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Principle	
(…)	[Comments: First sentence is added.] **This chapter should be read in conjunction with all relevant sections of the GMP guide.** (…)
General	
6.2 (…) The Quality Control Department as a whole will also have other duties, such as to establish, validate and implement all quality control procedures, **keep the reference samples of materials and products**, ensure the correct labelling of containers of materials and products, ensure the monitoring of the stability of the products, participate in the investigation of complaints related to the quality of the product, etc. (…)	6.2 (…) The Quality Control Department as a whole will also have other duties, such as to establish, validate and implement all quality control procedures, **oversee the control of the reference and/or retention samples of materials and products when applicable**, ensure the correct labelling of containers of materials and products, ensure the monitoring of the stability of the products, participate in the investigation of complaints related to the quality of the product, etc. (…)
Good Quality Control Laboratory Practice	
6.5 (…)	6.5 (…) **Laboratory equipment should not be routinely moved between high risk areas to avoid accidental cross-contamination. In particular, the microbiological laboratory should be arranged so as to minimize risk of cross-contamination.**
Documentation	
6.7 (…): • specifications; • sampling procedures; • testing procedures and records (including **analytical** worksheets and/or laboratory notebooks) **(…)**; • **analytical** reports and/or certificates **(…)**; • data from environmental **(…)** monitoring, where required; • validation records of test methods, where applicable; • procedures for and records of the calibration **(…)** of instruments and maintenance of equipment.	6.7 (…): i. Specifications; ii. Procedures describing sampling, testing, records (including **test** worksheets and/or laboratory notebooks), **recording and verifying**; iii. Procedures for and records of the calibration**/qualification** of instruments and maintenance of equipment; **iv. A procedure for the investigation of Out of Specification and Out Of Trend results;** v. **Testing** reports and/or certificates **of analysis**; vi. Data from environmental **(air, water and other utilities)** monitoring, where required; vii. Validation records of test methods, where applicable.
6.8 Any Quality Control documentation relating to a batch record should be retained **for one year after the expiry date of the batch and at least 5 years after the certification referred to in Article 51(3) of Directive 2001/83/EC.**	6.8 Any Quality Control documentation relating to a batch record should be retained **following the principles given in chapter 4 on retention of batch documentation.** [Comments: According to **Chapter 4: Documentation** of the EU GMP Guide and under the sections describing the rules for **Retention of Documents**, there is point 4.11 which states: 'Specific requirements apply to batch documentation which must be kept for one year after expiry of the batch to which it relates or at least five years after

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	certification of the batch by the Qualified Person, whichever is the longer. (…)']
6.9 For some kinds of data (e.g. **analytical** tests results, yields, environmental controls) **it is recommended that records are kept** in a manner permitting trend evaluation. **(…)**	6.9 Some kinds of data (e.g. tests results, yields, environmental controls) **should be recorded** in a manner permitting trend evaluation. **Any out of trend or out of specification data should be addressed and subject to investigation.**
6.10 In addition to the information which is part of the batch **record**, other **original data** such as laboratory notebooks and/or records should be retained and readily available.	6.10 In addition to the information which is part of the batch **documentation**, other **raw data** such as laboratory notebooks and/or records should be retained and readily available.
Sampling	
6.11 The sample taking should be done **(…)** in accordance with approved written procedures that describe: (…)	6.11 The sample taking should be done **and recorded** in accordance with approved written procedures that describe: (…)
6.12 **Reference** samples should be representative of the batch of materials or products from which they are taken. (…) **(…)**	6.12 Samples should be representative of the batch of materials or products from which they are taken. (…) **The sampling plan used should be appropriately justified and based on a risk management approach.**
6.13 (…) **(…)**	6.13 (…) **They should be managed in a manner to minimize the risk of mix-up and to protect the samples from adverse storage conditions.**
Testing	
6.15 **Analytical** methods should be validated. **(…)** All testing operations described in the marketing authorisation **(…)** should be carried out according to the approved methods.	6.15 **Testing** methods should be validated. **A laboratory that is using a testing method and which did not perform the original validation, should verify the appropriateness of the testing method.** All testing operations described in the marketing authorisation **or technical dossier** should be carried out according to the approved methods.
6.16 The results obtained should be recorded **(…)** and checked to make sure that they are consistent with each other. (…)	6.16 The results obtained should be recorded. **Results of parameters identified as quality attribute or as critical should be trended** and checked to make sure that they are consistent with each other. (…)
6.17 (…) viii. a clear statement of **release** or rejection (or other status decision) and the dated signature of the designated responsible person. **(…)**	6.17 (…) **viii.** A clear statement of **approval** or rejection (or other status decision) and the dated signature of the designated responsible person; **ix. Reference to the equipment used.**
6.19 Special attention should be given to the quality of laboratory reagents, **volumetric** glassware and solutions, reference standards and culture media. They should be prepared **(…)** in accordance with written procedures. **(…)**	6.19 Special attention should be given to the quality of laboratory reagents, solutions, glassware, reference standards and culture media. They should be prepared **and controlled** in accordance with written procedures. **The level of controls should be commensurate to their use and to the available stability data.**
	[Comments: New section 6.20 is inserted.] **6.20 Reference standards should be established as suitable for their intended use. Their qualification and certification**

