human Plasma	0.25 to 25 ng / mL	Heparin	5 mg
128	Olmesartan	LC-MS/MS (API 3200)	Human Plasma	2.5 to 2250 ng / mL	K ₂ EDTA	40 mg
129	Olmesartan	LC-MS/MS (API 3200)	Human Plasma	2.5 to 1500 ng / mL	K ₂ EDTA	20 mg
130	Omeprazole	LC-MS/MS (Waters)	Human Plasma	10 to 1500 ng / mL	K ₂ EDTA	20 mg



Sr. No.	Drug Name	Instrument	Matrix	Range	Anticoagulant	Dose
131	Omeprazole	LC-MS/MS (Waters)	Human Plasma	20 to 3000 ng / mL	K ₂ EDTA	40 mg
132	Ondansetron	LC-MS/MS (Waters)	Human Plasma	0.5 to 50 ng / mL	Heparin	8 mg
133	O-Desmethyl Venlafaxine	LC-MS/MS (Waters)	Human Plasma	1 to 350 ng / mL	K ₂ EDTA	50 mg / 100 mg
134	Oxcarbazepine	LC-MS/MS (API 3200)	Human Plasma	20 to 4000 ng / mL	K ₂ EDTA	600 mg
	10,11-dihydro-10-hydroxycarbamazepine	LC-MS/MS (API 3200)	Human Plasma	50 to 16000 ng / mL	K ₂ EDTA	-
135	Oxybutynin	LC-MS/MS (Waters)	Human Plasma	0.07 to 15 ng / mL	K ₂ EDTA	5 mg
	N-Desethyl Oxybutynin	LC-MS/MS (Waters)	Human Plasma	0.38 to 75 ng / mL	K ₂ EDTA	-
136	Paclitaxel (Total)	LC-MS/MS (Waters)	Human Plasma	10 to 4500 ng / mL	Heparin	175 mg
137	Paclitaxel (Total)	LC-MS/MS (Waters)	Human Blood	50 to 30000 ng / mL	Heparin	220 mg / m ² (IV)
138	Free paclitaxel	LC-MS/MS (Waters)	Human Plasma	5 to 2000 ng / mL	Heparin	220 mg / m ² (IV)
139	Paliperidone	LC-MS/MS (API 3200)	Human Plasma	0.5 to 40 ng / mL	K ₂ EDTA	6 mg
140	Pantoprazole	LC-MS/MS (API 3200)	Human Plasma	2 to 4000 ng / mL	Heparin	40 mg
141	Penicillin V	HPLC-UV	Human Plasma	0.1 to 4 µg / mL	Heparin	250 mg
142	Phenyl butyrate	LC-MS/MS (API 3200)	Human Plasma	0.1 to 50 µg / mL	K ₂ EDTA	500 mg
143	Pioglitazone	LC-MS/MS (API 2000)	Human Plasma	10 to 2500 ng / mL	Heparin	45 mg



