

Updated Product Development List of DelNova Healthcare LLP

Product	RLD Used For Product Development	Pilot BE		Pivotal BE		Current status
		Fed Bioequivalence	Fasting Bioequivalence	Fed Bioequivalence	Fasting Bioequivalence	
Generic Solid Oral Products						
Hydroxychloroquine Sulphate Tablets (200 mg)	Plaquenil (USA)	ND	ND	Passing	Passing	ANDA Filed
Melatonin Prolonong Released Tablets (1 mg and 5 mg)	Slenyto (UK)	ND	ND	ND	ND	Ready for TT
Melatonin Prolonong Released Tablets (2 mg)	Circardin (UK)	Passing	Passing	Passing	Passing	EB Done. Ready for Filing
Chlorpromazine Hydrochloride Tablets (10 mg, 25 mg, 50 mg, 100 mg, 200 mg)	USL (USA / UK)	Encouraging	Encouraging	Passing	Passing	ANDA Filed
Linezolid Tablets (600 mg)	Zyvox (Germany)	Biowaiver	Biowaiver	Biowaiver	Biowaiver	Dossier Filed
Olmesartan + HCTZ Tablets (20 + 12.5, 40 + 12.5, 40 + 25 mg)	Benicar HCT (Germany)	ND	ND	ND	ND	Ready for TT
Prochlorprazine Maleate Tablets (5 mg and 10 mg)	US RLD	Passing	Passing	Passing	Passing	ANDA Filed
Ibuprofen and Famotidine Tablets (800+ 26.6 mg)	Duexis (USA)	ND	ND	Passing	Passing	ANDA Ready
Dexamethasone Tablets (20 mg)	Hemedy (USA)	Encouraging	Encouraging	Passing	Passing	ANDA Filed
Abiraterone Acetate Tablets (250 mg and 500 mg)	Zytiga (USA / UK)	ND	Encouraging	ND	ND	Ready for TT
Nefidipine Extended-Release Tablets (30mg)	Adalat GITS (China)	ND	ND	ND	ND	Ready for TT
Metformin ER Tablets (500 and 1000 mg)	Glumetza (USA / Canada)	Encouraging	Encouraging	Ongoing	Ongoing	Ready for TT

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Metformin Extended Release + Dapagliflozin Tablets (2.5 +1000, 5 + 500, 5 +1000, 10 + 500, 10 + 1000 mg)	XIGDUO XR (USA)	ND	ND	ND	ND	Ongoing. Planed Pilot by Oct 2023
MethylPhenedate ER Tablets (17,36,54,72 mg)	Concerta	Passing	Passing	ND	ND	Ready for TT
Posaconazole DR Tablets (100 mg)	Noxafil (UK)	Encouraging	Encouraging	Passing	Passing	ANDA Approved
Fenofibrate Tablets (40 mg and 120 mg)	FENOGLIDE (USA)	Ongoing	Ongoing	ND	ND	Ready for TT
Etraverine Tablets (25 mg, 100 mg and 200 mg)	INTELENCE (USA)	ND	ND	ND	ND	Ready for TT
Tofacitinib Extended Release Tablets (11 and 22 mg)	XELJANZ XR (USA)	ND	ND	ND	ND	Ongoing Planed Pilot by Oct 2023
Propranolol Hydrochloride ER Capsules (60 mg ,80 mg,120 mg and 160 mg)	INDERAL LA (USA)	Ready For Pilot	Ready For Pilot	ND	ND	Ready For TT
Melatonin Oral solution 1mg/ml	Colonis (UK)	NA	NA	NA	NA	EB Done. Ready for Filing
Tofacitinib Oral solution (1mg/ml)	Xeljanz (USA)	NA	NA	NA	NA	Ready for TT
Bupropion Extended Release (105 mg) + Dexmethrophen Hydrobromide (45 mg)Tablets	AUVELITY (USA)	Encouraging	Encouraging	TBD	TBD	Ready for TT
Dexamethasone Tablets 1,2,4,6 mg	USA	TBD	TBD	TBD	TBD	Ready for TT
Baclofen Oral suspension 25 mg / 5ml	Fleqsuvy (USA)	TBD	TBD	TBD	TBD	Ongoing
Eltrombopag Olamine Tablets (Eq to Acid)12.5,25,50,75 mg	Promacta (USA)	TBD	TBD	TBD	TBD	Ongoing. Planed Pilot by Oct 2023
Eltrombopag Olamine For Suspension (Eq to Acid) 12.5, 25 mg	Promacta Kit (USA)	TBD	TBD	TBD	TBD	Ongoing. Planed Pilot by Oct 2023

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