European Directorate for the Quality of Medicines & HealthCare
Certification of Substances Department

Application Form
REQUEST FOR
NEW CERTIFICATE OF SUITABILITY

(to be filled in for each request for a new Certificate of Suitability to the monographs of the European Pharmacopoeia, in accordance with Resolution AP-CSP (07) 1)

Date of submission: ……./……/……

Please note that the format of the submission should be eCTD only.

1. General Information:

1.1. Type of application for a new Certificate of Suitability:
(Please tick the appropriate option-select one only)

☐ *Chemical* ☐ *Chemical and sterile* ☐ *TSE*

☐ *Double (Chemical and TSE)* ☐ *Double and sterile* ☐ *Herbal*

1.2 Name of the substance using the Recommended International Nonproprietary Name (rINN).
Specify any subtitle requested such as 'sterile', 'micronized':

1.3 Monograph(s) you are referring to:
(*Name, Number, Year of publication*)

1.4 Re-test period: *(not applicable for TSE Certificate of Suitability)*

Proposed re-test period (in months)	
Commercial packaging	
Recommended storage conditions, if applicable (T^o, others)	
Tick this box if you do **not** wish a re-test period	☐

2. Names and addresses

2.1 Intended certificate holder: (NB. for *exceptional cases where the holder will not be the manufacturer please refer to 4.4)*	
Name of the company*	
Address*	
Postcode*	
Town*	
Country*	
Telephone*	
E-mail*	
Name of a contact person within the company *(if different from 2.2)*	

Fields marked * are mandatory

2.2 Contact person authorised for communication on behalf of the intended holder: *(if different from manufacturer please provide an authorisation letter - see Annex 1)*	
Title* (Mrs, Mr, Dr)	
First name*	
Family name*	
Job title/Department	
Name of the company*	
Address for correspondence*	
Postcode*	
Town*	
Country*	
Telephone*	
E-mail*	

Fields marked * are mandatory

2.3 Manufacturing site(s): detailed name and address of all sites° involved in the manufacture of this substance *(if different from the intended holder, please also refer to 4.4)*

° All sites involved in the manufacture of the active substance from the introduction of starting material(s), including quality control / in process testing sites, intermediate manufacturers, milling, micronisation and sterilisation sites should be listed in separate boxes and their role should be specified.

Role*	
Name of the company/site*	
Address*	
Postcode*	
Town*	
Country*	
Telephone*	
E-mail*	

GPS (WGS 84) coordinates of the site*:
Latitude (S or N) and Longitude (E or W) expressed in Degrees Minutes Seconds to 1 decimal place
(Alternatively it can be expressed in Degrees to at least 5 decimal places or Degrees Minutes to at least 3 decimal places)
☐ main entrance
☐ if not main entrance, specify the place:

DUNS number	

Fields marked * are mandatory

Role*	
Name of the company/site*	
Address*	
Postcode*	
Town*	
Country*	
Telephone*	
E-mail*	

GPS (WGS 84) coordinates of the site*:
Latitude (S or N) and Longitude (E or W) expressed in Degrees Minutes Seconds to 1 decimal place
(Alternatively it can be expressed in Degrees to at least 5 decimal places or Degrees Minutes to at least 3 decimal places)
☐ main entrance
☐ if not main entrance, specify the place:

DUNS number	

Fields marked * are mandatory

3. History of the substance

3.1 List of marketed medicinal products

Please provide a list of marketed medicinal products **within the European Union containing the substance manufactured by your company according to the synthetic route presented in the dossier,** and key dates *(use additional sheets if necessary)*

Brand name of medicinal products and company name	Country	Registration number and date	Commercialisation date

3.2 List of submitted ASMF

Please provide a list of referenced Authorities/Jurisdictions (**within the European Union, Switzerland, Canada, Australia, New Zealand, Singapore, Brazil, Mexico, South Africa, Japan, China, South Korea, Taiwan, USA, WHO**) where your company has submitted an ASMF **for the substance manufactured by your company according to the synthetic route presented in the dossier**.

