



1  
2 **GOOD STORAGE AND DISTRIBUTION PRACTICES**

3  
4 (May 2019)

5 *DRAFT FOR COMMENTS*

Please send any comments you may have to Dr Sabine Kopp, Group Lead, Medicines Quality Assurance, Technologies Standards and Norms ([kopps@who.int](mailto:kopps@who.int)), with a copy to Ms Claire Vogel ([vogelc@who.int](mailto:vogelc@who.int)) by 15 June 2019.

**Medicines Quality Assurance working documents will be sent out electronically only. They will also be placed on the Medicines website for comment under “Current projects”. If you have not already received our draft working documents, please send your email address (to [jonessi@who.int](mailto:jonessi@who.int)) and we will add you to our electronic mailing list.**

6  
7  
8 © World Health Organization 2019

9 All rights reserved.

10  
11  
12 This draft is intended for a restricted audience only, i.e. the individuals and organizations having received this draft. The draft may not be reviewed, abstracted, quoted, reproduced, transmitted, distributed, translated or adapted, in part or in whole, in any form or by any means outside these individuals and organizations (including the organizations' concerned staff and member organizations) without the permission of the World Health Organization. The draft should not be displayed on any website.

13  
14  
15  
16  
17 Please send any request for permission to:

18  
19 Dr Sabine Kopp, Group Lead, Medicines Quality Assurance, Technologies Standards and Norms, Department of Essential Medicines and Health Products, World Health Organization, CH-1211 Geneva 27, Switzerland, fax: (41 22) 791 4856, email: [kopps@who.int](mailto:kopps@who.int).

20  
21  
22  
23 The designations employed and the presentation of the material in this draft do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted lines on maps represent approximate border lines for which there may not yet be full agreement.

24  
25  
26  
27  
28 The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by the World Health Organization in preference to others of a similar nature that are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.

29  
30  
31  
32 All reasonable precautions have been taken by the World Health Organization to verify the information contained in this draft. However, the printed material is being distributed without warranty of any kind, either expressed or implied. The responsibility for the interpretation and use of the material lies with the reader. In no event shall the World Health Organization be liable for damages arising from its use.

33  
34  
35  
36  
37 This draft does not necessarily represent the decisions or the stated policy of the World Health Organization.  
38

39  
40  
41

SCHEDULE FOR DRAFT WORKING DOCUMENT QAS/19.793:  
**GOOD STORAGE AND DISTRIBUTION PRACTICES**

<b>Description of Activity</b>	<b>Date</b>
During the Fifty-third WHO Expert Committee on Specifications for Pharmaceutical Preparations (ECSPP), the Expert Committee recommended consolidation of the <i>Good storage practices</i> and <i>Good distribution practices</i> for pharmaceutical products and the elements of good distribution channel guidance into one document.	22-26 October 2018
Preparation of first draft working document by Dr André Van Zyl, a member of the Fifty-third ECSPP.	December 2018 - March 2019
Mailing of working document to the Expert Advisory Panel on the International Pharmacopoeia and Pharmaceutical Preparations (EAP) inviting comments and posting of the working document on the WHO website for public consultation.	April – June 2019
Consolidation of comments received and review of feedbacks. Preparation of working document for discussion.	June 2019
Discussion of working document and feedbacks received during the informal Consultation on Good Practices for Health Products Manufacture and Inspection.	July 2019
Revision of the working document based on comments received during the informal Consultation on Good Practices for Health Products Manufacture and Inspection.	End of July 2019
Mailing of revised working document to the EAP inviting comments and posting the working document on the WHO website for public consultation.	August – September 2019
Consolidation of comments received and review of feedbacks. Preparation of working document for discussion.	End of September 2019
Presentation to the Fifty-fourth meeting of the ECSPP.	14 -18 October 2019
Any other follow-up action as required.	

## GOOD STORAGE AND DISTRIBUTION PRACTICES

### 1. INTRODUCTION

1.1. Storage and distribution are important activities in the supply chain management of medical products. Various people and entities are generally responsible for handling, storage and distribution. Products may be subjected to various risks at different stages in the supply chain, i.e. during purchasing, storage, distribution, transportation, repackaging, and relabelling. Further, substandard and falsified products are a real threat to public health and safety. Consequently, it is essential to protect the supply chain against the penetration of such products.

