

EU CTD Dossier

Sr. No.	Product Name	Dosage Form	Strength	Dossier Availability	DCP Status	Therapeutic Class
1	Apixaban	Tablet	2.5/5 mg	Available		Anti-coagulant
2	Aripiprazole	Tablet	5/10/15/30 mg	Available	Completed	Anti-psychotic
3	Amlodipine + Valsartan	Tablet	10+160/5+160/5+80 mg	Available	Completed	Anti-hypertensive
4	Amlodipine + Valsartan + HCTZ	Tablet	5+160+12.5/10+160+12.5/5+160+25/10+160+25/10+320+25 mg	Available	Completed	Anti-hypertensive
5	Atomoxetine	Capsule	10/18/25/40/60/80/100 mg	Available	Completed	ADHD
6	Canagliflozin	Tablet	100/300 mg	Available		Anti-diabetic
7	Candesartan	Tablet	2/4/8/16/32 mg	Available		Anti-hypertensive
8	Candesartan + HCTZ	Tablet	16+12.5 mg	Available		Anti-hypertensive
9	Celecoxib	Capsule	100/200 mg	Available	Completed	NSAID (Pain/Inflammation)
10	Cinacalcet	Tablet	30/60/90 mg	Available	Completed	Anti-hyperthyroidism
11	Clopidogrel	Tablet	75 mg	Available	Completed	Anti-platelet
12	Colchicine	Tablet	0.5/1 mg	Available	Completed	Anti-gout
13	Dapagliflozin	Tablet	5/10 mg	Available		Anti-diabetic
14	Donepezil	Tablet	5/10 mg	Available	Completed	Anti-psychotic
15	Donepezil ODT	OD Tablet	5/10 mg	Available		Anti-psychotic
16	Dimethyl Fumarate	Capsule	120/240 mg	Available		Multiple sclerosis
17	Empagliflozin	Tablet	10/25 mg	Available		Anti-diabetic
18	Escitalopram	Tablet	5/10/20 mg	Available	Completed	Anti-depressant
19	Febuxostat	Tablet	80/120 mg	Available	Completed	Anti-gout
20	Irbesartan	Tablet	75/150/300 mg	Available	Completed	Anti-hypertensive
21	Irbesartan + HCTZ	Tablet	150+12.5/300+12.5/300+25 mg	Available	Completed	Anti-hypertensive
22	Lacosamide	Tablet	50/100/150/200 mg	Available	Completed	Anti-psychotic
23	Lamivudine + Abacavir	Tablet	300 + 600 mg	Available	Oct, 2019	Anti-bacterial
24	Levofloxacin	Tablet	250/500 mg	Available	Completed	Anti-bacterial
25	Levodopa + Carbidopa + Entacapone	Tablet	50+12.5+200/75+18.75+200/100+25+200/125+31.25+200/150+37.5+200/200+50+200/43.75+175+200 mg	Available		Anti-Parkinson's
26	Linagliptin	Tablet	5 mg	Available		Anti-diabetic
27	Linezolid	Tablet	600 mg	Available		Antibiotics
28	Memantine HCL	Tablet	10/20 mg	Available	Completed	Anti-psychotic
29	Memantine	Oral Drops	10 mg/ml (5 mg/pump)	Available	Completed	Anti-Alzheimer
30	Montelukast	Tablet	10 mg	Available		Anti-asthmatic/ Bronchospasm prophylaxis
31	Moxifloxacin	Tablet	400 mg	Available	Completed	Antibiotics
32	Nebivolol	Tablet	2.5/5/10 mg	Available	Completed	Anti-hypertensive

All dossiers above are in EU-CTD format; bio-equivalence studies performed in GCP/ GLP certified labs against reference product from EU.

Sr. No.	Product Name	Dosage Form	Strength	Dossier Availability	DCP Status	Therapeutic Class
33	Nortriptyline	Tablet	10/25mg	Available	Completed	Anti-depressant
34	Norfloxacin	Tablet	400 mg	Available		Antibiotics
35	Olmesartan	Tablet	10/20/40 mg	Available	Completed	Anti-hypertensive
36	Olmesartan+HCTZ	Tablet	20+12.5/20+25/40+12.5/40+25 mg	Available	Completed	Anti-hypertensive
37	Olmesartan+Amlodipine	Tablet	20+5/20+10/40+5/40+10 mg	Available	Ongoing	Anti-hypertensive
38	Olmesartan+Amlodipine+HCTZ	Tablet	20+5+12.5/40+5+12.5/40+5+25/40+10+12.5/40+10+25 mg	Available	Ongoing	Anti-hypertensive
39	Pantoprazole	DR Tablet	20/40 mg	Available	Completed	Anti-ulcers/ Erosive esophgitis
40	Pirfenidone	Capsule	267 mg	Available		Anti-fibrotic
41	Pyrazinamide	Tablet	500 mg	Available	Completed	Anti-TB
42	Quetiapine	Tablet	25/100/200/300 mg	Available		Anti-psychotic
43	Rasagiline	Tablet	1 mg	Available	Completed	Anti-Parkinson's
44	Rosuvastatin	Tablet	5/10/20/40 mg	Available	Completed	Anti-hyperlipidemic
45	Rivaroxaban	Tablet	5/15/20 mg	Available		Anti-coagulant
46	Sildenafil	Tablet	25/50/100 mg	Available	Completed	Erectile dysfunction
47	Tadalafil	Tablet	2.5/5/10/20 mg	Available		Erectile dysfunction
48	Tamsulosin ER	Capsule	0.4 mg	Available	Completed	Benign Prostatic Hyperplasia (BPH)
49	Tenofovir	Tablet	300 mg	Available	Completed	Anti-retro viral
50	Tenofovir+Emtricitabine	Tablet	300+200 mg	Available	Completed	Anti-retro viral
51	Tenofovir+Emtricitabine+Efavirenz	Tablet	300+200+600 mg	Available	Completed	Anti-retro viral
52	Ticagrelor	Tablet	60/90 mg	Available		Anti-coagulant
53	Tolterodine ER	Capsule	2/4 mg	Available	Completed	Anti-spasmodic
54	Valsartan	Tablet	40/80/160/320 mg	Available	Completed	Anti-hypertensive
55	Valsartan+HCTZ	Tablet	160+25 mg	Available		Anti-hypertensive
56	Vortioxetine	Tablet	5/10/15/20 mg	Available		Anti-depressant
UPCOMING DOSSIER						
57	Ezetimibe+Simvastatin	Tablet	10+10/10+20/10+40/10+80 mg	Q4, 2019		Anti-hyperlipidemic
58	Sitagliptin	Tablet	25/50/100 mg	Q2, 2020		Anti-diabetic
59	Vildagliptin	Tablet	50 mg	Q2, 2020		Anti-diabetic
60	Varenicline	Tablet	0.5/1 mg	Q2, 2020		Smoking Cessation
61	Vildagliptin + Metformin	Tablet	50+1000/50+850 mg	Q3, 2020		Anti-diabetic
62	Sitagliptin + Metformin	Tablet	50+850/50+1000 mg	Q3, 2020		Anti-diabetic
63	Dabigatran	Capsule	75/110/150 mg	Q3, 2020		Anti-coagulant

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