

## US CTD Dossier

Sr. No.	Product Name	Strength	Reference Product	Dossier Availability
<b>ANALGESICS</b>				
1	Celecoxib Capsule	50/100/200/400 mg	Celebrex®	Available
2	Tramadol Tablet	50/100/200/300 mg	Ultram®	Available
3	Tramadol ER Tablet	100/200/300 mg	Ultram ER®	Available
4	Tramadol + Acetaminophen Tablet	37.5+325 mg	Ultracet®	Available
5	Colchicine Tablet	0.6 mg	Colcryx®	Available
<b>ANTI-DIABETIC</b>				
6	Canagliflozin + Metformin Tablet	50+500/50+1000/150+500/150+1000 mg	Invokamet®	Available
7	Canagliflozin Tablet	100/300 mg	Invokana®	Available
8	Dapagliflozin Tablet	5/10 mg	Farxiga®	Available
9	Dapagliflozin + Metformin Tablet	5+500/5+1000/10+500/10+1000 mg	Xigduo XR®	Available
10	Empagliflozin Tablet	10/25 mg	Jardiance®	Available
11	Empagliflozin + Metformin HCL Tablet	5+500/ 5+1000/ 12.5+500/12.5+1000 mg	Synjardy®	Available
12	Linagliptin + Empagliflozin Tablet	5+10/5+25 mg	Glyxambi®	Available
13	Linagliptin Tablet	5 mg	Tradjenta®	Available
14	Metformin + Pioglitazone Tablet	500+15/850+15 mg	Actoplusmet®	Available
15	Metformin ER Tablet	500/750 mg	Glucophage XR®	Available
16	Metformin ER Tablet	1000 mg	Glumetza®	Available
17	Metformin Tablet	500/850/1000 mg	Glucophage®	Available
18	Pioglitazone Tablet	15/30/45 mg	Actos®	Available
19	Repaglinide Tablet	0.5/1/2 mg	Prandin®	Available
20	Sitagliptin + Metformin Tablet	1000+50/500+50 mg	Janumet®	Available
21	Sitagliptin Tablet	25/50/100 mg	Januvia®	Available
<b>ANTI-OSTEOPOROTIC</b>				
22	Febuxostat Tablet	40/80 mg	Uloric®	Available
23	Ibandronate Tablet	150 mg	Boniva®	Available
24	Raloxifene Tablet	60 mg	Evista®	Available
25	Risedronate Tablet	5/30/35 mg	Actonel®	Available
<b>CARDIO VASCULAR SYSTEM</b>				
26	Apixaban Tablet	2.5/5 mg	Eliquis®	Available
27	Amlodipine Tablet	5/10 mg	Norvasc®	Available
28	Amlodipine + Benazepril Capsule	2.5+10/5+10/5+20/5+40/10+20/10+40 mg	Lotrel®	Available
29	Atorvastatin Tablet	10/20/40/80 mg	Lipitor®	Available
30	Candesartan + HCTZ Tablet	16+12.5/32+12.5/32+25 mg	Atacand HCT®	Available
31	Candesartan Tablet	2/4/8/16/32 mg	Atacand®	Available
32	Choline Fenofibrate Capsule	45/135 mg	Trilipix®	Available
33	Clopidogrel Tablet	75 mg	Plavix®	Available
34	Colesevelam Tablet	625 mg	Welchol®	Available
35	Ezetimibe Tablet	10 mg	Zetia®	Available

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36	Ezetimibe + Simvastatin Tablet	10+10/10+20/10+40/10+80 mg	Vytorin®	Available
37	Fenofibrate Tablet	54/160 mg	Triglide®	Available
38	Fenofibrate Tablet	48/145 mg	Triglide®	Available
39	Fenofibric Delayed Release Capsule	45/135 mg	Trilipix®	Available
40	Irbesartan + HCTZ Tablet	150+12.5/300+12.5/300+25 mg	Avapro HCT®	Available
41	Irbesartan Tablet	75/150/300 mg	Avapro®	Available
42	Losartan + HCTZ Tablet	50+12.5/100+12.5/100+25 mg	Hyzaar®	Available
43	Losartan Tablet	25/50/100 mg	Cozaar®	Available
44	Metoprolol ER Tablet	25/50/100/200 mg	Toprol XL®	Available
45	Nebivolol Tablet	2.5/5/10/20 mg	Bystolic®	Available
46	Niacin ER Tablet	500/750/1000 mg	Niaspan®	Available
47	Olmesartan + Amlodipine + HCTZ Tablet	20+5+12.5/40+5+12.5/40+5+25/40+10+12.5/40+10+25 mg	Tribenzor®	Available
48	Olmesartan + Amlodipine Tablet	20+5/20+10/40+5/40+10 mg	Azor®	Available
49	Olmesartan + HCTZ Tablet	20+12.5/40+12.5/40+25 mg	Benicar HCT®	Available
50	Olmesartan Tablet	5/10/20/40 mg	Benicar®	Available
51	Rivaroxaban Tablet	10/15/20 mg	Xarelto®	Available
52	Rosuvastatin Tablet	5/10/20/40 mg	Crestor®	Available
53	Telmisartan + HCTZ Tablet	12.5+40/12.5+80/25+80 mg	Micardis HCT®	Available
54	Telmisartan Tablet	20/40/80 mg	Micardis®	Available
55	Ticagrelor Tablet	60/90 mg	Brilinta®	Available
56	Triamterene + HCTZ Tablet	37.5+25/75+50 mg	Maxzide®	Available
57	Valsartan + Amlodipine + HCTZ Tablet	5+160+12.5/10+160+12.5/5+160+25/10+160+25/10+320+25 mg	Exforge HCT®	Available
58	Valsartan + Amlodipine Tablet	5+160/5+320/10+160/10+320 mg	Exforge®	Available
59	Valsartan + HCTZ Tablet	80+12.5/160+12.5/160+25/320+12.5/320+25 mg	Diovan HCT®	Available
60	Valsartan + Sacubitril Tablet	24+26/49+51/97+103 mg	Entresto®	Available
61	Valsartan Tablet	40/80/160/320 mg	Diovan®	Available
62	Warfarin Tablet	1/2/2.5/3/4/5/6/7.5/10 mg	Coumadin®	Available

