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# NORWICH Clinical Services Pvt. Ltd

147/F. 8<sup>th</sup> Main, 3<sup>rd</sup> Block, Koramangala

Bangalore- 560034

INDIA



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## Bioanalytical Information



**February 2017**

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## Bioanalytical Services:



**Bioanalytical Facility about 10,000 sq.ft**

- *Qualified, trained & experienced team of bioanalytical professionals*
- *Method development/validation for proprietary (NCE) and non-proprietary assays.*
- *Bioanalysis of drug and metabolites in a variety of biological matrices*
- *Ability to develop and validate highly sensitive assays in low pg/ml range.*
- *Ability to accommodate projects with rapid turn-around times*

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## Equipment Information:

3 LCMS/MS – API 4000 with WATERS UPLC

1 LCMS/MS - 5500 Triple QUAD

Standalone HPLC- Shimadzu

*We are one of the very few labs in India to have the latest 5500 LCMS/MS Bio analytical machine offering very high sensitivity and ability to conduct hormone studies etc*

Software: Analyst 1.5.1 for data processing & Instrument control. Fully validated & 21 CFR part 11 compliant

### Bioanalytical Methods Validated: 69

SL. No	MOLECULE NAME	CALIBRATION CURVE RANGE	LOQ	ANTICOAGULANT	MATRIX
1	ABIRATERONE	0.206 ng/mL to 79.419 ng/mL	0.206 ng/mL	SODIUM FLUORIDE+POTASSIUM OXALATE	PLASMA
2	AMOXICILLIN	0.0518 µg/ml to 10.2300 µg/ml	0.0518 µg/ml	K2EDTA	PLASMA
3	AMLODIPINE	75.060pg/mL-12078.160pg/mL	75.060pg/mL	K2EDTA	PLASMA
4	ATORVASTAIN	0.210 ng/ml to 302.187 ng/ml	0.210 ng/ml	K2EDTA	PLASMA
5	ASPIRIN + DIPYRIDAMOLE	Aspirin-6.354 ng/ml to 1186.216 ng/ml	Aspirin-6.354 ng/ml	K2EDTA	PLASMA
		Dipyridamole-0.0265 µg/ml to 4.9446 µg/ml	Dipyridamole-0.0265 µg/ml		
6	ARTEMETHER+DIHYDROARTIMISININ	Artemether - 1.085ng/ml to 202.585ng/ml	Artemether - 1.085ng/ml	K2EDTA	PLASMA
		Dihydroartimisinin 1.065ng/ml to 305.728ng/ml	Dihydroartimisinin 1.065ng/ml		
7	APIXABAN	1.026ng/ml to 252.481ng/ml	1.026ng/ml	K2EDTA	PLASMA
8	ATAZANAVIR+RITONAVIR	Atazanavir : 50.208ng/ml to 7051.564ng/ml	Atazanavir : 50.208ng/ml	K2EDTA	PLASMA
		Ritonavir: 20.012ng/ml to 4002.629ng/ml	Ritonavir: 20.012ng/ml		
9	BROMOCRIPTINE	0.800pg/ml to 156.380pg/ml	0.800pg/ml	K2EDTA	PLASMA
10	BUDESONIDE	10.194pg/ml to 7527.064pg/ml	10.194pg/ml	K2EDTA	PLASMA
11	BOSENTAN	10.419 ng/mL-3529.172 ng/mL	10.419 ng/mL	K2EDTA	PLASMA

