

## Bioavailability / Bioequivalence Studies (BE)

### List of Documents to be enclosed with MAI Application

1	BA/BE Studies Charges Reimbursement <b>APPLICATION FORM</b> duly completed & authenticated by CEO/CHAIRMAN/MD/PARTNER/PROPRIETOR ( <a href="#">Click here</a> )
2.	<b>Declaration</b> - On the letter head of the Company, duly completed & authenticated by CEO/CHAIRMAN/MD/PARTNER/PROPRIETOR ( <a href="#">Click here-refer page 4</a> )
3.	<b>Affidavit</b> - Completed & authenticated by CEO/CHAIRMAN/MD/ PARTNER/PROPRIETOR ( <a href="#">Click here-refer page 5</a> ) <b>Note:</b> a.) Declaration and Affidavit should be signed by the same person.
4.	CA Certificate mentioning the particulars of BA/BE study EXPENSES ( <a href="#">Click here-refer page 6</a> )
5.	CA Certificate mentioning the particulars of Investments in PLANT & MACHINERY (CA certificate stating company's total investment in plant and Machinery excluding land and building up to 31st March of previous Financial Year) ( <a href="#">Click here-refer page 7</a> )
6.	FOB Value of Exports for the preceding Financial Year ( <a href="#">Click here-refer page 8</a> )
7	Product Registration Certificates " <b>Original+Copy</b> " (Registration Certificate <b>SHOULD BE</b> on the Name of the Applicant <b>as <u>MARKETAUTHORIZATION HOLDER / MANUFACTURER</u></b> )  a. Originals Certificates need to be Verified/Attested by PHARMEXCIL Office (Hyderabad/Mumbai/Delhi). <ul style="list-style-type: none"><li>As in some cases where the Original product Registration certificates were not issued by the Particular Regulatory Authority then, we will verify those certificates through on-line providing us the Online Links to verify in Official website of drug regulatory authority, and Login credentials, if required (Login id and Password of the company for Verification).</li></ul>
8.	NABL certificate of Accreditation
9.	NOC for BA/BE studies issued by DCGI
10.	BA/BE report indicating that the Pre-Clinical work is satisfactory
11	BA/BE Study Protocol
12.	Invoices raised by the NABL laboratory for the clinical work
13.	Bank Transfer Remittance (SWIFT copy) showing the Customer Name, Beneficiary Name & Purpose of Payment details. a. Attestation/Round Seal by the Banker is MANDATORY on the Bank Transfer Remittance (Swift Copy) with Employee code.
14.	Manufacturing License issued by State Drugs Controller/Licensing Authority (in India) for the subject product
15.	Registration Guidelines, showing BA/BE studies requirements
16.	Self-Attested Translation copies in English wherever necessary (ex: Invoice/Registration Certificates/Receipts)
17.	Project contract agreement between applicant and NABL lab (lab conducting the BE studies)
18.	Compilation statement reflecting all claiming and correlating invoices & bank transaction details, which is duly attested by the Banker

#### Note:

- **Financial year of the claim**, is considered basing on the **DATE OF ISSUE OF REGISTRATION CERTIFICATE** (Financial year period: **1<sup>st</sup> April to 31<sup>st</sup> March**).

- Products **Registered in different Countries** need to be submitted in **different Applications**.
- Products **pertaining to different Financial Years** to be submitted in **different Applications**.
- For all the MAI claims filed by Exporters to Pharmexcil from 26th June 2023, the following two provisions would apply:
  - 90 days' timeline for submission of MAI claims by Exporter to Pharmexcil
  - Limitation of reimbursement to the exporters having f.o.b value of exports up to Rs. 100 crore during the preceding financial year.
- In case of unaudited F.O.B Values of Exports ( April- September) - applicants have to submit the Chartered Accountant Certificate w.r.t FOB value of Exports during the preceding FY along with GST returns filed during the preceding year.
- Application will be accepted only if the company submit all the mandatory documents and confirm the application on-line.
- Processing fee of 5% will be charged on sanction of the amount.

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)	

**On Companies Letter Head**

**Declaration**

I solemnly declare that the particulars given in the above statement are correct. I bound myself and the company accountable and responsible for any incorrect information given in the above statement and shall immediately refund amount received on the basis of wrong information provided in the above statement.