## CENTRAL NERVOUS SYSTEM

63	Aripiprazole Tablet	2/5/10/15/20/30 mg	Abilify®	Available
64	Desvenlafaxine ER Tablet	100 mg	Pristiq®	Available
65	Donepezil ER Tablet	23 mg	Aricept®	Available
66	Donepezil OD Tablet	5/10 mg	Aricept ODT®	Available
67	Donepezil Tablet	5/10 mg	Aricept®	Available
68	Duloxetine ER Capsule	20/30/60 mg	Cymbalta®	Available
69	Entacapone Tablet	200 mg	Stalevo®	Available
70	Escitalopram Oral Solution	5 mg/5 ml	Lexapro®	Available
71	Escitalopram Tablet	5/10/20 mg	Lexapro®	Available
72	Eszopiclone Tablet	1/2/3 mg	Lunesta®	Available
73	Lacosamide Tablet	50/100/150/200 mg	Vimpat®	Available
74	Lurasidone Tablet	20/40/60/80/120 mg	Latuda®	Available
75	Memantine ER + Donepezil Capsule	14+10/28+10 mg	Namzaric®	Available
76	Memantine ER Capsule	7/14/21/28 mg	Namenda XR®	Available
77	Memantine Oral Solution	2 mg/ml	Namenda®	Available
78	Memantine Tablet	5/10 mg	Namenda®	Available

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79	Milnacipran Tablet	12.5/25/50/100 mg	Savella®	Available
80	Olanzapine OD Tablet	5/10/15/20 mg	Zyprexa Zydis®	Available
81	Olanzapine Tablet	2.5/5/7.5/10/15/20 mg	Zyprexa®	Available
82	Oxcarbazepine Suspension	300 mg/5 ml	Trileptal®	Available
83	Perphenazine Tablet	2/4/8/16 mg	Perphenazine®	Available
84	Pramipexole ER Tablet	0.375/0.75/1.5/2.25/3/3.75/4.5 mg	Mirapex ER®	Available
85	Pramipexole IR Tablet	0.125/0.25/0.5/1.0/1.5 mg	Mirapex®	Available
86	Pregabalin Capsule	25/50/75/100/150/200/225/300 mg	Lyrica®	Available
87	Quetiapine IR Tablet	25/50/100/150/200/300/400 mg	Seroquel®	Available
88	Quetiapine SR Tablet	50/150/200/300/400 mg	Seroquel XR®	Available
89	Rasagiline Tablet	0.5/1 mg	Azilect®	Available
90	Rivastigmine Capsule	1.5/3/4.5/6 mg	Exelon®	Available
91	Rizatriptan OD Tablet	5/10 mg	Maxalt MLT®	Available
92	Rizatriptan Tablet	5/10 mg	Maxalt®	Available
93	Venlafaxine ER Capsule	37.5/75/150 mg	Effexor SR®	Available
94	Ziprasidone Capsule	20/40/60/80 mg	Geodon®	Available
95	Zolmitriptan Film Coated Tablet	2.5/5 mg	Zomig®	Available
96	Zolmitriptan OD Tablet	2.5/5 mg	Zomig ZMT®	Available

## ERECTILE DYSFUNCTION

97	Sildenafil Citrate Tablet	20/25/50/100 mg	Viagra®	Available
98	Tadalafil Tablet	2.5/5/10/20 mg	Cialis®	Available
99	Vardenafil IR Tablet	2.5/5/10/20 mg	Levitra®	Available
100	Vardenafil OD Tablet	10 mg	Staxyn®	Available