SL. No	MOLECULE NAME	CALIBRATION CURVE RANGE	LOQ	ANTICOAGULANT	MATRIX
12	CARBAMAZEPINE	0.0252 µg/ml to 5.3083 µg/ml	0.0252 µg/ml	K2EDTA	PLASMA
13	CARBIDOPA	0.410 ng/ml to 250.412 ng/ml	0.410 ng/ml	K2EDTA	PLASMA
14	CINACALCET	0.207ng/ml to 120.953ng/ml	0.207ng/ml	K2EDTA	PLASMA
15	CETIRIZINE+AMBROXOL	Cetirizine 4.028 ng/ml -606.378 ng/ml	Cetirizine 4.028 ng/ml	K2EDTA	PLASMA
		Ambroxol-1.018 ng/ml -301.718 ng/ml	Ambroxol-1.018 ng/ml		
16	CLOMIPRAMINE+METABOLITE	Clomipramine-0.512ng/ml to 200.534ng/ml	0.512ng/ml	K2EDTA	PLASMA
		N-Desmethyl Clomipramine-0.513ng/ml to 200.763ng/ml	0.513ng/ml		
17	DAPSONE	0.0501 µg/ml to 8.0566 µg/ml	0.0501 µg/ml	K2EDTA	PLASMA
18	DANTROLENE	2.040 ng/ml to 1483.958ng/ml	2.040 ng/ml	K2EDTA	PLASMA
19	DOLUTEGRAVIR	30.219ng/ml to 8058.984ng/ml	30.219ng/ml	K2EDTA	PLASMA
20	DILTIAZEM +METABOLITES	Diltiazem-2.001 ng/ml to 602.463 ng/ml	Diltiazem-2.001 ng/ml	K2EDTA	PLASMA
		Desacetyl diltiazem-0.301 ng/ml to 62.445 ng/ml	Desacetyl diltiazem-0.301 ng/ml		
		N-demethyl diltiazem-1.005 ng/ml to 208.371ng/ml	N-demethyl diltiazem-1.005 ng/ml		
21	EFAVIRENZ	0.0309 µg/ml to 5.3662 µg/ml	0.0309 µg/ml	K2EDTA	PLASMA
22	FREE EZETIMIBE	75.140 pg/mL-15315.580 pg/mL	75.140 pg/mL	K2EDTA	PLASMA
23	TOTAL EZETIMIBE	1.087 ng/ml to 304.400 ng/ml	1.087 ng/ml	K2EDTA	PLASMA
24	EMITRICETABINE+TENOFVIR	Emtricitabine-0.0323 µg/ml to 5.0603 µg/ml	Emtricitabine-0.0323 µg/ml	K2EDTA	PLASMA
		Tenofvir - 5.217 ng/ml to 793.228 ng/ml	Tenofvir - 5.217 ng/ml		

SL. No	MOLECULE NAME	CALIBRATION CURVE RANGE	LOQ	ANTICOAGULANT	MATRIX
25	ERLOTINIB	5.018ng/ml to 2506.721ng/ml	5.018ng/ml	K2EDTA	PLASMA
26	FELODIPINE	0.103 ng/ml to 20.177 ng/ml	0.103ng/ml	K2EDTA	PLASMA
27	GLICLAZIDE	8.032 ng/ml to 6026.128 ng/ml	8.032 ng/ml	K2EDTA	PLASMA
28	GLIPIZIDE	5.090 ng/ml to 849.708 ng/ml	5.090 ng/ml	K2EDTA	PLASMA
29	GEFITINIB	1.206 ng/ml to 253.224 ng/ml	1.206 ng/ml	K2EDTA	PLASMA
30	ISRADIPINE	50.856 pg/ml to 30916.089 pg/ml	50.856pg/ml	K2EDTA	PLASMA
31	ISONIAZID	0.0302µg/ml to 10.0519µg/ml	0.0302µg/ml	K2EDTA	PLASMA
32	LEVOFLOXACIN	0.0547 µg/ml to 11.8712 µg/ml	0.0547 µg/ml	K2EDTA	PLASMA
33	LAMIVUDINE+ZIDOVUDINE+NEVIRAPINE	Lamivudine - 9.505ng/ml to 1473.327ng/ml	Lamivudine - 9.505ng/ml	K2EDTA	PLASMA
		Zidovudine - 10.373ng/ml to 1607.896ng/ml	Zidovudine - 10.373ng/ml		
		Nevirapine - 15.066ng/ml to 2418.780ng/ml	Nevirapine - 15.066ng/ml		
34	LEVOMILNACIPRAN	2.039ng/ml to 504.911ng/ml	2.039ng/ml	K2EDTA	PLASMA
35	LUMEFANTRINE	0.1073 µg/ml to 10.2977 µg/ml	0.1073 µg/ml	K2EDTA	PLASMA
36	LAMOTRIGENE	10.017ng/ml to 8040.682ng/ml	10.017ng/ml	K2EDTA	PLASMA
37	LENALIDOMIDE	2.065ng/ml to 855.284ng/ml	2.065ng/ml	K2EDTA	PLASMA
38	LAMIVUDINE+ABACAVIR	0.0999µg/ml to 17.9387µg/ml for Abacavir	Abacavir:0.0999µg/ml	K2EDTA	PLASMA
		0.0309µg/ml to 4.0113µg/ml for Lamivudine	Lamivudine : 0.0309µg/ml		
39	METAXALONE	0.0500 µg/ml to 8.0391 µg/ml	0.0500 µg/ml	K2EDTA	PLASMA

