

Certification of Substances Division

FBG/CB

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Certification of suitability to the Monographs of the European Pharmacopoeia

Inspection fees and travel costs charged to companies inspected by EDQM

Date of implementation: 1st March 2015

The costs for an EDQM inspection are charged to inspected companies and cover two areas:

- Inspection fees
- Travel and subsistence expenses for the inspectors.

Payment should be made before the inspection takes place, after receipt of the invoice sent by EDQM.

Specific financial provisions may be applicable when joint inspections are organised either outside the EU/EEA with non EU/EEA inspectorates, or inside the EU/EEA with the local competent authority.

1- Inspection fees

Inspection fees are defined in advance based on the number of inspection days. See FORM/001: "Fees and inspection costs" available on the EDQM Certification webpages.

2- Travel and subsistence expenses during the inspection

A fixed amount is charged to the company by EDQM to cover travel and subsistence expenses of the inspection team and of the interpreter, if applicable. The fixed amount has been defined for the following areas: "Asia", "Europe" and "Other countries" based on the average cost of such inspections over the years.

See FORM/001: "Fees and inspection costs" available on the EDQM Certification webpages.

Local transport of inspectors and interpreters hired by EDQM during the inspection are treated separately and should be paid for directly by the company.

Lunches during the inspection days are treated separately and should be provided or paid for directly by the company.