Sr. No.	Drug Name	Instrument	Matrix	Range	Anticoagulant	Dose
144	Pioglitazone	LC-MS/MS (API 2000)	Human Plasma	15 to 2500 ng / mL	Heparin	45 mg
	Pioglitazone hydroxyl metabolite	LC-MS/MS (API 2000)	Human Plasma	10 to 1500 ng / mL	Heparin	-
145	Metformin	LC-MS/MS (Waters)	Human Plasma	25 to 3000 ng / mL	Heparin	850 mg
	Pioglitazone	LC-MS/MS (Waters)	Human Plasma	5 to 1000 ng / mL	Heparin	20 mg
	Keto Pioglitazone	LC-MS/MS (Waters)	Human Plasma	1 to 200 ng / mL	Heparin	-
	Hydroxy Pioglitazone	LC-MS/MS (Waters)	Human Plasma	1 to 200 ng / mL	Heparin	-
146	Pramipexole	LC-MS/MS (Waters)	Human Plasma	25 to 5000 pg / mL	K ₂ EDTA	0.25 mg
147	Pravastatin	LC-MS/MS (Waters)	Human Plasma	2 to 600 ng / mL	K ₂ EDTA	80 mg
	Pravastatin metabolite	LC-MS/MS (Waters)	Human Plasma	2 to 400 ng / mL	K ₂ EDTA	-
148	Pravastatin	LC-MS/MS (Waters)	Human Plasma	2 to 600 ng / mL	K ₃ EDTA	80 mg
	Pravastatin metabolite	LC-MS/MS (Waters)	Human Plasma	2 to 400 ng / mL	K ₃ EDTA	-
149	Prochlorperazine	LC-MS/MS (API 4000)	Human Plasma	5 to 300 pg / mL	Heparin	5 mg
150	Propafenone	LC-MS/MS (Waters)	Human Plasma	0.5 to 500 ng / mL	K ₂ EDTA	300 mg
	5-Hydroxy Propafenone	LC-MS/MS (Waters)	Human Plasma	0.5 to 400 ng/mL	K ₂ EDTA	-
151	Pseudoephedrine	LC-MS/MS (API 3200)	Human Plasma	2 to 400 ng /mL	Heparin	30 mg
152	2-Pyridylacetic acid	LC-MS/MS (Waters)	Human Plasma	5 to 800 ng / mL	K ₂ EDTA	16 mg
153	Quetiapine	LC-MS/MS (Waters)	Human Plasma	0.5 to 200 ng / mL	Heparin	25 mg
	N-desalkyl Quetiapine	LC-MS/MS (Waters)	Human Plasma	0.08 to 20 ng / mL	Heparin	-
154	Quetiapine	LC-MS/MS (API 2000)	Human Plasma	0.2 to 400 ng / mL	K ₂ EDTA	50 mg
	N-desalkyl Quetiapine	LC-MS/MS (API 2000)	Human Plasma	0.2 to 50 ng / mL	K ₂ EDTA	-



Sr. No.	Drug Name	Instrument	Matrix	Range	Anticoagulant	Dose
155	Quetiapine	LC-MS/MS (API 2000)	Human Plasma	2 to 1500 ng / mL	Heparin	200 mg
	N-Des Alkylated Quetiapine	LC-MS/MS (API 2000)	Human Plasma	0.5 to 150 ng / mL	Heparin	-
156	Quinine	LC-MS/MS (Waters)	Human Plasma	25 to 5000 ng /mL	K ₂ EDTA	300 mg
157	Rabeprazole	LC-MS/MS (API 3200)	Human Plasma	5 to 1000 ng / mL	K ₂ EDTA / K ₃ EDTA / Heparin	20 mg
158	Ramipril	LC-MS/MS (API 4000)	Human Plasma	0.2 to 50 ng / mL	Heparin	10 mg
	Ramiprilat	LC-MS/MS (API 4000)	Human Plasma	0.5 to 50 ng / mL	Heparin	-
159	Ranitidine	LC-MS/MS (API 2000)	Human Plasma	10 to 2000 ng / mL	Heparin	150 / 300 mg
160	Ranitidine	HPLC-UV	Human Plasma	25 to 1500 ng / mL	K ₂ EDTA / Heparin	300 mg
161	Ranitidine	LC-MS/MS (API 2000)	Human Plasma	5 to 600 ng / mL	K ₂ EDTA / Heparin	75 mg
162	Rasagiline	LC-MS/MS (Waters)	Human Plasma	40 to 20000 pg / mL	K ₂ EDTA	1 mg
163	Repaglinide	LC-MS/MS (API 3200)	Human Plasma	0.25 to 30 ng / mL	K ₂ EDTA	2 mg
164	Risedronate	LC-MS/MS (Thermo)	Human Plasma	0.1 to 80 ng / mL	Heparin	35 mg
165	Risperidone	LC-MS/MS (API 4000)	Human Plasma	0.1 to 15 ng / mL	Heparin	1 mg
	9- hydroxy Risperidone	LC-MS/MS (API 4000)	Human Plasma	0.1 to 15 ng / mL	Heparin	-
166	Rosiglitazone	LC-MS/MS (API 2000)	Human Plasma	15 to 900 ng / mL	K ₂ EDTA	8 mg
167	Rosiglitazone	LC-MS/MS (API 2000)	Human Plasma	5 to 500 ng / mL	K ₂ EDTA	4 mg
168	Rosuvastatin	LC-MS/MS (Waters)	Human Plasma	0.2 to 25 ng / mL	K ₂ EDTA	10 mg
169	Rosuvastatin	LC-MS/MS (Waters)	Human Plasma	0.5 to 80 ng / mL	K ₂ EDTA	40 mg
170	S-citalopram	LC-MS/MS (API 3200)	Human Plasma	0.25 to 50 ng / mL	K ₂ EDTA	20 mg
	S- desmethyl citalopram	LC-MS/MS (API 3200)	Human Plasma	0.125 to 8 ng / mL	K ₂ EDTA	-



