#### OBTAINING QUALITY CERTIFICATIONS FOR NATURAL PRODUCTS (AYUSH PRODUCTS/NUTRACEUTICALS) (EQC)

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

- 1. Obtaining Quality Certifications for Natural Products Reimbursement Application form. Annexure-I duly completed & authenticated by CEO/CHAIRMAN/MD /PARTNER/PROPRIETOR/Authorized Person (Click Here)
- 2. **Declaration** On the letter head of the Company, duly completed & authenticated by CEO/CHAIRMAN/MD/PARTNER/PROPRIETOR (Click here Refer page 4)
- 3. Affidavit Completed & authenticated by CEO/CHAIRMAN/MD/ PARTNER/PROPRIETOR (Click here <u>– Refer page 5</u>)

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/PROPRIETOR, Power of Attorney (or) Board Resolution in the name of signed person.
- 4. CA Certificate mentioning the particulars of Expenses incurred for Quality Certification of plant/products with Exchange rate (Click here Refer page 6)
- 5. FOB Value of Exports for the preceding Financial Year (Click here Refer page 7)
- 6. Invoices issued by the Agency that issued the Quality certifications / payment receipts issued by the Agency if any.
- 7. 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.
- 7(b.) Foreign Outward Remittance to known the exchange rate as on payment date.
- 8. If the payment is made by Cheque or Demand Draft directly to the Inspecting Agency, then Receipt issued by agency (original to be verified and attested by Pharmexcil)
- 9. If the payment is made by 3rd party, necessary documents like Debits Note raised and payment by the company to the 3rd party etc., should be submitted
- 10. Guidelines issued by the agency, showing the Fee structure
- 11.If the claim is for Renewal of the Quality Certification, submit a brief report on how the quality certification helped in enhancing exports.
- 12. Copy of the Plant Inspection Report, if the quality certificate is issued for Plant (Original to be verified and attested by Pharmexcil)
- 12.a. Quality Certificates of product "Original Copy" (Quality Certificates SHOULD BE on the Name of the Applicant as MARKETAUTHORIZATION HOLDER / MANUFACTURER)
  - (i).Originals Certificates need to be Verified/Attested by PHARMEXCIL Office (Hyderabad/Mumbai/Delhi).
    - 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).
  - (ii). After Verification, the Originals will be returned back immediately.

## 13. Self-Attested Translation copies of certificates in English wherever necessary

- 14. Valid Manufacturing Drug License issued for the plant along with list products/Valid Manufacturing Drug License issued for product.
- 15. If the plant is re-inspected (renewal), then need to enclose the Previous GMP/Registration certificate/ if the product is re-registered, then the details of previous registration along with date of registration and its validity period and a copy of the registration certificate.

Note:

- a) Quality Certificates obtained on or after 7<sup>th</sup> January 2019 only are eligible for reimbursement
- b) Processing Fee of 5% will be charged on sanction of the amount
- c) Claim to be submitted within 90 days of the receipt of Quality certificate/Plant approval certificate
- Financial year of the claim, is considered basing on the DATE OF ISSUE OF PRODUCT REGISTRATION CERTIFICATE (Financial year period: 1st April to 31st 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.

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- 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.

# APPLICATION FORM FOR CLAIMING REIMBURSEMNT OF EXPENSES INCURRED FOR OBTAINING QUALITY CERTIFICATIONS FOR NATURAL PRODUCTS (AYUSH PRODUCTS / NUTRACEUTICALS)

		Date.
1	Name of the company with address	
2	IEC No.	
3	RCMC No.	
4.	FOB Value of the exports for the preceding financial years	
5.	Details of the Quality Certificate	Name of the Certificate:
	(Original certificate to be attested by Pharmexcil)	Number :
		Date of Issue :
		Date of Expiry :
6.	Name and address of the Agency that issued the Certificate	
7.	Whether the claim is for first time Registration or Renewal?	
8.	Whether the Certification is issued for Products or for Plant	
9.	If the Quality Certificate is issued for Products, please provide	Name of the product :
		Manufacturing License No:
		(enclose copy)
10.	If the Quality Certificate is issued for plant, please provide	Address of the manufacturing plant:
		Date of Plant inspection, if it is required (enclose copy of the inspection report)
11.	Actual amount incurred (100%)	
12.	Amount claimed (50% of actual amount is eligible for reimbursement)	

Date:

## 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

## <u>AFFIDAVIT</u>

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 Expenses incurred for obtaining Quality certifications for Natural products(AYUSH/NUTRACEUTICALS 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:

Place:	_
Date:	_

On CA Letter Head

## **TO WHOMSOEVER IT MAY CONCERN**

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.

	Particulars	Amount in					
S.N o.	of Expenses	USD/EUROS	Exchange	RUPEES			
	(each product names/ Inspected plant in individual cells)		rate				
1							
2							
3							
4							
5							

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 WHOM SO EVER 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 proceeding financial year as mentioned below:

S.No	Financial Year	Amount in Crores (Only)
1		

Signature & Stamp/Seal of the Signatory:

Signature:

Name:

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

Full Address:

Name and address of the Institution where registered.

Place:
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Date:	

Date:

#### SELF DECLARATION

## TO WHOM SOEVER IT MAY CONCERN

We, M/s.....(Company name)......, hereby confirm that the following application (Application No. ....) was submitted to Pharmexcil towards reimbursement of expenses incurred for obtaining Quality Certification for Natural Products.

Quality certification details are as given in the trailing table.

We confirm that the application towards reimbursement of Quality Certification charges for Natural Products was submitted to Drug Regulatory Authority on or after 07.01.2019.

Name and address of the Agency issuing the certification	Date of submission of application to the Agency towards Quality certification	Date of issue of certificate.		

Yours sincerely,

(Authorize person signature) Designation:

## 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 claimed products/Plant.

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

## And also mention the Purpose of payment:

Yours sincerely,

(Authorize person signature)

Designation: