

FBG/pja

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

**Information to applicants for CEPs
Data for localisation of manufacturing sites (GPS and DUNS)**

From 15 April 2011, applicants for new certificates of suitability (CEP) or revisions of CEPs are requested to provide information in the EDQM application forms to better identify the location of their manufacturing site(s). These additional data are 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 program. Experience with CEP applications showed that the way the applicants express their address may be either incomplete or inconstant. Typical examples are:

- Addresses mention a street or road name without a number
- Street/road name or number has changed following urban or administrative reorganization by the local authorities.

Therefore the GMPS coordinates or DUNS number will allow EDQM to identify the location of a site. Beside, this requirement is in line with the recently revised explanatory note for industry on preparation of a Site Master File issued by PIC/S and by the European Commission.

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

1- GPS CO-ORDINATES

Which system (or datum)?

> Provide GPS co-ordinates as per the WGS 84 system.

Which unit should be used for GPS coordinates?

> Latitude (North or South) and longitude (East or West), preferably expressed in the format DD MM.MMM (degree, minutes to three decimal places).

Example: N 48° 35.770' E 7° 46.689'

Which location?

> Co-ordinates should preferably identify the main entrance of the manufacturing site involved in the production of the substance to be covered by the CEP. If the location for which the co-ordinates are given is not the main entrance, this should be specified clearly in the application form.

> Co-ordinates should be provided for each manufacturing site involved in the production of the substance.

How to measure/obtain GPS coordinates?

> Preferably, use a GPS device, calibrated with the units and system mentioned above.

or

> Use Google Earth to identify the site entrance and copy the co-ordinates displayed in the lower part of the map, with the format of the units and system mentioned above.

2- DUNS NUMBER

DUNS (Data Universal Numbering System) is a unique number developed by the private company Duns & Bradstreet. This number can be applied for through the company website (<http://www.dnb.com/>). Providing the DUNS number is not mandatory in the frame of the submission of a CEP dossier.