

Oral Solids

Sr.	Product	Strength	RLD used in BE Study	Therapeutic Category
1	Acitretin Capsules	10mg, 25mg	Soriatane/ Neotigason	Dermatology
2	Amlodipine Besylate + Perindopril Erbumine Tablets	4mg+5mg, 4mg+10mg, 8mg+5mg, 8mg+10mg	Coveram	CVS
3	Apixaban Tablets	2.5mg, 5mg	Eliquis	Anti-Coagulant
4	Clopidogrel IR Tablets	75mg	Plavix	Anti-Platelet
5	Donepezil Tablets	5mg, 10mg	Aricept	Alzheimer's Disease
6	Etoricoxib Tablets	30mg, 60mg, 90mg, 120mg	Arcoxia	NSAID
7	Felodipine ER Tablets	2.5mg, 5mg, 10mg	Plendil/ Modip	CVS
8	Glycopyrrolate Tablets	1mg, 2mg	Robinul/ Robinul Forte	Anti-Cholinergic
9	Irbesartan Tablets	150mg, 300mg	Aprovel	CVS
10	Metformin + Glibenclamide	500mg+5mg	Glucovance	Anti-Diabetic
11	Metformin + Glimepiride Tablets	500mg+2mg	Glucophage XR 500, Amaryl 2 Mg	Anti-Diabetic
12	Metformin + Vildagliptin Tablets	500mg+50mg, 850mg+50mg, 1000mg+50mg	Eucreas	Anti-Diabetic
13	Metformin IR Tablets	500mg, 850mg, 1000mg	Glucophage	Anti-Diabetic
14	Metformin SR Tablets	500mg, 750mg, 1000mg	Glucovance XR	Anti-Diabetic
15	Naratriptan HCl Tablets	1mg, 2.5mg	Amerge/ Naramig	Anti-Migraine
16	Rivaroxaban Tablets	2.5mg, 10mg, 15mg, 20mg	Xarelto	Anti-Coagulant
17	Rosuvastatin Tablets	5mg, 10mg, 20mg, 40mg	Crestor	CVS
18	Ticagrelor IR Tablets	60mg, 90mg	Brilinta/ Brilique	CVS

Injectables

Sr.	Product	Strength	RLD used in BE Study	Therapeutic Category
1	Glycopyrrolate Injection	(0.2mg/ml) 1ml & 2ml single dose vial; 5ml & 20ml multidose vial	Robinul	Anti-Cholinergic
2	Icatibant Acetate Injection	10mg/ml - 3ml PFS	Firazyr	Hereditary Angioedema
3	Octreotide Injection	50mcg/ml, 100mcg/ml, 500mcg/ml single dose 1ml vial & 200mcg/ml, 1000mcg/ml multidose 5ml vial (2-8°C)	Sandostatin	Growth hormone, glucagon, and insulin inhibitor
4	Palonosetron Injection	0.05mg/ml-5ml vial	Aloxi	Anti-Emetic
5	Peg. Filgrastim Injection	6mg/0.6ml PFS (2-8°C)	Neulasta	Immuno Modulator
6	Regadenoson Monohydrate Injection	0.08mg/ml - 5ml PFS	Lexiscan	Diagnostic Imaging Agent
7	Sugammadex Sodium Injection	100mg/ml - 2ml & 5ml vial	Bridion	Neuromuscular
8	Zoledronic Acid Injection	4mg/5ml Liquid Concentrate vial	Zometa	Bone Disease

Ophthalmic

Sr.	Product	Strength	RLD used in BE Study	Therapeutic Category
1	Olopatadine HCl Ophthalmic Solution	0.1% -5ml Bottle	Patanol	Anti-Histaminic
2	Olopatadine HCl Ophthalmic Solution	0.2% -2.5ml Bottle	Pataday	Anti-Histaminic