1.2. This document sets out appropriate steps to assist in fulfilling the responsibilities involved in the different stages within the supply chain and to avoid the introduction of substandard and falsified products into the market. The relevant sections should be considered as particular roles that entities play in the storage and distribution of medical products.

1.3. This guideline is intended to be applicable to all persons and outlets involved in any aspect of the storage and distribution of medical products from the premises of the manufacturer of the product to the person dispensing or providing pharmaceutical products directly to a patient or his or her agent. This includes all parties involved in trade, storage and distribution of medical products, manufacturers and wholesalers, as well as other parties such as brokers, suppliers, distributors, logistics providers, traders, transport companies and forwarding agents and their employees.

1.4. The relevant sections of this guideline should also be considered for implementation by, amongst others, governments, regulatory bodies, international procurement organizations, donor agencies and certifying bodies, as well as all parties involved in any aspect of the trade and distribution of pharmaceutical products, including health care workers.

1.5. The guidelines can also be used as a tool in the prevention of the distribution of substandard and falsified products. It should, however, be noted that these are general

74 guidelines which may be adapted to suit the prevailing situations and conditions in individual  
75 countries. National or regional guidelines may be developed to meet specific needs and  
76 situations in a particular region or country.

77

78 1.6. To maintain the original quality of medical products, every party active in the supply  
79 chain has to comply with the applicable legislation and regulations. Every activity in the storage  
80 and distribution of medical products should be carried out according to the principles of good  
81 manufacturing practices (GMP), good storage practice (GSP) and good distribution practice  
82 (GDP) as applicable.

83

84 1.7. This guideline does not deal with dispensing to patients as this is addressed in the World  
85 Health Organization (WHO) good pharmacy practice (GPP) guide (xx). These guidelines  
86 should also be read in conjunction with other WHO guidelines (xx).

87

## 88 **2. SCOPE**

89

90 2.1. This document lays down guidelines for the storage and distribution of medical  
91 products. It is closely linked to other existing guidelines recommended by the WHO  
92 Expert Committee on Specifications for Pharmaceutical Preparations, such as  
93 referenced in section (xyz).

94

95 2.2. Depending on the national and regional legislation, these guidelines may apply equally  
96 to products for human and for veterinary use. The guidelines thus cover products for which a  
97 prescription is required by the patient, products which may be provided to a patient without a  
98 prescription, biologicals, vaccines and medical devices.

99

100 2.3. The document does not specifically cover GMP aspects of finished products in bulk,  
101 distribution of labels or packaging as these aspects are considered to be covered by other  
102 guidelines. The principles for the distribution of starting materials (active pharmaceutical  
103 ingredients (APIs) and excipients) are also not covered here. These are laid down in the WHO  
104 guidance “Good Trade and Distribution Practices for Pharmaceutical Starting Materials” (7).

105

106 **3. GLOSSARY**

107

108 The definitions provided below apply to the words and phrases used in this guideline. Although  
109 an effort has been made to use standard definitions as far as possible, they may have different  
110 meanings in other contexts and documents.

111

112 *active pharmaceutical ingredient (API)*

113 Any substance or mixture of substances intended to be used in the manufacture of a  
114 pharmaceutical dosage form and that, when used in the production of a drug, becomes  
115 an active ingredient of that drug. Such substances are intended to furnish  
116 pharmacological activity or other direct effect in the diagnosis, cure, mitigation,  
117 treatment or prevention of disease, or to affect the structure and function of the body.

118

119 *ALCOA*

120 A commonly used acronym for “attributable, legible, contemporaneous, original and accurate”.

121

122 *Auditing*

123 An independent and objective activity designed to add value and improve an organization’s  
124 operations by helping the organization to accomplish its objectives by using a systematic,  
125 disciplined approach to evaluate and improve the effectiveness of risk management, control  
126 and governance processes.

127

128 *batch*

129 A defined quantity of pharmaceutical products processed in a single process or series of  
130 processes so that it is expected to be homogeneous.

