

EU-CTD Dossier Product List

S. No	PRODUCT NAME	PHARMACEUTICAL FORM	STRENGTH	THERAPEUTIC CLASS /MAIN INDICATION	DOSSIER READINESS TIMELINE
CARDIOVASCULAR PRODUCTS					
1	RIVAROXABAN	Film-Coated Tablet	2.5mg, 10mg, 15mg, 20mg	Anti-Coagulant /Antithrombotic	Ready
2	AMIODARONE	Tablet	100mg, 200mg	Anti-Arrhythmic Agent	Ready
3	AMLODIPINE	Tablet	5mg, 10mg	Anti-Hypertensive Drug	Ready
4	APIXABAN	Film Coated Tablet	2.5mg, 5mg	AntiCoagulant/ Antithrombotic	Q3-21
5	TICAGRELOR	Film-Coated Tablet	60mg, 90mg	Anti-Platelet Drug	Q4-21
6	EDOXABAN TOSYLATE	Film Coated Tablet	15mg, 30mg, 60mg	Antithrombotic	Q4-22
ENT & RESPIRATORY PRODUCTS					
7	CETIRIZINE	Film-Coated Tablet	10mg	Anti-Histamine Drug	Ready
8	BILASTINE	Film-Coated Tablet	20mg	Anti-Histamine Drug	Ready
9	BILASTINE	Orodispersible Tablet (ODT)	10mg	Anti-Histamine Drug	Q1-22
10	DESLORATADINE	Film-Coated Tablet	5mg	Anti-Histamine Drug	Ready
11	PIRFENIDONE	Film Coated Tablet	267mg, 801mg	Idiopathic pulmonary fibrosis	Q4-21
12	BETAHISTINE	Tablet	8mg, 16mg, 24mg	Anti Vertigo Drug	Q2-21
13	MONTELUKAST	Film Coated Tablet	10mg	Anti Asthmatic Drug	Q1-22
14	DEXCHLORPHENIR AMINE	Tablet	2mg	Anti-Histamine Drug	Ready
ANTI DIABETIC PRODUCTS					
15	CANAGLIFLOZIN	Film Coated Tablet	100mg, 300mg	Anti Diabetic Drug	Q1-23
16	LINAGLIPTIN	Film Coated Tablet	5mg	Anti Diabetic Drug	Q1-22
17	DAPAGLIFLOZIN	Film Coated Tablet	5mg, 10mg	Anti Diabetic Drug	Q1-23
18	DAPAGLIFLOZIN-METFORMIN	Film Coated Tablet	5mg+850mg, 5mg+1g	Anti Diabetic Drug	Q1-23
19	EMPAGLIFLOZIN	Film Coated Tablet	10mg, 25mg	Anti Diabetic Drug	Q1-23
INFLAMMATION & IMMUNOLOGY					
20	APREMILAST	Film Coated Tablet	10mg, 20mg, 30mg	Anti Rheumatic Drug	Q4-22
CNS PRODUCTS					
21	SUMATRIPTAN	Film-Coated Tablet	25mg, 50mg, 100mg	Anti-Migraine Drug	Ready

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CNS PRODUCTS					
22	MEMANTINE	Film Coated Tablet	5mg, 10mg,15mg, 20mg	Anti Alzheimer Drug	Q3-21
23	MIRTAZAPINE	Film Coated Tablet	15mg, 30mg, 45mg	Anti-Depressant	Q4-21
24	ZOPICLONE	Film Coated Tablet	3.75mg, 5mg, 7.5mg	For Insomnia	Q3-21
25	PERAMPANEL	Film Coated Tablet	2mg, 4mg, 6mg, 8mg, 10mg, 12mg	Anti-Epileptics	Q4-22
26	CLOZAPINE	Tablet	25mg, 50mg, 100mg	Anti-Depressant	Q1-22
27	ATOMOXETINE	Capsule	10mg, 18mg, 25mg,40mg,60mg, 80mg,100mg	Anti-Depressant	Q4-21
UROLOGY					
28	SOLIFENACIN	Film Coated Tablet	5mg,10mg	For BPH	Q3-21
SMOKING CESSATION PRODUCT					
29	VARENICLINE	Film-Coated Tablet	0.5mg, 1mg	Smoking Cessation Agent	Ready
PAIN MANAGEMENT					
30	PARACETAMOL	Uncoated Tablet	500mg,1000mg	Analgesics / Anti-Pyretic	Ready
LIPID LOWERING AGENT					
31	EZETIMIBE	Tablet	10mg	For Hypercholesterolemia / Hyperlipidemia	Q4-21
VITAMIN PRODUCT					
32	THIAMINE	Tablet	50mg, 100mg	Treat or prevent vitamin B1 deficiency	Q4-21
33	CHOLECALCIFEROL	Tablet	800IU, 1000IU	Use in vitamin D deficiency or related disorder such as rickets or osteomalacia	Q4-22