European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé

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General European OMCL Network (GEON)
QUALITY MANAGEMENT DOCUMENT

PA/PH/OMCL (14) 39 R2

QUALIFICATION OF TESTING SERVICE PROVIDER

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N.B. This OMCL Quality Management System document is applicable to members of the European OMCL Network only. Other laboratories might use the document on a voluntary basis. However, please note that the EDQM cannot treat any questions related to the application of the documents submitted by laboratories other than the OMCLs of the Network.

ANNEX I

QUALIFICATION OF TESTING SERVICE PROVIDER

1. Description

Testing service provider	
Division	
Address	
Postcode / City / Country	
Contact person / Tel.	
Responsible / Qualified Person	
Title and professional training	
Type of test / Remarks	
Test parameter / Test method	

2. QS Status

– Test accredited according to ISO 17025 – Test covered by MJA scope – GLP certification – GMP certification – Pre-qualification programme of WHO	☐ ☐ ☐ ☐ ☐
Accreditation body / Certification company/ MJA performed by	
Accreditation / Certification / MJA attestation number	

If accredited or certified, please skip section 3 and continue to section 4*. Archiving*

3. Qualification requirements for the testing service provider

Qualification requirement		
Quality system in place	☐ yes ☐ no	Please specify:
Standard Operating Procedure (SOP) in place	☐ yes ☐ no	SOP No. / version:
OOS procedure in place	☐ yes ☐ no	
Method validation in place	☐ yes ☐ no	VA No. / version:
Metrological traceability of reference material	☐ yes ☐ no	Type / method of qualification:
Monitoring of environmental conditions	☐ yes ☐ no	
Qualification of the equipment	☐ yes ☐ no	Calibration programme in place ☐ yes ☐ no
Qualification of laboratory personnel	☐ yes ☐ no	Training programme in place ☐ yes ☐ no
Participation in proficiency testing studies or other collaborative studies?	☐ yes ☐ no	
Scientific publications?	☐ yes ☐ no	
References/reputation of the laboratory?	☐ yes ☐ no	
Notes		

4. Archiving

Archiving of test results (records)	☐ yes ☐ no	Retention time:
Archiving of samples	☐ yes ☐ no	Storage time:

Person responsible for accuracy of the declaration, i.e. the Responsible / Qualified Person	Date Signature Name

To be completed by the OMCL

5. Decision

Testing service provider suitable?	
Evaluation of QS-Manager ☐ yes ☐ no	Date / Signature
Decision of Responsible Person ☐ yes ☐ no	Date / Signature
Remarks	