Country / Jurisdiction	Registration Number	ASMF Holder's version number and Date of submission	ASMF Holder's version number and Date of the last update when relevant

4. Declarations (mandatory, see templates in Annex)

4.1. **Signed declaration of manufacture (for each manufacturing site, if relevant) in accordance with the dossier and according to GMP rules** *(as described in Annex 3a)* **(or, if the substance is not a drug substance, a suitable quality assurance system**, **specifying which rules/guidelines/standards are followed**, *as described in Annex 3b).*

4.2. **Signed declaration of willingness to be inspected (for each manufacturing site, if relevant).** This also applies for holders when different from manufacturers *(as described in Annex 4).*

4.3. **Signed declaration on use or non-use of materials of human or animal origin including TSE risk materials (not to be submitted in case of an application for a TSE certificate***) (as described in Annex 5).*

4.4. **Holder different from manufacturer:**

In exceptional cases where the holder of the certificate will not be the manufacturer, please provide the following declarations:

- A declaration from the manufacturer to commit to inform the holder of any change made so that the dossier submitted to the EDQM can be updated without any delay by the holder *(see Annex 2)*.
- Declarations of willingness to be inspected from both the holder and the manufacturer *(as described in Annex 4).*

4.5. **Signed declaration of commitment to provide samples if requested by the EDQM (not to be submitted in case of an application for a TSE certificate***) (as described in Annex 6).*

4.6. **Signed declaration of holder's commitments** *(as described in Annex 7).*

5. Way of submission

Electronic submissions should be sent via the Common European Submission Portal "CESP". Users can register for a CESP account on the CESP website.

6. Invoicing details (mandatory)

Following receipt of the application EDQM will send you an invoice. Please proceed with payment **after** you receive the invoice.

CEP number:		Name of the substance:	
Date of receipt of the application (for EDQM):			

Reference	Item	Fee	Tick as appropriate
CEP 028	Simple chemical certificate	5000 €	☐
CEP 027	Simple TSE or herbal certificate	3000 €	☐
CEP 026	Double certificate (chemical + TSE)*	8000 €	☐
CEP 025	Certificate for chemical purity and sterility	8000 €	☐
CEP 024	Certificate for chemical purity and sterility + TSE**	9000 €	☐

* In the case of TSE supported by a CEP the fees are only 5000 €.

** In the case of TSE supported by a CEP the fees are only 8000 €.

Contact person for the application, authorised for communication on behalf of the intended holder:	
Title* (Mrs, Mr, Dr)	
Contact first name*	
Contact family name*	
Job title/Department	
Company name*	
Address*	
Postcode*	
City*	
Country*	
Telephone*	
Email*	

Fields marked * are mandatory

	INVOICING ADDRESS
COMPANY DETAILS	
EDQM Client Code	
Company name (*):	

Address(*)	
City (*):	
Postcode (*)	
Region/State	
Country (*)	
VAT Number (**)	
Tel (switchboard) (*)	
Fax (*)	
Email (*)	
Contact name(*)	
Contact first name (*)	
Job title (*)	
Department (*)	
Tel (*)	
Email (*)	
Your purchase order number (if applicable)	

Fields marked (*) are mandatory. Fields marked with (**) are required for EU only.

Please note that new customers and customers who did not place any order during the last 18 months on their EDQM account, will have to complete a Customer account & Credit application form which will be sent before the invoice is issued.

If payment will come from several sources, please identify below the names of those companies that will pay:

_____
____

_____
____

PREFERRED LANGUAGE (for invoicing/accounting only): □ English □ French

AREA OF ACTIVITY/OCCUPATION (please tick the appropriate box):

❒ Manufacturer of raw material
❒ Manufacturer of pharmaceutical products
❒ Manufacturer of other products (e.g. cosmetics)
❒ National Authority, Regulatory Authority, Supervising Authority, OMCL
❒ Retail
❒ Distributor
❒ University
❒ Private Laboratory
❒ Other
❒ Hospital

PAYMENT

Following receipt of your application, we will send you an invoice. Please note that we must receive payment within 30 days end of month. No certificate will be issued without receipt of payment. Details of payment methods will be outlined on the invoice. You will be able to settle your invoice by:

1. BANK TRANSFER

2. CREDIT CARD

Annex 1

Template letter of Authorisation

[address of the manufacturer]

[date and place]

LETTER OF AUTHORISATION

We, [name of the manufacturer], hereby authorise, [name of the authorised representative], to act as official representative for our Certificate of Suitability for [name of the substance].

Signature

Annex 2

Template declaration in cases where the manufacturer is not the intended holder of a Certificate of Suitability

[name and address of the manufacturer]

[date and place]

LETTER OF AGREEMENT

We [name of the manufacturer] commit ourselves to inform [name of the intended holder], intended holder, of any necessary information and also of any change in the content of the dossier for the Certificate of Suitability for [name of the substance] so that they may be notified to the European Directorate for the Quality of Medicines & HealthCare by the holder during the assessment of the dossier and/or after the certificate has been granted.

