

PLANT INSPECTION CHARGES (PIC)

List of Documents to be enclosed with MAI Application

1	Plant Inspection Charges Reimbursement APPLICATION FORM
2	DECLARATION by CEO/CHAIRMAN/MD
3	AFFIDAVIT by CEO/CHAIRMAN/MD
4	CA Certificate mentioning the particulars of EXPENSES (Plant Inspection)
5	EXPORT TURN OVER (FOB) & the TOTAL TURN OVER details of the company for the last three financial years duly attested by CA
6	APPROVAL CERTIFICATE (GMP/Plant Registration Certificate) (Original Certificates need to be Verified/Attested by PHARMEXCIL Office)
7	Inspection REPORT
8	Inspection NOTICE
9	ID CARD of Vising Inspector/s
10	INVOICES & RECEIPTS raised by Drug Registration Authorities/Inspecting Agency as Proof of Payment
11	If the payment is made by 3 rd PARTY, then necessary documents like DEBIT NOTE raised & the RECEIPT copy should be submitted.
12.1	Bank Transfer Remittance (SWIFT copy) showing the Customer Name, Beneficiary Name & Payment details Attestation/Round Seal by the Banker is MANDATORY on the Bank Transfer Remittance (Swift Copy)
12.2	If the payment is made by Cheque/Demand Draft directly to the Drug Registration Authorities/Inspecting Agency, then the Receipt issued by FDA/Agency is mandatory (Original Receipt need to be Verified/Attested by PHARMEXCIL Office)
13	Self-Attested TRANSLATION COPIES IN ENGLISH wherever necessary (Registration Certificates / Invoice / Receipts)
14	VALID Manufacturing DRUG LICENSE issued for the PLANT
15	REGISTRATION GUIDELINES of FDA, showing the details of Inspection Fee to be paid and Inspection requirements etc.

1. Approval Certificate **“Original + Copy”**

- a. Original Certificates need to be Verified/Attested by PHARMEXCIL Office (Hyderabad)
- b. After Verification, the Originals will be returned back immediately

2. Processing Fee of 5% will be charged on sanction of the amount

Note:

- **Plant Inspection Charges incurred on or after 7th January 2019 only are eligible for reimbursement**
- **Financial year of the claim, is considered basing on the DATE OF ISSUE OF APPROVAL CERTIFICATE (Financial year period : **1st April to 31st March**)**
 - Applications FY 2018-19 from 01-Apr-2018 onwards Government has issued Revised Guidelines and all the Claims to be filed within 90 days from the date of Approval Certificate. Claims received after this date will not be considered
- **Claim of eligible only when the Plant is Approved**

APPLICATION FORM FOR CLAIMING REIMBURSEMENT OF PLANT INSPECTION CHARGES

Ref. No.

Date:

1	Name of the company with address	
2	IEC No.	
3	RCMC No.	
4	Contact details of the person making the application	Name: Designation: Email: Mobile:
5.	FOB Value of the exports for the last 3 financial years	
6	Total turnover of the company for the last 3 years	
7.	Name and address of the Drug Regulatory agency inspected the plant	
8.	Address of the plant inspected by the Agency	
9.	Manufacturing license issued for the plant with validity (enclose copy)	
10.	Category of drugs manufactured in the plant	
11	Whether Plant is inspected by Agency physically or approval is given based on documents submitted by your company? In case Plant is approved based on documents submitted, enclose relevant guidelines issued by agency indicating the same	
12	Whether Inspection of plant is for the first time or Renewal	First time inspection / Renewal
13	Date of Inspection	
14	Whether Inspection is completed successfully If yes, enclose the Inspection Report / GMP / Registration certificate issued by the agency	Yes/ NO
15	Actual amount incurred	
16	Amount claimed	

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 of the Company:

Signature: _____

Name: _____

Designation: _____

Office seal: _____

Place: _____

Date: _____

AFFIDAVIT

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

That I am CEO/CHAIRMAN/Managing Director/Director/Partner/Proprietor of M/s..... on whose behalf an application is made for claiming reimbursement of amount paid towards Plant Inspection Charges paid abroad of Pharmaceutical / Biotechnological Products 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
US\$/EUROS as per following details.

S.No.	Particulars of Expenses (plant inspection address)	Amount in	
		USD/EUROS	RUPEES
1			

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)** & the **Total Turnover** for the last three financial years as mentioned below:

S.No.	Financial Year	Amount in Crores	
		FOB value of Export	Total Turnover
1			
2			
3			

Signature & Stamp/Seal of the Signatory:

Signature: _____

Name: _____

Membership No.: _____

Full Address: _____

Name and address of the Institution where registered.

Place: _____

Date: _____