## GASTRO INTESTINAL SYSTEM

101	Esomeprazole Capsule	20/40 mg	Nexium®	Available
102	Lansoprazole Capsule	15 mg/30 mg	Prevacid®	Available
103	Pantoprazole Sodium DR Tablet	20/40 mg	Protonix®	Available
104	Rabeprazole Enteric Coated Tablet	10/20 mg	Aciphex®	Available

## URINARY SYSTEM

105	Darifenacin ER Tablet	7.5/15 mg	Enablex®	Available
106	Sildenafil IR Capsule	2/4 mg	Rapaflo®	Available
107	Solifenacin Tablet	5/10 mg	Vesicare®	Available
108	Tamsulosin Capsule	0.4 mg	Flomax®	Available
109	Tolterodine IR Tablet	1/2 mg	Detrol®	Available
110	Trospium Tablet	20 mg	Sanctura®	Available

## MISCELLANEOUS

111	Apremilast Tablet	10/20/30 mg	Otezla®	Available
112	Atomoxetine Capsule	10/18/25/40/60/80/100 mg	Strattera®	Available
113	Cevimeline Capsule	30 mg	Evxac®	Available
114	Cholestyramine Oral Powder for Suspension	4 gm	Cholestyramine®	Available
115	Clorthalidone Tablet	25/50 mg	Chlorthalidone®	Available
116	Cinacalcet Tablet	30/60/90 mg	Sensipar®	Available
117	Cyclobenzaprine ER Capsule	15/30 mg	Amrix®	Available

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118	Dimethylfumarate DR Capsule	120/240 mg	Tecfidera®	Available
119	Doxycycline Capsule	40 mg	Oracea®	Available
120	Doxycycline Hyclate Tablet	100 mg	Acticlate®	Available
121	Doxycycline Hyclate IR Capsule	100 mg	Vibramycin®	Available
122	Famciclovir Tablet	125/250/500 mg	Famvir®	Available
123	Hydralazine Tablet	10/25/50/100 mg	Piiva®	Available
124	Levocetirizine Tablet	5 mg	Xyzal®	Available
125	Levofloxacin Oral Solution	25 mg/ml	Levaquin®	Available
126	Levofloxacin Tablet	250/500/750 mg	Levaquin®	Available
127	Levothyroxine Tablet	25/50/75/88/100/112/125/137/150/175/200/300 mcg	Synthroid®	Available
128	Linezolid Tablet	600 mg	Zyvox®	Available
129	Metaxalone Tablet	800 mg	Skelaxin®	Available
130	Methimazole Tablet	5/10 mg	Methimazol®	Available
131	Montelukast Chewable Tablet	4/5 mg	Singulair®	Available
132	Montelukast Tablet	10 mg	Singulair®	Available
133	Moxifloxacin Tablet	400 mg	Avalox®	Available
134	Nitrofurantoin Capsule	25/50/100 mg	Macrodentine®	Available
135	Oseltamivir Capsule	30/45/75 mg	Tamiflu®	Available
136	Pirfenidone Capsule	267 mg	Esbriet®	Available
137	Sevelamer Carbonate Suspension	800/2.4 mg/ packet	Renvela®	Available
138	Sevelamer Carbonate Tablet	800 mg	Renvela®	Available
139	Sevelamer HCL Tablet	400/800 mg	Renagel®	Available
140	Vortioxetine Tablet	5/10/20 mg	Trintellix®	Available
<b>UNDER DEVELOPMENT</b>				
141	Brexipiprazole Tablet	0.25/0.5/1/2/3 mg	Rexulti®	Nov-19
142	Carbidopa + Levodopa + Entacapone Tablet	12.5+50+200/18.75+75+200/ 25+100+200/31.25+125+200/37.5+150+200/ 43.75+175+200/50+200+200 mg	Stalevo®	Nov-19
143	Lansoprazole OD Tablet	15/30 mg	Prevacid®	Nov-19
144	Nitrofurantoin Suspension	25 mg/5 ml	Furadantin®	Nov-19
145	Potassium Chloride ER Tablet	8/10 meq	Kolr Con®	Nov-19
146	Phenytoin Na Capsule	100 mg	Dilantin ER®	Dec-19
147	Triamterene + HCTZ Capsule	37.5+25 mg	Dyazide®	Dec-19
148	Aspirin + Dipyridamole ER Capsule	25+200mg	Aggrenox®	Jan-20
149	Carvedilol ER Tablet	10/20/40/80 mg	Coreg CR®	Apr-20
150	Carbamazepine ER Tablet	100/200/400 mg	Tegetrol®	Aug-20
151	Mexiletine Capsule	150/200/250 mg	Mexilitine HCL®	Aug-20
152	Rifaximin Tablet	200/550 mg	Xifaxan®	Nov-20
153	Dexlansoprazole DR Capsule	30/60 mg	Dexilant®	Jan-21
154	Mirabegron Tablet	25/50 mg	Myrbetriq®	Jan-21