SL. No	MOLECULE NAME	CALIBRATION CURVE RANGE	LOQ	ANTICOAGULANT	MATRIX
40	MELPHALAN	2.049 ng/ml to 444.663 ng/ml	2.049 ng/ml	K2EDTA	PLASMA
41	METFORMIN	10.895 ng/ml to 2521.895 ng/ml	10.895ng/ml	K2EDTA	PLASMA
42	METOPROLOL	1.024 ng/ml to 150.509 ng/ml	1.024ng/ml	K2EDTA	PLASMA
43	MOXIFLOXACIN	0.0508µg/ml to 6.0511µg/ml	0.0508µg/ml	K2EDTA	PLASMA
44	METFORMIN+SITAGLIPTIN	Metformin-10.045 ng/ml to 2206.210 ng/ml	Metformin-10.045 ng/ml	K2EDTA	PLASMA
		Sitagliptin - 3.013 ng/ml to 800.530 ng/ml	Sitagliptin - 3.013 ng/ml		
45	NATEGLINIDE	0.049 µg/ml to 8.0840 µg/ml	0.049 µg/ml	K2EDTA	PLASMA
46	NAPROXEN	0.5246 µg/ml to 124.2584 µg/ml	0.5246 µg/ml	K2EDTA	PLASMA
47	NIFEDIPINE	1.558 ng/ml to 360.561ng/ml	1.558ng/ml	K2EDTA	PLASMA
48	NEVIRAPINE	15.070 ng/ml to 6031.800 ng/ml	15.070 ng/ml	K2EDTA	PLASMA
49	OLANZAPINE	0.108ng/ml to 40.218ng/ml	0.108ng/ml	K2EDTA	PLASMA
50	OXYBUTYNIN + DESETHYL OXYBUTYNIN	Oxybutynin-0.103 ng/ml to 8.642 ng/ml	Oxybutynin-0.103 ng/ml	K2EDTA	PLASMA
		Desethyl oxybutynin-0.201 ng/ml to 70.041ng/ml	Desethyl oxybutynin-0.201 ng/ml		
51	OSELTAMAVIR + OSELTAMIVIR CARBOXYLATE	Oseltamivir-0.517ng/ml to 206.862ng/ml	Oseltamivir-0.517ng/ml	SODIUM FLUORIDE+POTASSIUM OXALATE	PLASMA
		Oseltamivir carboxylate - 4.079ng/ml to 1202.421ng/ml	Oseltamivir carboxylate - 4.079ng/ml		
52	OXCARBAZEPINE + MHD	Oxcarbazepine - 4.985 ng/ml to 4096.668 ng/ml	Oxcarbazepine - 4.985 ng/ml	K2EDTA	PLASMA