131

132 *batch number*

133 A distinctive combination of numbers and/or letters which uniquely identifies a batch, for  
134 example, on the labels, its batch records and corresponding certificates of analysis.

135

136

137

138 *consignment*

139 The quantity of pharmaceutical products supplied at one time in response to a particular request  
140 or order. A consignment may comprise of one or more packages or containers and may include  
141 pharmaceutical products belonging to more than one batch.

142

143 *container*

144 The material employed in the packaging of a pharmaceutical product. Containers include  
145 primary, secondary and transportation containers. Containers are referred to as primary if they  
146 are intended to be in direct contact with the product. Secondary containers are not intended to  
147 be in direct contact with the product.

148

149 *contamination*

150 The undesired introduction of impurities of a chemical or microbiological nature, or of foreign  
151 matter, into or on to a starting material, intermediate or pharmaceutical product during handling,  
152 production, sampling, packaging or repackaging, storage or transportation.

153

154 *contract*

155 Business agreement for the supply of goods or performance of work at a specified price.

156

157 *corrective and preventative actions (CAPA)*

158 A system for implementing corrective actions and preventive actions resulting from an  
159 investigation of complaints, product rejections, non-conformances, recalls, deviations, audits,  
160 regulatory inspections and findings, and trends from process performance and product quality  
161 monitoring.

162

163 *cross-contamination*

164 Contamination of a starting material, intermediate product or finished pharmaceutical product  
165 with another starting material or product during production, storage and transportation.

166

167

168

169

170 *distribution*

171 The procuring, purchasing, holding, storing, selling, supplying, importing, exporting, or  
172 movement of pharmaceutical products, with the exception of the dispensing or providing  
173 pharmaceutical products directly to a patient or his or her agent.

174

175 *excipient*

176 A substance, other than the active ingredient, which has been appropriately evaluated  
177 for safety and is included in a drug delivery system to aid in the processing of the drug  
178 delivery system during its manufacture; protect, support or enhance stability,  
179 bioavailability, or patient acceptability; assist in product identification; or enhance any  
180 other attribute of the overall safety and effectiveness of the drug during storage or use.

181

182 *expiry date*

183 The date given on the individual container (usually on the label) of a pharmaceutical product  
184 up to and including the date on which the product is expected to remain within specifications, if  
185 stored correctly. It is established for each batch by adding the shelf life to the date of  
186 manufacture.

187

188 *first expiry/first out (FEFO)*

189 A distribution procedure that ensures that the stock with the earliest expiry date is distributed  
190 and/or used before an identical stock item with a later expiry date is distributed and/or used.

191

192 *forwarding agent*

193 A person or entity engaged in providing, either directly or indirectly, any service concerned  
194 with clearing and forwarding operations in any manner to any other person and includes a  
195 consignment agent.

196

197 *good distribution practices (GDP)*

198 That part of quality assurance that ensures that the quality of a pharmaceutical product is  
199 maintained by means of adequate control of the numerous activities which occur during the  
200 distribution process as well as providing a tool to secure the distribution system from

201 counterfeits, unapproved, illegally imported, stolen, counterfeit, substandard, adulterated,  
202 and/or misbranded pharmaceutical products.

203

204 *good manufacturing practices (GMP)*

205 That part of quality assurance which ensures that pharmaceutical products are consistently  
206 produced and controlled to the quality standards appropriate to their intended use and as required  
207 by the marketing authorization.

208

209 *good pharmacy practice (GPP)*

210 The practice of pharmacy aimed at providing and promoting the best use of medicines and  
211 other health care services and products, by patients and members of the public. It requires that  
212 the welfare of the patient is the pharmacist's prime concern at all times.

213

214 *good storage practices (GSP)*

215 That part of quality assurance that ensures that the quality of pharmaceutical products is  
216 maintained by means of adequate control throughout the storage thereof.

217

218 *good trade and distribution practices (GTDP)*

219 That part of quality assurance that ensures that the quality of pharmaceutical products is  
220 maintained by means of adequate control throughout the numerous activities which occur during  
221 the trade and the distribution process.

