##### REQUEST FOR TECHNICAL ADVICE MEETING

##### FOR CERTIFICATION OF SUITABILITY

to be completed for each request for a Technical Advice meeting related to the procedure for
Certificate of Suitability to the monographs of the European Pharmacopoeia AP-CSP (07) 1

## Date of submission: …… /…… /……

1. **GENERAL INFORMATION:**

## 1.1 Dates proposed for the technical advice meeting *(at least 2, preferably 3):*

* **(dd/mm/yyyy)**
* **(dd/mm/yyyy)**
* **(dd/mm/yyyy)**

NB: This form should be sent in electronic format to CEP@edqm.eu one month before any proposed meeting dates.

## 1.2 Organisational matter - tick box, as appropriate:

[ ]  Meeting at EDQM premises or [ ]  Visioconference

1. **SCOPE FOR THE QUESTIONS FOR THE TECHNICAL ADVICE**

**-** *tick box(es), as appropriate.*

**[ ]  Implementation of resolution, procedures and policies for certification**

**[ ]  Application(s) for new certificate(s) of suitability**

**[ ]  Revision(s) or renewal(s) of existing certificate(s)**

 **CEP number(s):**

 **Name(s) of substance(s) + subtitle (if applicable):**

**[ ]  Preparation of answers to deficiency letter**

 **CEP number(s):**

 **Name(s) of substance(s) + subtitle (if applicable):**

**[ ]  Other, please specify:**

1. **LIST OF QUESTIONS AND DOCUMENTATION**

|  |
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| **Questions and relevant documentation shall be attached;** the request cannot be accepted if missing (*see annex 2*)**The relevance of the Technical Advice request will be decided at receipt by the EDQM.** |

1. **CONTACT & COMPANY’S DETAILS - NAMES AND ADDRESSES**

|  |
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| **4.1 Contact** **person** authorised for communication related to the technical advice procedure.  if the contact person does not belong to (intended) CEP holder company annex 1 should be included |
| **Title\* (Ms, Mr, Dr)** |  |
| **First name\*** |  |
| **FAMILY NAME\*** |  |
| **Job title/Department** |  |
| **Telephone\*** |  |
| **E-mail\*a** |  |
| **NAME OF THE COMPANY APPLYING FOR THE TECHNICAL ADVICE\*** |  |
| **Address for correspondence\*** |  |
| **City/Town\*** |  |
| **Postcode\*** |  |
| **Country\*** |  |

Fields marked \* are mandatory

a please provide one email address. Shared mailboxes are strongly preferred.

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| **4.2 Names of participants in the technical advice meeting (***Max 4). If different from the company above mentioned please specify the link and justify his/her presence.**If not yet available that the list of participants should be sent to the EDQM at the latest 10 days before the meeting.*  |
| Title and Family Name | First name | Name of the company | Department |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

1. **INVOICING DETAILS (MANDATORY)**

Following receipt of the request for technical advice the EDQM will send you an invoice. Please proceed with payment **after** you receive the invoice.

|  |  |
| --- | --- |
| Reference | Item |
| CEP11 | Technical advice |

|  |  |  |  |
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| **CEP number**(if applicable): |  | Name of the **substance**: |  |
| *Date of receipt of the application (for EDQM):* |  |

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| **5.1 Contact** **person** authorised for communication related to the technical advice procedure. |
| **Title\* (Ms, Mr, Dr)** |  |
| **First name\*** |  |
| **FAMILY NAME\*** |  |
| **Job title/Department** |  |
| **Telephone\*** |  |
| **E-mail\*** |  |
| **NAME OF THE COMPANY APPLYING FOR THE TECHNICAL ADVICE\*** |  |
| **Address for correspondence\*** |  |
| **City/Town\*** |  |
| **Postcode\*** |  |
| **Country\*** |  |

Fields marked \* are mandatory

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| **5.2 Invoicing details (mandatory)** |
| **COMPANY DETAILS** |
| EDQM Client Code |  |
| *If applicable*: your purchase order number |  |
| NAME OF THE COMPANY\* |  |
| Address\* |  |
| City/Town\* |  |
| Postcode\* |  |
| State/Province |  |
| Country\* |  |
| Tel (switchboard)\* |  |
| Contact family name\* |  |
| Contact First name\* |  |
| Job title\* |  |
| Department\* |  |
| Tel\* |  |
| Email\* |  |

Fields marked \* are mandatory.

Please note that new customers and/or 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 multiple sources, please identify below the names of those companies that will pay:

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**PREFERRED LANGUAGE (for invoicing/accounting only)**: [ ]  English [ ]  French

Fields marked (\*) are mandatory.

**PAYMENT**

**Following validation of the technical advice meeting, we will send you an invoice. Please note that we must receive payment within 30 days end of month. 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 for letter of Authorisation

[address of the (intended) CEP Holder]

[date and place]

LETTER OF AUTHORISATION

We, [name of the (intended) CEP Holder], hereby authorise, [name of the authorised representative], to act as contact for our request for technical advice for Certificate(s) of Suitability for [name(s) of the substance(s)].

Signature

**Annex 2**

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| Technical Advice questions & documentation:***(To be filled in if not, the request cannot be accepted.*** ***Full supportive documentation should also be provided, if needed, as annexes)*** |