USV North America

Sr.No.	Product	Strength	RLD used in BE Study	Therapeutic Category
1	Carbamazepine ER Tablets	100mg, 200mg, 400mg	Tegretol XR	Anti-Convulsant
2	Carbamazepine IR Tablets	200mg	Tegretol	Anti-Convulsant
3	Chlorthalidone IR Tablets	25mg, 50mg	Mylan-RS	Diuretic
4	Colesevelam HCl IR Tablets	625mg	Welchol	Dyslipidaemic Agent
5	Colestipol IR Tablets	1gm	Amneal-RS	Dyslipidaemic Agent
6	Divalproex DR Capsules	125mg	Dipakote Sprinkles	Anti-Convulsant
7	Donepezil HCl Tablets	5mg, 10mg	Aricept	Alzheimer's disease
8	Etelcalcetide injection	(5mg/ml) 0.5ml, 1ml & 2ml single dose vial	Parsabiv	Hyperparathyroidism
9	Glycopyrrolate Injection	0.2ml/ml , 1ml & 2ml single dose vial; 5ml & 20ml multidose vial	Robinul	Anti-Cholinergic
10	Metformin HCl ER Tablets	500mg, 750mg	Glucophage	Anti-Diabetic
11	Metformin HCl ER Tablets	1000mg	Glumetza	Anti-Diabetic
12	Metformin HCl IR Tablets	500mg, 850mg, 1000mg	Glucophage	Anti-Diabetic
13	Metolazone IR Tablets	2.5mg, 5mg, 10mg	Sandoz-RS	Diuretic
14	Minocycline HCl IR Tablets	50mg, 75mg, 100mg	Dynacin	Antibiotic
15	Olopatadine HCl Ophthalmic solution	0.2%-2.5ml, Bottle	Pataday	Anti-Histaminic
16	Phenytoin ER Capsules	100mg, 200mg, 300mg	Dilantin	Anti-Convulsant
17	Prazosin IR Capsules	1mg, 2mg, 5mg	Minipress	Anti-Hypertensive
18	Prochlorperazine IR Tablets	5mg, 10mg, 25mg	Jubilant Cadista- RS	Anti-Vertigo
19	Rivaroxaban Tablets	2.5mg, 10mg, 15mg, 20mg	Xarelto	Anti-Coagulant
20	Ticagrelor Tablets	60mg, 90mg	Brilinta/ Brilique	CVS

Commercial Scale

Sr.No.	Product	USDMF	EDMF	CEP	JDMF	DMF	Therapeutic Category
1	Acitretin	✓	✓	✓*		✓	Treatment of Psoriasis
2	Barnidipine Hydrochloride		✓#				Anti-hypertensive
3	Bicalutamide		✓		✓	✓	Treatment of Prostate Cancer
4	Blended Metformin (0.5% Mag. Stearate)	✓					Anti-Diabetic
5	Clopidogrel Hydrogen Sulphate		✓	✓*			Anti-Platelet
6	Dolasetron Mesylate	✓					Nausea & vomiting (chemo induced)
7	Donepezil Hydrochloride Monohydrate (Form-I)	✓	✓	✓*			Dementia
8	Etelcalcetide Hydrochloride	✓					Anti-Diabetic
9	Glimepiride	✓		✓	✓	✓	Anti-Diabetic
10	Glipizide	✓	✓				Anti-Diabetic
11	Glyburide / Glibenclamide	✓		✓		✓	Anti-Diabetic
12	Icatibant Acetate	✓	✓			✓	Immunomodulators
13	Imiquimod	✓				✓	Immune Response Modifiers
14	Metformin Hydrochloride DC Granules 86.66% & 95% w/w	✓	✓			✓	Anti-Diabetic
15	Metformin Hydrochloride with (0.5%/ 1%/ 5% Silicon Dioxide)		✓				Anti-Diabetic
16	Metformin Hydrochloride	✓		✓	✓	✓	Anti-Diabetic
17	Naratriptan Hydrochloride	✓	✓		✓	✓	Pain Management
18	Nateglinide	✓				✓	Anti-Diabetic
19	Octreotide Acetate	✓				✓	Treatment of Severe Diarrhea
20	Olopatadine Hydrochloride	✓	✓			✓	Anti-Histamine
21	Palonosetron Hydrochloride	✓	✓			✓	Nausea & vomiting (chemo induced)
22	Pioglitazone Hydrochloride	✓	✓				Anti-Diabetic
23	Regadenoson Monohydrate	✓					Pharmacologic Stress Testing
24	Repaglinide	✓		✓		✓	Anti-Diabetic
25	Rivaroxaban			✓#			Anti-Coagulant
26	Ropinirole Hydrochloride	✓	✓			✓	Treatment of Parkinson's Disease
27	Sugammadex Sodium	✓	✓		✓	✓	Neuromuscular reversal
28	Ticagrelor	✓	✓	✓#			Cardiovascular
29	Trimetazidine Di-Hydrochloride	✓		✓		✓	Cardiovascular
30	Zoledronic Acid	✓	✓	✓*		✓	Treatment of Hypercalcemia

*products under review

products to be filed

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