222

223 *heating, ventilation and air conditioning systems (HVAC)*

224 Heating, ventilation and air-conditioning, also referred to as environmental control system  
225 (ECS).

226

227 *importation*

228 The act of bringing or causing any goods to be brought into a customs territory (national  
229 territory, excluding any free zone).

230

231

232



233 *intermediate product*

234 Partly processed product that must undergo further manufacturing steps before it becomes a  
235 bulk finished product.

236

237 *labelling*

238 Process of identifying a pharmaceutical product including the following information, as  
239 appropriate: name of the product; active ingredient(s), type and amount; batch number; expiry  
240 date; special storage conditions or handling precautions; directions for use, warnings and  
241 precautions; names and addresses of the manufacturer and/or the supplier.

242

243 *manufacture*

244 All operations of purchase of materials and products, production, packaging, labelling, quality  
245 control, release, storage and distribution of pharmaceutical products, and the related controls.

246

247 *marketing authorization*

248 A legal document issued by the competent medicines regulatory authority for the purpose of  
249 marketing or free distribution of a product after evaluation for safety, efficacy and quality. It  
250 must set out, inter alia, the name of the product, the pharmaceutical dosage form, the quantitative  
251 formula (including excipients) per unit dose (using International Nonproprietary Names (INNs)  
252 or national generic names where they exist), the shelf life and storage conditions, and packaging  
253 characteristics. It specifies the information on which authorization is based (e.g. “The  
254 product(s) must conform to all the details provided in your application and as modified in  
255 subsequent correspondence”). It also contains the product information approved for health  
256 professionals and the public, the sales category, the name and address of the holder of the  
257 authorization and the period of validity of the authorization. Once a product has been given  
258 marketing authorization, it is included on a list of authorized products - the register - and is often  
259 said to be “registered” or to “have registration”. Market authorization may occasionally also  
260 be referred to as a “licence” or “product licence”.

261

262

263

264

265 *material*

266 A general term used to denote starting materials (active pharmaceutical ingredients  
267 and excipients), reagents, solvents, process aids, intermediates, packaging materials  
268 and labelling materials.

269

270 *packaging material*

271 Any material, including printed material, employed in the packaging of a  
272 pharmaceutical product, but excluding any outer packaging used for transportation or  
273 shipment. Packaging materials are referred to as primary or secondary according to  
274 whether or not they are intended to be in direct contact with the product.

275

276 *pedigree*

277 A complete record that traces the ownership of and transactions relating to a pharmaceutical  
278 product as it is distributed through the supply chain.

279

280 *pharmaceutical product*

281 Any product intended for human use, or veterinary product intended for administration to food-  
282 producing animals, presented in its finished dosage form, which is subject to control by  
283 pharmaceutical legislation in either the exporting or the importing state and includes products  
284 for which a prescription is required, products which may be sold to patients without a  
285 prescription, biologicals and vaccines. It does not, however, include medical devices.

286

287 *product recall*

288 A process for withdrawing or removing a pharmaceutical product from the pharmaceutical  
289 distribution chain because of defects in the product, complaints of serious adverse reactions  
290 to the product and/or concerns that the product is or may be counterfeit. The recall might be  
291 initiated by the manufacturer, importer, wholesaler, distributor or a responsible agency.

292

293 *production*

294 All operations involved in the preparation of a pharmaceutical product, from receipt of  
295 materials through processing, packaging and repackaging, labelling and relabelling, to  
296 completion of the finished product.

297 *quality assurance*

298 A wide-ranging concept covering all matters that individually or collectively influence the  
299 quality of a product. It is the totality of the arrangements made with the object of ensuring that  
300 pharmaceutical products are of the quality required for their intended use.

301

302 *quality risk management*

303 A systematic process for the assessment, control, communication and review of risks to the  
304 quality of pharmaceutical products across the product life-cycle.

305

306 *quality system*

307 An appropriate infrastructure, encompassing the organizational structure, procedures,  
308 processes and resources and systematic actions necessary to ensure adequate confidence that a  
309 product (or services) will satisfy given requirements for quality.

310

311 *quarantine*

312 The status of pharmaceutical products isolated physically or by other effective means while a  
313 decision is awaited on their release, rejection or reprocessing.

