

Certification of Substances Department

FBG/HB

PUBLIC DOCUMENT

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Certification of suitability to the Monographs of the European Pharmacopoeia

Data on location of manufacturing sites (GPS coordinates)

linked to CEP applications

Implementation date	April 2022
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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.

Background

Since 2011, applicants for new certificates of suitability (CEP) or revisions of CEPs have been requested to provide information in the application form to better identify the location of their manufacturing sites with GPS co-ordinates, and (if available) a DUNS number.

The purpose is to provide more reliability of the site location, in particular in the context of the EDQM inspection programme. Experience with CEP applications showed that the way the applicants expressed their address was sometimes incomplete or inconsistent. Typical examples are:

- Address mentions a street or road name without a number
- Street/Road/Area name or number has changed following administrative reorganisation by the local authorities.

Therefore the EDQM relies on GPS coordinates, which are aimed allowing to unambiguously identify the location of a site. This requirement is in line with the explanatory note for Industry on preparation of a Site Master File issued by PIC/S and by the European Commission, as well as with the PIC/S guidance on Unique Facilities Identifiers.

This document gives details on how to provide these data to EDQM.

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 only as per the internationally recognized WGS 84 system.

Which unit and format ?

- Latitude (North or South) and longitude (East or West), only expressed in Degrees to at least 5 decimal places (DD.DDDDD)
- Numeric only (no N, S, E, W), with positive and/or negative symbols:
 - o Latitude: North="+" or blank, South="-"
 - o Longitude: East="+" or blank, West="-"

Which location?

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

How to make sure that coordinates are accurate and consistent ?

- Check recorded coordinates against web application using the same WGS 84 geodetic system.
- Review previously captured or supplied (CEP dossier or SMF) coordinates, and make sure they are consistent.