Sr. No.	Drug Name	Instrument	Matrix	Range	Anticoagulant	Dose
171	S-citalopram	LC-MS/MS (API 3200)	Human Plasma	0.25 to 50 ng / mL	Heparin	20 mg
	S- desmethyl citalopram	LC-MS/MS (API 3200)	Human Plasma	0.125 to 25 ng / mL	Heparin	-
172	Sertraline	LC-MS/MS (API 2000)	Human Plasma	1 to 100 ng / mL	Heparin	100 mg
173	Sertaraline	LC-MS/MS (Waters)	Human Plasma	0.5 to 40 ng / mL	Heparin	50 mg
174	Sibutramine	LC-MS/MS (Waters)	Human Plasma	100 to 20000 pg / mL	K ₂ EDTA / Heparin	15 mg
	Desmethyl Sibutramine	LC-MS/MS (Waters)	Human Plasma	50 to 10000 pg / mL	K ₂ EDTA / Heparin	-
	Didesmethyl Sibutramine	LC-MS/MS (Waters)	Human Plasma	75 to 15000 pg / mL	K ₂ EDTA / Heparin	-
175	Sildenafil	LC-MS/MS (API 3200)	Human Plasma	2 to 1000 ng / mL	K ₂ EDTA	100 mg
	Desmethyl Sildenafil	LC-MS/MS (API 3200)	Human Plasma	1 to 150 ng / mL	K ₂ EDTA	-
176	Simvastatin	LC-MS/MS (API 4000)	Human Plasma	0.3 to 75 ng / mL	Heparin	80 mg
	Simvastatin acid	LC-MS/MS (API 4000)	Human Plasma	0.3 to 50 ng / mL	Heparin	-
177	Simvastatin	LC-MS/MS (API 4000)	Human Plasma	0.1 to 75 ng / mL	Heparin	40 mg
	Simvastatin acid	LC-MS/MS (API 4000)	Human Plasma	0.1 to 50 ng / mL	Heparin	-
178	Spironolactone	LC-MS/MS (API 3200)	Human Plasma	0.5 to 300 ng / mL	K ₂ EDTA	100 mg
	Canrenone	LC-MS/MS (API 3200)	Human Plasma	1 to 200 ng / mL	K ₂ EDTA	-
179	Sumatriptan	LC-MS/MS (API 2000)	Human Plasma	1 to 100 ng / mL	Heparin	100 mg
180	Tacrolimus	LC-MS/MS (Waters)	Human Blood	40 to 10000 pg / mL	K ₂ EDTA	0.5 mg
181	Tacrolimus	LC-MS/MS (Waters)	Human Blood	0.25 to 50 ng / mL	K ₂ EDTA	5 mg
182	Tamsulosin	LC-MS/MS (Waters)	Human Plasma	0.1 to 50 ng / mL	K ₂ EDTA	0.4 mg



