

Certification of Substances Division

Title:	Refusal of information from third parties in reply to EDQM's request for information
Reference Document:	PA/PH/CEP (11) 18 (EN)

During the evaluation of an application any information requested by EDQM should be provided by the holder/applicant or the nominated contact. Recently EDQM has observed an increase in partial responses provided by third parties (e.g. from manufacturers of starting material or purchased intermediates) accompanied by a request that this information is kept confidential from the CEP holder/applicant. This is not acceptable as it is considered necessary that manufacturers of a final substance detain full information on the manufacture of a starting material or intermediate in order to suitably control the quality of the final substance. Therefore in such cases, the information received will not be retained and both the person/company submitting the data and the CEP holder/applicant will be advised of this and of the fact that this has not been accepted as a response to the request for information.