

FORM FOR CLAIMING REIMBURSEMENT OF BIO-EQUIVALENCE STUDIES CHARGES

Date:

1	Name of the firm with full address:	
2	IEC No:	
3	RCMC No:	
4	FOB value of exports for preceding financial years	
5	Particulars of BE studies:	
	a) Name of the Country where products are Approved/Registered:	
	b) Name of the products for which BA/BE studies are carried out.	
	c) Date of BA/BE report. (enclose copy)	
	d) Date of issue of Product Registration Certificate (Enclose copy: Original to be verified by Pharmexcil)	
	e) Name and Address of the Agency conducting BA/BE studies:	
	f) whether the Agency is approved by NABL : (enclose copy of the certificate)	Yes/No:
g) Whether the pre-clinical study is satisfactory: (enclose copy)	Yes/No:	
7	Cost of Study:	
	a) Amount Incurred:	
	b) Claimed Amount:	
8	Registration guidelines (showing BA/BE studies as mandatory requirements. (copy enclosed)	Yes/No:
9	Manufacturing license issued by State Drugs Controller/Licensing Authority (in India) for the subject product. (Enclose copy)	