Signature [Company Representative of the manufacturer of the substance]

Annex 3a

Template letter of declaration that the manufacture of the drug substance is according to the presented dossier and to GMP

[name and address of the manufacturer]

[date and place]

LETTER OF DECLARATION OF MANUFACTURE ACCORDING TO THE PRESENTED DOSSIER AND TO GMP RULES FOR APIs

We [name of the manufacturer] hereby declare that we manufacture [name of the substance] according to the presented dossier and to the GMP requirements:

- EU guidelines on Good Manufacturing Practice for Active Substances used as Starting Materials (as published in the Rules governing Medicinal Products in the European Union, Volume 4, Part II)
- If the substance is sterile, EU guidelines on Manufacture of sterile medicinal products (as published in the Rules governing Medicinal Products in the European Union, Volume 4, Annex I)

Signature [Company Representative of the manufacturer of the substance]

Annex 3b

Template letter of declaration that the manufacture of the substance is according to the presented dossier and to GMP rules / quality assurance system

(applies to TSE risk substances or excipients).

[name and address of the manufacturer]

[date and place]

LETTER OF DECLARATION OF MANUFACTURE ACCORDING TO THE PRESENTED DOSSIER AND TO GMP RULES AND / OR A QUALITY ASSURANCE SYSTEM

We [name of the manufacturer] hereby declare that we manufacture/produce [name of the substance] according to the presented dossier and to the following GMP rules and / or quality assurance system:
(*Please specify the rules applied: give full text reference and date of implementation*)

Signature [Company Representative of the manufacturer of the substance]

Annex 4

Template letter of declaration of willingness to be inspected

[name and address of the manufacturer/holder]

[date and place]

LETTER OF DECLARATION OF WILLINGNESS TO BE INSPECTED ACCORDING TO THE PRESENTED DOSSIER AND TO THE GMP RULES

We [name of the manufacturer/holder] hereby declare that we are willing to be inspected concerning the manufacture/production of [name of the substance] if requested by a relevant authority.

Signature [Company Representative of the manufacturer/holder]

Note : In cases where the holder would not be the manufacturer but an authorised agent the same letter of declaration should ***also*** *be supplied by the intended holder (authorised agent).*

Annex 5

Template declaration on the use of substances of animal/human origin

(not applicable for applications for TSE risk)

[name and address of the manufacturer]

[date and place]

LETTER OF DECLARATION OF MANUFACTURE REGARDING THE USE OF MATERIAL OF HUMAN OR ANIMAL ORIGIN INCLUDING SUBSTANCES AT RISK OF TRANSMITTING AGENTS OF ANIMAL SPONGIFORM ENCEPHALOPATHIES

☐ We, [name of COMPANY], hereby confirm that materials used in the manufacturing process of [name of SUBSTANCE] are not of human or animal origin.

OR *

☐ We, [name of COMPANY], hereby confirm that the following materials of human or animal origin are used in the manufacturing process of [name of SUBSTANCE] (Table below to be filled in):

Name of the material	Function[1]		Animal origin susceptible to TSE[2]	Other animal origin	Human origin
	SM	R			
	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐

1 SM = Starting Material, R= Reagent

2 As defined in the section 2 (scope) of *Ph. Eur. chapter 5.2.8 Minimising the risk of transmitting animal spongiform encephalopathy agents via medicinal products and the related general monograph no. 1483*

☐ If a Ph. Eur. Certificate of Suitability for TSE is available, tick and attach it.

Signature [Company Representative of the manufacturer of the substance]

**please tick the relevant paragraph*

Annex 6

Template letter of commitment to provide samples upon request by the EDQM

(not applicable for applications for TSE risk)

[name and address of the manufacturer]

[date and place]

LETTER OF COMMITMENT TO PROVIDE SAMPLES
IF REQUESTED BY THE EDQM

We [name of the manufacturer] hereby commit to provide samples of [name of the substance] and/or its impurities if requested by the EDQM at any time during the life cycle of the application for a certificate of suitability.

Signature [Company Representative of the manufacturer of the substance]

Annex 7

Declaration of Holder's commitments

[name and address of the intended holder]

[CEP application for: XX (substance name)]

[date and place]

HOLDER'S COMMITMENTS

We certify that we have read the Resolution AP-CSP (07) 1 governing the Certification procedure and the administrative provisions associated with this procedure. These provisions may be subject to change during the evaluation of the dossier according to the administrative and/or regulatory requirements in force, and we accept this.

We hereby commit ourselves to inform without delay all our customers of any revision, suspension, or cancellation of our Certificate of Suitability.

We are informed of and accept that the Certification of Substances Department of the European Directorate for the Quality of Medicines & Healthcare may share the assessment reports for this application with the National Competent Authorities of the Ph. Eur. member states, and with the EMA including EMA committees and working parties/groups and the members and experts thereof.

We agree to the procedure for the destruction of the submitted documents:

- Electronic files and scanned documents are kept for at least 5 years after the dossier is closed.

Signature [Company Representative of the holder]