



KWALITY
PHARMACEUTICALS LTD.

GLOBAL DEVELOPMENT PROGRAMMES



Global Development Portfolio						
Oncology (EU - GMP Accredited)						
S.No.	Product Name	RLD Details	CEP Availability	CRO Partner	BE Completion	Dossier Readiness
1	Abiraterone Tablets 250 mg	Zytiga, Janssen-Cilag	Yes	Bioradius India	Done	Available
2	Nilotinib Capsule 200 mg	Tasigna, Novartis	Under Filing	Clinsync, India	Done	Available
3	Hydroxycarbamide Capsule 500 mg	Hydrea,Cheplapharma Arzneimittel	Yes	Clinsync, India	Done	Available
4	Vandetanib Tablet 100mg,300 mg	Caprelsa, Sanofi	No	Clinsync, India	Done	Available
5	Abiraterone Tablets 500 mg	Zytiga, Janssen-Cilag	Yes	Vimta, India	On Going	Q4,2026
6	Palbociclib Tablet 75mg, 100mg, 125 mg	PalBace, Pfizer	No (CEP filing Underway)	Raptim, India	Oct-26	Q4,2026
7	Enzalutamide Tablets 40mg, 80mg, 160mg	Xtandi, Astellas	No (CEP filing Underway)	Raptim, India	Nov-26	Q1,2027
8	Sunitinib Capsule 50mg	Sutent, CP Pharmaceuticals	No (CEP filing Underway)	Clinsync, India	Nov-26	Q1,2027
9	Dasatinib Tablets 140 mg	Sprycel, BMS	Yes	Vimta, India	Nov-26	Q1,2027
S.No.	Product Name	RLD Details	CEP Availability	CRO Partner	BE Completion	Dossier Readiness
1	Azacitidine for Injection 100mg	Vidaza, Baxter	Yes	Raptim, India	Done (In-Vitro Study)	Available
2	Octreotide LAR Injection 20mg,30 mg	Sandostatrin LAR, Novartis	Yes	Raptim, India	On Going	Q4,2026
General Category (EU - GMP Accredited)						
S.No.	Product Name	RLD Details	CEP Availability	CRO Partner	BE Completion	Dossier Readiness
1	Tadalafil Tablet 5mg	Cialis, Eli Lilly	Yes	Bioradius, India	Done	Available
2	Onansetron Tablet 8 mg	Zofran , Sandoz	Yes	Zenrise, India	Done	Available
3	Deflazacort Tablet 6mg, 18mg, 30mg	Defal, Faes Farma	DMF Available	Genecht, India	Done	Available
4	Pioglitazone Metformin Tablet 15mg / 850mg	Actosmet, Daito	Yes	Bioradius, India	Done	Available
5	Empagliflozin Metformin Tablet 5mg / 1000mg	Synjardy, Boehringer Ingelheim	No (CEP filing Underway)	Bioradius, India	Done	Available
6	Empagliflozin Metformin Tablet 12.5mg / 1000mg	Synjardy, Boehringer Ingelheim	No (CEP filing Underway)	Bioradius, India	Done	Available
7	Telmisartan Hydrochlorothiazide Tablet 80 mg /12.5 mg	Micardis Plus, Boehringer Ingelheim	Yes	Bioradius, India	Done	Available
8	Cabergoline Tablet 500 mcg	Dostinex, Pfizer	DMF Available	Clinsync, India	Done	Available
9	Empagliflozin Linagliptin Tablet 10mg / 5mg	Glyxambi, Boehringer Ingelheim	No (CEP filing Underway)	Bioradius, India	Done	Available
10	Phenazopyridine Tablet 100 mg	Phenazopyridine, Amneal	DMF Available	Genecht, India	Done	Available
11	Atorvastatin Ezetimibe Tablet 10mg /10 mg; 10mg /20 mg ; 10mg /40 mg	Atozet, Organon	DMF Available	Raptim, India	On Going	Q4,2026
12	Dapagliflozin Tablets 5mg, 10 mg	Forxiga, AstraZeneca	Yes	Raptim, India	On Going	Q4,2026
13	Linagliptin Metformin Tablet 2.5mg / 850mg	Jentadueto, Boehringer Ingelheim	No (CEP filing Underway)	Bioradius, India	Oct-26	Q4,2026
14	Tamsulosin Dutasteride Capsule 0.4mg/0.5mg	Duodart, GSK	Yes	Clinsync, India	Oct-26	Q1,2027
15	Sacubitril Valsartan Tablet 100mg, 200mg	Entresto, Novartis	No (CEP filing Underway)	Bioradius, India	Oct-26	Q1,2027
16	Nitrofurantoin Retard Capsule 100 mg (Macrocrystalline)	Uvamin Retard, Acino Pharma	Yes	Vimta, India	Nov-26	Q1,2027
17	Hydroxychloroquine Tablet 200 mg	Plaquenil, Sanofi	Yes	Clinsync, India	Nov-26	Q1,2027
18	Sodium Valproate Gastro-resistant Tablets 500 mg	Depakine, Sanofi	Yes	Vimta, India	Nov-26	Q1,2027
19	Raltegravir Tablets 400mg	Isentress,MSD	No (CEP filing Underway)	Raptim, India	Dec-26	Q1,2027
20	Dapagliflozin Metformin Extended Release Tablet 10mg / 1gm	Xigduo, AstraZeneca	Yes	Bioradius, India	Jan-27	Q1,2027
21	Misoprostol Tablet 200mcg	Cytotec, Pfizer	Yes	Bioradius, India	Jan-27	Q1,2027
22	Empagliflozin Linagliptin Metformin Extended Release Tablet 10mg / 5mg / 1000mg	Trijardy-XR, Boehringer Ingelheim	Yes	Bioradius, India	Jan-27	Q1,2027
S.No.	Product Name	RLD Details	CEP Availability	CRO Partner	BE Completion	Dossier Readiness
1	Propofol Injectable Emulsion 10mg/ml	Diprivan, Fresenius Kabi	Yes	-	Done	Available
2	Betamethasone (as Dipropionate) 10 mg / 2 ml and Betamethasone (as Sodium Phosphate) 4 mg / 2 ml) Suspension	Diprofos, MSD	Yes	Genecht ,India	Done	Available
3	Amphotericin B Liposomal Injection 50 mg	Ambisome, Gilead	Yes	Raptim, India	Ongoing	Q4,2026
4	Enoxaparin Sodium 100mg/ml	Lovenox, Sanofi	Yes	Raptim, India	Oct-26	Q1,2027
Liquid Orals (PIC/S Accredited)						
S.No.	Product Name	RLD Details	CEP Availability	CRO Partner	BE Completion	Dossier Readiness
1	Carbamazepine Oral Suspension 100mg/5ml	Tegretol, Novartis	No (CEP filing Underway)	Clinsync, India	Dec-26	Q1,2027
BETA LACTAM						
Oral Solids (EU-GMP Accredited)						
S.No.	Product Name	RLD Details	CEP Availability	CRO Partner	BE Completion	Dossier Readiness
1	Amoxicillin Clavulanate Tablet 500 mg/125mg	Augmentin, GSK	Yes	Clinsync, India	Done	Available
2	Amoxicillin Clavulanate Tablet 875 mg/125mg	AUGMENTIN, GSK	Yes	Clinsync, India	Done	Available