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	as such should be clearly stated and documented. Whenever compendial reference standards from an officially recognised source exist, these should preferably be used as primary reference standards unless fully justified (the use of secondary standards is permitted once their traceability to primary standards has been demonstrated and is documented). These compendial materials should be used for the purpose described in the appropriate monograph unless otherwise authorised by the National Competent Authority.
6.20 Laboratory reagents **(…) intended for prolonged use** should be marked with the preparation **(…)** date and the signature of the person who prepared them. The expiry date of **unstable** reagents and culture media should be indicated on the label, together with specific storage conditions. (…)	**6.21** Laboratory reagents, **solutions, reference standards and culture media** should be marked with the preparation **and opening** date and the signature of the person who prepared them. The expiry date of reagents and culture media should be indicated on the label, together with specific storage conditions. (…)
6.21 Where necessary, the date of receipt of any substance used for testing operations (e.g. reagents **(…)** and reference standards) should be indicated on the container. (…)	**6.22** Where necessary, the date of receipt of any substance used for testing operations (e.g. reagents, **solutions** and reference standards) should be indicated on the container. (…)
	[Comments: New section 6.23 is inserted.] **6.23 Culture media should be prepared in accordance with the media manufacturer's requirements unless scientifically justified. The performance of all culture media should be verified prior to use.**
	[Comments: New section 6.24 is inserted.] **6.24 Used microbiological media and strains should be decontaminated according to a standard procedure and disposed of in a manner to prevent the cross-contamination and retention of residues. The in-use shelf life of microbiological media should be established, documented and scientifically justified.**
On-going stability programme	
6.27 (…) • description of the conditions of storage (standardised ICH **(…)** conditions for long term testing, consistent with the product labelling, should be used) (…)	**6.30** (…) vii. Description of the conditions of storage (standardised ICH**/VICH** conditions for long term testing, consistent with the product labelling, should be used); (…)
6.28 The protocol for the on-going stability programme can be different from that of the initial long-term stability study as submitted in the marketing authorisation dossier provided that this is justified and documented in the protocol (for example the frequency of testing, or when updating to ICH **(…)** recommendations).	**6.31** The protocol for the on-going stability programme can be different from that of the initial long-term stability study as submitted in the marketing authorisation dossier provided that this is justified and documented in the protocol (for example the frequency of testing, or when updating to ICH**/VICH** recommendations).

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6.32 (…) Any confirmed out of specification result, or significant negative trend, **(…)** should be reported to the relevant competent authorities. (…)	**6.35** (…) Any confirmed out of specification result, or significant negative trend, **affecting product batches released on the market** should be reported to the relevant competent authorities. (…)
[Comments: New chapter is inserted.] **Technical transfer of testing methods**	
	6.37 Prior to transferring a test method, the transferring site should verify that the test method(s) comply with those as described in the Marketing Authorisation or the relevant technical dossier. The original validation of the test method(s) should be reviewed to ensure compliance with current ICH/VICH requirements. A gap analysis should be performed and documented to identify any supplementary validation that should be performed, prior to commencing the technical transfer process.
	6.38 The transfer of testing methods from one laboratory (transferring laboratory) to another laboratory (receiving laboratory) should be described in a detailed protocol.
	6.39 The transfer protocol should include, but not be limited to, the following parameters: **i. Identification of the testing to be performed and the relevant test method(s) undergoing transfer;** **ii. Identification of the additional training requirements;** **iii. Identification of standards and samples to be tested;** **iv. Identification of any special transport and storage conditions of test items;** **v. The acceptance criteria which should be based upon the current validation study of the methodology and with respect to ICH/VICH requirements.**
	6.40 Deviations from the protocol should be investigated prior to closure of the technical transfer process. The technical transfer report should document the comparative outcome of the process and should identify areas requiring further test method revalidation, if applicable.
	6.41 Where appropriate, specific requirements described in others European Guidelines, should be addressed for the transfer of particular testing methods (e.g Near Infrared Spectroscopy).

Explanations:

(…) – there is no changes in the text;

(…) – text in current version is amended in this place;

red and bold writing – text is deleted, corrected, changed;

blue and bold writing – text is inserted, corrected, changed, amended.