

**European Directorate for the Quality of Medicines & HealthCare –
Certification of Substances Department**

FEES AND INSPECTION COSTS

Reference	Item	Fee
NEW APPLICATIONS		
CEP 028	Simple chemical certificate	5000 €
CEP 027	Simple TSE or herbal certificate	3000 €
CEP 026	Double certificate (chemical + TSE)*	8000 €
CEP 025	Certificate for chemical purity and sterility	8000 €
CEP 024	Certificate for chemical purity and sterility + TSE**	9000 €
* In the case of TSE supported by a CEP the fees are only 5000 €.		
** In the case of TSE supported by a CEP the fees are only 8000 €.		
REVISIONS OF CERTIFICATES		
CEP 009	Notification	1000 €
CEP 005	Minor revision	1500 €
CEP 019	Grouped revision (affecting several dossiers)	2000 €
CEP 006	Transfer of holdership	1500 €
CEP 020	Major revision (may include minor changes and notifications)	2000 €
CEP 004	Renewal	1500 €
CEP 015	Evaluation of sterility data	3000 €
TECHNICAL ADVICE		
CEP 011	Technical advice	1000 €
INSPECTIONS		
CEP 016	Inspection requested by company and approved by EDQM	9000 €
CEP 023	Inspection or re-inspection decided by EDQM (4 days)	6500 €
CEP 002	Inspection or re-inspection decided by EDQM (3 days)	5000 €
CEP 021	Inspection or re-inspection decided by EDQM (2 days)	3500 €
CEP 022	Inspection or re-inspection decided by EDQM (1 day)	2000 €
CEP 030	Remote Inspection	6500 €
INS003	Travel and subsistence expenses during an inspection in Asia	6000 €
INS004	Travel and subsistence expenses during an inspection in Europe	800 €
INS005	Travel and subsistence expenses during an inspection elsewhere	4500 €