UNDER-DEVELOPMENT PROGRAMMES

ONCOLOGY PRODUCT LIST			
Oral Solids (EU-GMP Accredited)			
S.No.	Product Name	RLD Details	Dossier Readiness
1	Bicalutamide Tablet 50mg	Casodex, Ani Pharmaceuticals	Q2,2027
2	Ruxolitinib Tablet 5mg, 15mg, 25mg, 55mg	Jakafi, Incyte	Q2,2027
3	Venetoclax Tablet 10mg, 50mg, 100mg	Venclexta, Abbvie	Q2,2027
4	Osimertinib Mesylate Tablet 40mg, 80mg	Tagrisso, Astrazeneca	Q2,2027
5	Apalutamide Tablet 60mg, 240mg	Erleada, Janssen	Q3,2027
6	Cabozantinib Tablet 20mg, 40mg, 60mg	Cabometyx, Exelixis	Q4,2027
7	Regorafenib Tablet 40mg	Stivarga, Bayer healthcare	Q4,2027
Complex Injectables (EU-GMP Accredited)			
S.No.	Product Name	RLD Details	Dossier Readiness
1	Leuprolide Acetate Depot for Injection 3.75mg, 7.5mg,11.25mg, 22.5mg, 45mg (Lyophilized)	Lupron Depot, AbbVie	Q1,2027 On Going (For 11.25mg, 45mg) Q2,2027
2	Paclitaxel NAB Powder Injection 100mg	Abraxane, BMS	Q2,2027