SL. No	MOLECULE NAME	CALIBRATION CURVE RANGE	LOQ	ANTICOAGULANT	MATRIX
		MHD - 0.0508 µg/ml to 12.3593 µg/ml	MHD - 0.0508 µg/ml		
53	PALIPERIDONE	0.101 ng/mL-30.216 ng/mL	0.101 ng/mL	K2EDTA	PLASMA
54	PIROXICAM	0.0318 µg/ml to 4.2438µg/ml	0.0318 µg/ml	K2EDTA	PLASMA
55	PRAZQUANTEL	1.012 ng/ml -751.552 ng/ml	1.012 ng/ml	K2EDTA	PLASMA
56	PYRIMETHAMINE	2.032 ng/ml to 424.004 ng/ml	2.032 ng/ml	K2EDTA	PLASMA
57	RAMIPRIL	0.227 ng/ml to 50.797 ng/ml	0.227 ng/ml	K2EDTA	PLASMA
58	RIFAXIMIN	20.447 pg/ml to 10158.758 pg/ml	20.447 pg/ml	K2EDTA	PLASMA
59	ROFLUMILAST	75.700pg/ml to 16149.460pg/ml	75.700pg/ml	K2EDTA	PLASMA
60	RIFAMPIN+25-DESACETYL RIFAMPIN	0.0255µg/ml to 10.0890µg/ml for Rifampin	Rifampin:0.0255µg/ml	K2EDTA	PLASMA
		4.059 ng/ml to 1234.392 ng/ml for Desacetyl Rifampin	Desacetyl Rifampin:4.059 ng/ml		
61	TENOFOVIR	5.285 ng/ml to 807.165 ng/ml	5.285 ng/ml	-	SERUM
62	TOPIRAMATE	10.034 ng/ml to 4379.213 ng/ml	10.034 ng/ml	K2EDTA	PLASMA
63	TERIFLUNOMIDE	10.338 ng/ml to 3922.369 ng/ml	10.338 ng/ml	K2EDTA	PLASMA
64	TOLCAPONE	20.141 ng/ml to 7519.611 ng/ml	20.141 ng/ml	K2EDTA	PLASMA

SL. No	MOLECULE NAME	CALIBRATION CURVE RANGE	LOQ	ANTICOAGULANT	MATRIX
65	TRIMETAZIDINE	0.500ng/ml to 403.877ng/ml	0.500ng/ml	K2EDTA	PLASMA
66	TENOFVIR+LAMIVUDINE	Lamivudine : 0.0304µg/ml to 4.5405µg/ml	Lamivudine : 0.0304µg/ml	K2EDTA	PLASMA
		Tenofovir: 5.281ng/ml to 804.784ng/ml	Tenofovir: 5.281ng/ml		
67	SIMVASTATIN+ METABOLITE	Simvastatin-0.514 ng/ml -104.571 ng/ml	Simvastatin-0.514 ng/ml	K2EDTA	PLASMA
		Simvastatin hydroxy acid -0.110 ng/ml -15.640 ng/ml	Simvastatin hydroxy acid -0.110 ng/ml		
68	SULFADOXINE	0.0997 µg/ml to 100.4417 µg/ml	0.0997 µg/ml	K2EDTA	PLASMA
69	VINORELBINE	1.063 ng/ml to 507.505 ng/ml	1.063 ng/ml	SODIUM FLUORIDE+POTASSIUM OXALATE	BLOOD

### Bio-analytical Methods ( Partial Validation required):

SI. No	MOLECULE NAME	CALIBRATION CURVE RANGE	ANTICOAGULANT	MATRIX
1	ARMODAFINIL	0.077ng/ml to 10.000ng/ml	K2EDTA	PLASMA
2	BEPOTASTINE	0.500 ng/ml to 540.000ng/ml	K2EDTA	PLASMA
3	BUPROPION_HYDROXY BUPROPION	BUPROPION- 2.000ng/ml to 260.000ng/ml	K2EDTA	PLASMA
		HYDROXY BUPROPION-10.000ng/ml to 680.000ng/ml		
		Tenofovir - 5.217 ng/ml to 793.228 ng/ml		
4	FLUPIRTINE+METABOLITE	FLUPIRTINE- 9.000ng/ml to 1600.000 ng/ml	K2EDTA	PLASMA
		Acetylated Fluirtine metabolite-D13223- 2.000ng/ml to 360.000 ng/ml		
5	OLMESARTAN	4.000ng/ml to 4100.000ng/ml	K2EDTA	PLASMA
6	PANTOPRAZOLE	10.000ng/ml to 3000.000ng/ml	K2EDTA	PLASMA



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7	PREGABLIN	10.000 ng/ml to 10000.000 ng/ml	K2EDTA	PLASMA
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## Bio-analytical Methods under Development

SL NO	MOLECULE NAME
1	NITROGLYCERINE+METABOLITES
2	EPINEPHRINE+ NOREPINEPHRINE
3	PAZOPANIB
4	POSACONAZOLE

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