Sr. No.	Drug Name	Instrument	Matrix	Range	Anticoagulant	Dose
183	Tamoxifen	LC-MS/MS (API 3200)	Human Plasma	0.5 to 100 ng / mL	K ₂ EDTA	20 mg
	Endoxifen	LC-MS/MS (API 3200)	Human Plasma	0.5 to 100 ng / mL	K ₂ EDTA	20 mg
184	Telmisartan	LC-MS/MS (Waters)	Human Plasma	2 to 750 ng / mL	K ₂ EDTA	80 mg
185	Tenoxicam	HPLC-UV	Human Plasma	0.05 to 5 µg / mL	K ₂ EDTA / Heparin	20 mg
186	Terbinafine	HPLC-UV	Human Plasma	10 to 1600 ng / mL	Heparin	250 mg
187	Tolterodine	LC-MS/MS (Waters)	Human Plasma	50 to 25000 pg / mL	Heparin	4 mg
	5-Hydroxymethyl tolterodine	LC-MS/MS (Waters)	Human Plasma	20 to 10000 pg / mL	Heparin	-
188	Tolterodine	LC-MS/MS (Waters)	Human Plasma	20 to 5000 pg / mL	Heparin	2 mg
	5-hydroxymethyl Tolterodine	LC-MS/MS (Waters)	Human Plasma	10 to 5000 pg / mL	Heparin	-
189	Topiramate	LC-MS/MS (API 2000)	Human Plasma	10 to 1500 ng / mL	CPD	50 mg
190	Topiramate	LC-MS/MS (API 2000)	Human Plasma	100 to 7000 ng / mL	Heparin	200 mg
191	Tramadol	LC-MS/MS (Waters)	Human Plasma	2.5 to 500 ng / mL	Heparin	50 mg
	O-desmethyl Tramadol	LC-MS/MS (Waters)	Human Plasma	1 to 100 ng / mL	Heparin	-
192	Trandolapril	LC-MS/MS (Waters)	Human Plasma	0.1 to 30 ng / mL	Heparin	-
	Trandolaprilat	LC-MS/MS (Waters)	Human Plasma	0.2 to 31 ng / mL	Heparin	-
193	Trifluoperazine	LC-MS/MS (API 2000)	Human Plasma	0.05 to 10 ng / mL	CPD	-
194	Trimebutine	LC-MS/MS (API 3200)	Human Plasma	0.1 to 30 ng / mL	K ₂ EDTA	96 mg
	N-Desmethyl Trimebutine	LC-MS/MS (API 3200)	Human Plasma	1 to 400 ng / mL	K ₂ EDTA	-
195	Trimetazidine	LC-MS/MS (Waters)	Human Plasma	0.25 to 150 ng / mL	Heparin	35 mg



Sr. No.	Drug Name	Instrument	Matrix	Range	Anticoagulant	Dose
196	Trimethoprim	HPLC-UV	Human Plasma	0.025 to 2.5 µg / mL	CPD	50 mg
197	Valacyclovir	LC-MS/MS (API 2000)	Human Plasma	3 to 300 ng / mL	Heparin	500 mg
	Acyclovir	LC-MS/MS (API 2000)	Human Plasma	40 to 4000 ng / mL	Heparin	-
198	Valacyclovir	LC-MS/MS (API 2000)	Human Plasma	3 to 600 ng / mL	Heparin	1000 mg
	Acyclovir	LC-MS/MS (API 2000)	Human Plasma	40 to 8000 ng / mL	Heparin	-
199	Valganciclovir	LC-MS/MS (API 2000)	Human Plasma	4 to 500 ng / mL	K ₂ EDTA	450 mg
	Ganciclovir	LC-MS/MS (API 2000)	Human Plasma	50 to 10000 ng / mL	K ₂ EDTA	-
200	Valproic acid	HPLC-UV	Human Plasma	1 to 110 µg / mL	Heparin	500 mg
201	Valproic acid	LC-MS/MS (Waters)	Human Plasma	1 to 80 µg / mL	Heparin	500 mg
202	Valsartan	LC-MS/MS (API 3200)	Human Plasma	20 to 2000 ng / mL	Heparin	40 mg
203	Valsartan	LC-MS/MS (API 3200)	Human Plasma	50 to 8000 ng / mL	Heparin	160 mg
204	Valsartan	LC-MS/MS (API 3200)	Human Plasma	100 to 20000 ng / mL	Heparin	320 mg
205	Venlafaxine	LC-MS/MS (Waters)	Human Plasma	0.5 to 300 ng / mL	Heparin	150 mg
	ODM-Venlafaxine	LC-MS/MS (Waters)	Human Plasma	1 to 300 ng / mL	Heparin	-
206	Venlafaxine	LC-MS/MS (Waters)	Human Plasma	0.5 to 150 ng / mL	Heparin	75 mg
	ODM-Venlafaxine	LC-MS/MS (Waters)	Human Plasma	1 to 150 ng / mL	Heparin	-
207	Verapamil	HPLC - Fluorescence	Human Plasma	2 to 250 ng / mL	Heparin	-
	Norverapamil	HPLC - Fluorescence	Human Plasma	2 to 250 ng / mL	Heparin	-



