

Appendix 6 Analysis and testing laboratories (O2, O8, O9, O10)

Testing of quality specifications must be performed by laboratories, which are accredited to the current standard and fulfil the general requirements in the standard EN ISO/IEC 17025 or have official GLP status. A non-accredited laboratory may perform tests if the laboratory has applied for accreditation according to the current testing method, but has not yet been granted approval, or if accreditation is not available for the technical specification or proposed standard. In such case, the laboratory must prove that it is an independent, competent laboratory.

The manufacturer's analysis laboratory/test procedure may be approved for analysis and testing if:

- Sampling and analysis are monitored by the authorities; or
- The manufacturer's quality assurance system covers analyses and sampling and is certified to ISO 9001; or
- The manufacturer can demonstrate agreement between a first-time test conducted at the manufacturer's own laboratory, and testing carried out in parallel at an independent test institute, and the manufacturer takes samples in accordance with a fixed sampling schedule.