PROJECT PROPOSAL -



READY DOSSIER

Ser No.	Product	Territo ries	Dossier Comments	Dossier USD	Finished Supply USD FOB
1.	Omeprazole Pellets 8.5%	USA	Dossier Pilot Bio Study Inclusive		
2.	Lansoprazole	USA	Pellets 8.5%-30mg OTC 15mg		
3.	Esomeprazole Pellets 8.5%	USA	Dossier Pilot Bio Study Inclusive		
4.	Itraconazole Pellets 22%	USA	Dossier Pilot Bio Study Inclusive		
5.	Orlistat Pellets 50%	USA	Dossier Pilot Bio Study Inclusive. End Point Clinical not available		
6.	Clarythromycin 42%	USA	Dossier. Pilot Bio Study not required		
7.	Tacrolimus Pellets 5%	USA	Dossier Pilot Bio Study Inclusive		
8.	SAMe	USA	Product Development nearly complete. Stability study in process. OTC 400mg, 500mg		
9.	Amlodipine 2.5mg, 5mg, 10mg	USA	ANDA was filed with the USFDA on 2/21/13 and filing was accepted. The ANDA is under review. Pilot bioequivalence inclusive to the Reference Listed Drug. At this time, we are just waiting for the FDA to complete their review		
10.	Felodipine 2.5mg, 5mg, 10mg	USA	Completed Phase III development work including exploratory stability. Based on the f2 testing, we are equivalent to the RLD. The next step is to complete a pilot biostudy with the 10mg tablet to confirm bioequivalence to the Reference Listed Drug.		