GENERAL CATEGORY			
Oral Solids (EU-GMP Accredited)			
S.No.	Product Name	RLD Details	Dossier Readiness
1	Carbamazepine Prolonged-release Tablet 200mg, 400mg	Tegretol, Novartis	Q2,2027
2	Phenytoin Sodium Capsule 100 mg	Epanutin, Viartis	Q2,2027
3	Levetiracetam Tablet 1000 mg	Keppra, UCB Pharma SA	Q2,2027
4	Naproxen Tablet 500 mg	Naxen, Siegfried Rhein	Q2,2027
5	Naproxen sodium, Paracetamol Tablet 275 mg ,300 mg	Febrax, Siegfried Rhein	Q2,2027
6	Pregabalin Capsule 150 mg, 75 mg	Lyrica, Pfizer	Q2,2027
7	Hyoscine Butylbromide, Ibuprofen Tablet 20 mg , 400 mg	Buscopina , Sanofi	Q3,2027
8	Paracetamol, Ibuprofen Tablet 325 mg , 200 mg	Algitrin, Grimann	Q3,2027
9	Ibuprofen Tablet 400mg, 600 mg, 800mg,	Motrin, Pfizer	Q3,2027
11	Diosmin, Hesperidin Tablet 450mg , 50mg	Daflon , Les Laboratoires	Q4,2027
12	Mesalazine Tablet 500 mg	Salofalk, Schwabe	Q4,2027
Complex Injectables (EU-GMP Accredited)			
S.No.	Product Name	RLD Details	Dossier Readiness
1	Buprenorphine Injection 0.3mg/ml	Buprenex, Indivior	Q1,2028
2	Aripiprazole IM Injection 300mg/ml	Abilify Asimtufii, Otsuka	Q1,2028
3	Lanreotide Acetate Injection 60mg/0.2ml, 90mg/0.3ml, 120mg/0.5ml	Somatuline Depot, Ipsen	Q2,2028
4	Exenatide Injection 2mg/ml	Bydureon, Astrazeneca	Q2,2028
Liquid Orals (PIC/S Accredited)			
S.No.	Product Name	RLD Details	Dossier Readiness
1	Ferrous Sulfate 125 mg / ml	Valdefer, Laboratorios Valecasas	Q2,2027
2	Ferrous Solution 40 mg / 15 ml	Fisiofer, Italfarmaco	Q2,2027
3	Dropropizina, Ambroxol 3mg, 3mg /ml, 120 ml	Troferit, Chinoin	Q2,2027
4	Ambroxol, Levodropropisne, 300 mg , 600 mg / 100 ml, 120 ml	Dizolvin Flux, Rayere	Q2,2027
5	Guaifenesina , Oxolamina 2 g , 1 g / 100ml , 140 ml	Histiadil, Sanofi	Q2,2027
6	Kaolin, Pectin, Neomycin 10 g ,0.700 g , 0.733 g / 100 ml, 75 ml	Treda, Grimann	Q3,2027
7	Magaldrate, Dimethicone, 8 g , 1 g / 100 ml ,250 ml	Graloxen, Mavi Pharmaceutical	Q3,2027

BETA LACTAM			
Oral Solids (EU-GMP Accredited)			
S.No.	Product Name	RLD Details	Dossier Readiness
1	Co-Trimoxazole Tablet 480mg, 960mg, 120mg (Sulfamethoxazole-Trimethoprim)	Bactrim, Sun Pharmaceutical	Q2,2027
2	Sultamicillin Tablet 375, 750mg	Unasyn, Pfizer	Q3,2027

CEPHALOSPORINS			
Oral Solids (EU-GMP Accredited)			
S.No.	Product Name	RLD Details	Dossier Readiness
1	Cefixime Tablet 400mg	Suprax, Lupin	Q2,2027
2	Cephalexin Tablet 250mg, 500mg	Keflet, Eli Lilly	Q2,2027
3	Cefuroxime Axetil Tablet 125mg, 200mg, 500mg	Ceftin, GSK	Q2,2027



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Innovating for Healthier Tomorrow

