PLANT INSPECTION CHARGES (PIC)
List of Documents to be enclosed with MAI Application

1	Plant Inspection Charges Reimbursement **APPLICATION FORM** duly completed & authenticated by CEO/CHAIRMAN/MD/PARTNER/PROPRIETOR (Click here)
2	**Declaration -** On the letter head of the Company, duly completed & authenticated by CEO/CHAIRMAN/MD/PARTNER/PROPRIETOR (Click here-Refer page -3)
3	**Affidavit -** Completed & authenticated by CEO/CHAIRMAN/MD/ PARTNER/PROPRIETOR (Click here-Refer page -4) **Note:** a.) Declaration and Affidavit should be signed by the same person. b.) If Declaration and Affidavit both were signed by other than CEO/CHAIRMAN/MD/PARTNER/PROPRITOR, Power of Attorney (or) Board Resolution in the name of signed person.
4	CA Certificate mentioning the particulars of Plant Inspection expenses with exchange rate (Click here-Refer page -5)
5.	FOB Value of Exports for the preceding Financial Year (Click here-Refer page -6)
6	GMP APPROVAL CERTIFICATE (issued by Overseas Drug Regulatory Authority) (Original Certificates need to be Verified/Attested by PHARMEXCIL Office- Hyderabad/Mumbai/Delhi) a) As in some cases where the Original GMP approval certificates were not issued by the Particular Drug 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).
7	If the plant is re-inspected (renewal), then need to enclose the Previous GMP approval certificate.
8	Self-attested Inspection REPORT
9	Self-attested Inspection NOTICE
10	Passport copies /Visiting cards/ ID CARD of Vising Inspector/s
11	INVOICES & RECEIPTS raised by Drug Registration Authorities/Inspecting Agency as Proof of Payment
12	If the payment is made by 3rd PARTY, then necessary documents like DEBIT NOTE raised by the agent towards plant inspection & the RECEIPT copy (raised by the Drug Regulatory Agency) should be Submitted.
13.1	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) along with employee code
13.2	If the payment is made by Cheque/Demand Draft directly to the Drug Regulatory Authorities/Inspecting Agency, then the Receipt issued by FDA/Agency is mandatory (Original Receipt need to be Verified/Attested by PHARMEXCIL Office).
14	Self-Attested TRANSLATION COPIES IN ENGLISH wherever necessary (GMP approval Certificates / Invoice / Receipts/Regulatory guidelines reflecting plant inspection fee)
15	VALID Manufacturing DRUG LICENSE issued for the PLANT, along with list of products manufactured in the inspected plant.
16	REGISTRATION GUIDELINES of FDA, showing the details of Inspection Fee to be paid and Inspection requirements etc.
17	First e-mail communication between the claiming company and the Drug Regulatory Authority/Agency Reflecting the initiation of process of plant inspection. a.If application towards plant inspection charges was submitted to the Drug Regulatory Authority in the form of hard copy, submit the copy of acknowledgement letter/acknowledgement receipt with concerned Regulatory Authority/Agency stamp.
18	Self-declaration on the letter head of the company reflecting the initiation of process of plant inspection
19	Inspection request letter submitted by the Company to the Drug Regulatory Agency towards plant inspection.
20	Applicant name should be clear from DGFT DEL STATUS (Denied Entity List)
21	Foreign Outward Remittance to known the exchange rate as on payment date.

Note:

- **Expenses made towards plant inspection charges will be reimbursed if application is made to the concerned Drug Regulatory Authority/Agency on or after 07.01.2019 only.**

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

- 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.
- Claims will be eligible only when the Plant is approved.
- Processing fee of 5% will be charged on sanction of the amount.

APPLICATION FORM FOR CLAIMING REIMBURSEMNT OF PLANT INSPECTION CHARGES

Date:

1.	Name of the company with address	
2.	IEC No.	
3.	RCMC No.	
4.	FOB Value of exports for the preceding financial year	
5.	Name and address of the Drug Regulatory agency inspected the plant	
6.	Address of the plant inspected by the Agency	
7.	Manufacturing license issued for the plant with validity (enclose copy)	
8.	Category of drugs manufactured in the plant	
9.	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	
10.	Whether Inspection of plant is for the first time or Renewal	First time inspection / Renewal
11.	Date of Inspection	
12.	Whether Inspection is completed successfully If yes, enclose the Inspection Report / GMP / Registration certificate issued by the agency	Yes / No
13.	Actual amount incurred (100 %)	
14.	Amount claimed (50%)	

Contd…

On Company 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: _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _

Contd…

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 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/PARTNER/PROPRIETOR of the company:

Signature: _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _

Name: _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _

Designation: _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _

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

Place: _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _

Date: _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _

Contd…

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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-as reflecting in GMP certificate)		Amount in	
		USD/EUROS	Exchange rate	RUPEES
1				

Signature & Stamp/Seal of the Signatory:

Signature : _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _

Name : _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _

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

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

Name and address of the Institution where registered.

Place: _ _ _ _ _ _ _ _ _ _ _ _ _ _ _

Date: _ _ _ _ _ _ _ _ _ _ _ _ _ _ _

Contd…

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 year as mentioned below:**

S.No.	Financial Year	Amount in Crores
		FOB value of Export
1		

Signature & Stamp/Seal of the Signatory:

Signature :_ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _

Name : _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _

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

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

Name and address of the Institution where registered.

Place: _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _

Date: _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _

Contd…

On Companies Letter Head

SELF DECLARATION

TO WHOM SOEVER IT MAY CONCERN

We, M/s…… (Company name)……, hereby confirm that the following application (MAI Claim Application No. ……) was submitted to Pharmexcil towards reimbursement of Plant Inspection Charges.

Inspection details are as given in the trailing table.

We confirm that the application towards Plant inspection charges was submitted to Drug Regulatory Authority on or after 07.01.2019.

Name and address of the Drug Regulatory agency inspected the Plant	**Address of the plant inspected by the agency**	**GMP – Certificate No**	**Date of submission of application towards Plant Inspection Charges to the Drug Regulatory Authority (1st communication date)**	**Date of GMP approval certificate.**

Yours sincerely,

(Authorize person signature)

Signature: _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _

Name: _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _

Designation: _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _

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

Place: _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _

Date: _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _

ON Company letter head

To Whom So Ever It May Concern

We M/s……(Company name) hereby providing the following details towards payment for the Inspected plant.

S.NO	Plant address	Invoice. No.	Invoice Date	Receipt No	Receipt Date	Debit Note No.	Debit Note date	Bank statement Date	TT reference Number	Amount in Foreign currency
1										
2										
3										

And also mention the Purpose of payment:

Yours sincerely,

(Authorize person signature)

Designation: