

Certification of Substances Department

FBG/HB

**PUBLIC DOCUMENT**

(Level 1)

**PA/PH/CEP (10) 118, 4R**

Strasbourg, March 2024

**Certification of suitability to the Monographs of the European Pharmacopoeia**

**Unique identification of manufacturing sites linked to CEP applications,  
using SPOR OMS and GPS coordinates**

Implementation date	April 2024
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## Revision history of the document

Revision N°	Revision date	Reason
Initial version	March 2011	Need to provide more reliability of the site location. Therefore GPS (WGS84) coordinates or DUNS number are requested in the application form.
R1	July 2011	Extend the possible GPS formats from “preferably expressed in DD MM.MMM (degree, minutes to three decimal places)” to “Alternatively the latitude and longitude may be expressed in Degrees to at least 5 decimal places or Degrees Minutes to at least 3 decimal places.”
R2	February 2022	Restrict the GPS format to “Degrees to at least 5 decimal places”. Remove requirement to provide DUNS number.
R3	April 2023	Provide more details and give examples of GPS coordinates. This version was not published.
R4	March 2024	Inclusion of reference to SPOR OMS data. Update of the title accordingly.

## 1. **BACKGROUND**

Applicants for new certificates of suitability (CEP) or revisions of CEPs are requested to provide information in the application form to unambiguously identify their sites as well as their respective locations, which is needed in particular in the context of the EDQM inspection programme.

Currently, the EDQM relies on:

- GPS coordinates, which have been requested for all CEP application since 2011, in line with the Pharmaceutical Inspection Co-operation Scheme (PIC/S) and European Commission guidance referenced at the end of this document.
- EMA SPOR OMS ORG (organisation) and LOC (location) identification numbers, which have been made mandatory for all CEP application since June 2023.

This document gives details on how to obtain the data for their submission to EDQM.

## 2. **GPS COORDINATES**

### **How to measure/obtain GPS coordinates?**

Use a smartphone or GPS device, set up with the system and units mentioned below.

### **Which geodetic system?**

Provide GPS coordinates in the internationally recognized WGS 84 system.

### **Which unit and format?**

- Latitude (North or South) and longitude (East or West), expressed in Degrees to at least 5 decimal places:
  - $\pm DD$  = three-digit integer degrees part of latitude (through  $-90 \sim -00 \sim +90$ )
  - $\pm DDD$  = four-digit integer degrees part of longitude (through  $-180 \sim -000 \sim +180$ )
  - $.DDDDD$  = variable-length decimal part in degrees
- Numeric only (no N, S, E, W), with positive and/or negative symbols:
  - Latitude: North="+" or blank, South="-"
  - Longitude: East ="+" or blank, West ="-"

### **Examples (Latitude, Longitude)**

+48.59617 +7.77824	EDQM, Strasbourg, France
+28.61702 +77.20754	Parliament of India, New Delhi, India
39.90512 116.39393	National People's Congress, Beijing, China
+38.88988 -77.00957	Capitol, Washington, USA
-15.79968 -47.86417	Palácio do Congresso Nacional, Brasília, Brazil
-35.30720 +149.12527	Australian Parliament, Canberra, Australia

### **Which location?**

- Primary coordinate: Just outside the door (within a meter), standing at the initial entry of primary reception location for the manufacturing plant.
- Secondary coordinate (optional): Just outside the door (within a meter), at entry to special or dedicated manufacturing building/suite.

### **How to make sure that coordinates are accurate and consistent?**

- Check recorded coordinates by pasting them into a web application using the same WGS 84 geodetic system.
- Provide the same coordinates for each regulatory authority and to each customer if any.

### **3. EMA SPOR OMS ORG and LOC IDENTIFICATION NUMBERS**

ORG\_ID and LOC\_ID identifiers are assigned and managed by the European Medicines Agency (EMA), using the SPOR/OMS database. More information on the SPOR/OMS database and how to register an organisation in the database is available on the EMA website: <https://spor.ema.europa.eu/sporwi/>. Any questions related to obtaining the necessary SPOR/OMS identifiers should be addressed to the EMA service desk <https://servicedesk.ema.europa.eu>.

Companies should ensure that their organisation name and location address(es) given to the EDQM are in line with the data published in the SPOR/OMS database. EDQM will use the entries in the SPOR/OMS database as a reference in order to have consistent data.

### **4. REFERENCES**

[Explanatory note for Industry on preparation of a Site Master File issued by PIC/S \(PE 008-4\)](#)

[Explanatory Notes on the preparation of a Site Master File issued by the European Commission](#)

<https://spor.ema.europa.eu/omswi/#/viewDocuments>