Signature : \_\_\_\_\_

Name : \_\_\_\_\_

Designation : \_\_\_\_\_

Office Seal : \_\_\_\_\_

**Countersigned by CEO/CHAIRMAN/MD/PARTNER/PROPRIETOR of the Company:**

Signature : \_\_\_\_\_

Name : \_\_\_\_\_

Designation : \_\_\_\_\_

Office Seal : \_\_\_\_\_

Place: \_\_\_\_\_

Date: \_\_\_\_\_

**Affidavit to be submitted on Rs.50/- Non-Judicial Stamp Paper**

**AFFIDAVIT**

I, ..... S/o ..... aged about ..... Years  
Resident of ..... do here by affirm on oath as under.

That I am CEO/CHAIRMAN/Managing Director/Partner/Proprietor M/s..... on whose behalf an application is made for claiming reimbursement of Bioequivalence study charges paid for Pharmaceutical / Biotechnological Products.....(product name/s) to the Department of Commerce, Ministry of Commerce and Industry, Government of India, New Delhi Under MAI Scheme.

I, solemnly declare that the particulars given in the above application are correct. I bound myself and the company accountable and responsible for any information given in the application. If any of the information and documents found false by any agency, we are responsible for any action initiated by the Government under any law and we will also refund that amount as per govt. rules, immediately.

Signature of the CEO/CHAIRMAN/MD/Proprietor of the company:

Signature : \_\_\_\_\_

Name : \_\_\_\_\_

Designation : \_\_\_\_\_

Office seal : \_\_\_\_\_

Place: \_\_\_\_\_

Date: \_\_\_\_\_

On CA Letter Head

**CERTIFICATE**

This is to certify that we have verified the records of **M/s.....Company Name & Address.....** and found that they incurred to carry out **BE-Study** of .....  
(Product name) is **Rs. . .....**

On verification of records produced before us, we have checked the books of accounts of the company, the Invoice(s) of the clinics/laboratories, etc. and hereby certify that the aforesaid information is verified and found to be true.

Signature & Stamp/Seal of the Signatory:

Signature: -----

Name: -----

Membership No.:-----

Full Address: -----

Name and address of the Institution where registered.

Place: -----

Date: -----

On CA Letter Head

**CERTIFICATE**

This is to certify that we have verified the records of **M/s.....Company Name & Address.....** have called upon us to certify the amount of Investments made in Plant & Machinery is **Rs.....** as on 31<sup>st</sup> March..... excluding Land & Building and other Miscellaneous Assets.

On verification of records produced before us, we have checked the books of accounts of the company, the Invoice(s), Fixed Assets schedule as on 31<sup>st</sup> March ....., etc. and hereby certify that the aforesaid information is verified and found to be true.

Signature & Stamp/Seal of the Signatory:

Signature: \_\_\_\_\_

Name: \_\_\_\_\_

Membership No.: \_\_\_\_\_

Full Address: \_\_\_\_\_

Name and address of the Institution where registered.

Place: \_\_\_\_\_

Date: \_\_\_\_\_

On CA letter Head

**TO WHOMSOEVER IT MAY CONCERN**

This is to certify that the company **M/s..... (Company Name)** having its registered office **(Address).....**, has the **Export Turnover (FOB values of export)** for the preceding financial years as mentioned below:

S.No.	Financial year	Amounts in crores only

Signature & Stamp/Seal of the Signatory:

Signature : \_\_\_\_\_

Name : \_\_\_\_\_

Membership No. : \_\_\_\_\_

Full Address : \_\_\_\_\_

Name and address of the Institution where registered.

Place: \_\_\_\_\_

Date: \_\_\_\_\_



## Compilation statement

Company name :  
Application :  
Number :  
Name of the :  
Products :

### Payment details

S.No	Invocie Number	Invoice date	Taxable value	Amount claimed	Date of Payment
1					
2					
3					
Total :					

### Bank payment reference and reconciliation

S.No	Invocie Number	Invoice date	Taxable value	GST	TDS	Amount paid to Vendor (Taxable value +GST-TDS)	Comments
1							
2							
3							
4							
Total							