Sr. No.	Drug Name	Instrument	Matrix	Range	Anticoagulant	Dose
208	Verapamil	LC-MS/MS (Waters)	Human Plasma	4 to 300 ng / mL	Heparin	240 mg
	Norverapamil	LC-MS/MS (Waters)	Human Plasma	2 to 177 ng / mL	Heparin	-
209	Verapamil	LC-MS/MS (Waters)	Human Plasma	4 to 300 ng / mL	Heparin	240 mg
	Norverapamil	LC-MS/MS (Waters)	Human Plasma	2 to 177 ng / mL	Heparin	-
	Trandolapril	LC-MS/MS (Waters)	Human Plasma	0.05 to 15 ng / mL	Heparin	4 mg
	Trandolaprilat	LC-MS/MS (Waters)	Human Plasma	0.4 to 31 ng / mL	Heparin	-
210	Vardenafil	LC-MS/MS (Waters)	Human Plasma	0.2 to 40 ng / mL	Heparin	20 mg
211	Ulipristal acetate	LC-MS/MS (API 4000)	Human Plasma	0.1 to 250 ng / mL	K ₂ EDTA	30 mg
	11-demethylated Ulipristal acetate	LC-MS/MS (API 4000)	Human Plasma	0.1 to 100 ng / mL	K ₂ EDTA	-
212	Warfarin	HPLC - Fluorescence	Human Plasma	10 to 750 ng / mL	Heparin	5 mg
213	Warfarin	HPLC - Fluorescence	Human Plasma	20 to 2500 ng / mL	Heparin	10 mg
214	Ziprasidone	HPLC - Fluorescence	Human Serum	1.5 to 200 ng / mL	NA	40 mg
215	Zolmitriptan	LC-MS/MS (Waters)	Human Plasma	0.2 to 30 ng / mL	Heparin	5 mg
	N-desmethyl zolmitriptan	LC-MS/MS (Waters)	Human Plasma	0.2 to 20 ng / mL	Heparin	-
216	Zolpidem	LC-MS/MS (API 3200)	Human	1 to 300 ng / mL	K ₂ EDTA	10 mg
217	Zonisamide	HPLC-UV	Human Serum	25 to 3000 ng / mL	NA	100 mg



NEW CHEMICAL ENTITIES

(FULL NAME WITHHELD DUE TO CONFIDENTIALITY)	
Sr. No	Drug Name
1	NCE-01
2	NCE-02
3	NCE-03
4	NCE-04
5	NCE-05
6	NCE-06



Part C

List of Methods Under Development





METHODS UNDER DEVELOPMENT

Sr. No.	Drug Name	Strength
1	Nicotine	21 mg / 24 hrs
2	Solefenacin	10 mg
3	Lapatinib	250 mg
4	Atenolol + Nifedipine	50 mg + 20 mg
5	Doxorubicin Total & Free	50 mg
6	Propranolol (R & S)	40 mg
7	Fenspride	80 mg
8	Pregabalin	300 mg
9	Dexamethasone	2 mg



NEW MODALITY OF TESTING

IMMUNOGENICITY TESTING CAPABILITIES	
1	First Laboratory in India to provide Immunogenicity testing services for biosimilars.
2	Method development, Method Validation and Patient sample testing for Human recombinant Erythropoietin.
3	Screening Antibody assays (ELISA based)
4	Neutralizing Antibody Assay (Cell based assay)

NEW METHODS VALIDATED AT CLINICAL LABORATORY

Sr. No.	Drug Name	Strength
1	Potassium Chloride	10 & 20 mEq (750 mg & 1500 mg)
2	Enoxaparin	100 mg / mL
3	Bivaluridin	250 mg / vial



METHODS VALIDATED FOR PD MARKERS

Sr. No	PD Markers
1	CD 34
2	Reticulocyte Count
3	Sputum Eosinophil & Neutrophil
4	Granulocyte Colony-Stimulating Factor (G-CSF)
5	TNF- α
6	Erythropoetin
7	Factor Xa & Factor IIa
8	BAP (Bone specific Alkalinephosphatase) by ELISA
9	Urine Alpha-GST (ELISA)

METHODS UNDER VALIDATION: PD MARKERS

Sr. No	PD Markers
1	Human Serum Adiponectin-HMW
2	Human Serum Adiponectin-Total
3	hs-CRP
4	Apolipoprotein B
5	TRAP(Tartrate Resistant Alkaline phosphatase)
6	NEFA/FFA (Non Esterified Fatty Acids/Free Fatty Acid)
7	Lipoprotein (a)
8	IL-6 (Interleukin-6)
9	Insulin
10	C-peptide
11	ACTH (Adrenocorticotropic hormone)
12	Free T3 & Free T4

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