314

315 *retest date*

316 The date when a material should be re-examined to ensure that it is still suitable for  
317 use.

318

319 *sampling*

320 Operations designed to obtain a representative portion of a pharmaceutical product, based on  
321 an appropriate statistical procedure, for a defined purpose, e.g. acceptance of consignments or  
322 batch release.

323

324 *shelf life*

325 The period of time during which a pharmaceutical product, if stored correctly, is expected to  
326 comply with the specification as determined by stability studies on a number of batches of the  
327 product. The shelf life is used to establish the expiry date of each batch.

328

329 *standard operating procedure (SOP)*

330 An authorized, written procedure giving instructions for performing operations not necessarily  
331 specific to a given product but of a more general nature (e.g. equipment operation, maintenance  
332 and cleaning, validation, cleaning of premises and environmental control, sampling and  
333 inspection).

334

335 *storage*

336 The storing of pharmaceutical products up to the point of use.

337

338 *supplier*

339 A person or entity engaged in the activity of providing products and/or services.

340

341 *transit*

342 The period during which pharmaceutical products are in the process of being carried, conveyed,  
343 or transported across, over or through a passage or route to reach the destination.

344

345 *vehicles*

346 Trucks, vans, buses, minibuses, cars, trailers, aircraft, railway carriages, boats and other means  
347 which are used to convey pharmaceutical products

348

#### 349 **4. GENERAL PRINCIPLES**

350

351 4.1. There should be collaboration between all parties, including governments, customs  
352 agencies, law enforcement agencies, regulatory authorities, manufacturers, distributors and  
353 entities responsible for the supply of medical products to patients, to ensure the quality and  
354 safety of these products; to prevent the exposure of patients to substandard and falsified  
355 products and to ensure that the integrity of the distribution chain is maintained.

356

357 4.2. The principles of GSP and GDP should be included in national legislation and  
358 guidelines for the storage and distribution of medical products, in a country or region as  
359 applicable, as a means of establishing minimum standards. The principles of GSP and GDP are  
360 applicable to:

- 361 • products moving forward in the distribution chain from the manufacturer;  
362 • products which are moving backwards in the chain, for example, as a result of the return  
363 or recall thereof; and  
364 • donations of products.

365

## 366 **5. QUALITY MANAGEMENT**

367

### 368 *Quality Systems*

369

370 5.1. Entities involved in the storage and distribution of medical products must have a  
371 comprehensively designed and correctly implemented, documented, quality system that  
372 incorporates good storage practices, good distribution practices, quality risk management and  
373 management review.

374

375 5.2. Senior management has the ultimate responsibility to ensure an effective quality system  
376 is established, is adequately resourced, implemented and maintained. The effectiveness, roles,  
377 responsibilities and authorities should be defined, communicated and implemented throughout  
378 the organization.

379

380 5.3. The quality system should ensure that:

381

- 382 • GSP and GDP is adopted and managed through satisfactory arrangements to ensure, as  
383 far as possible, that the medical products are stored, distributed and subsequently  
384 handled so that quality is maintained throughout their shelf-life in the supply-chain;  
385 • products are appropriately procured, stored, distributed and delivered to the right  
386 recipients;  
387 • operations are clearly specified in a written procedures;  
388 • responsibilities are clearly specified in job descriptions;  
389 • all risks are identified and necessary, effective controls are implemented;  
390 • processes are in place to assure the management of outsourced activities;  
391 • there is a procedure for self-inspection and/or quality audit;  
392 • there is a system for quality risk management (QRM);

- 393 • there are systems for managing returns, complaints and recalls;  
394 • systems are in place to manage changes, deviations and corrective and preventive  
395 actions (CAPAs).

396

397 5.4. There should be an authorized, written quality policy describing the overall intentions  
398 and requirements regarding quality. This may be reflected in a quality manual.

399

400 5.5. There should be an appropriate organizational structure. This should be presented in  
401 an authorized organizational chart. The responsibility, authority and interrelationships of all  
402 personnel should be clearly indicated.

403

404 5.6. Duties and responsibilities should be clearly defined and understood by the individuals  
405 concerned and recorded as written job descriptions.

406

407 5.7. The quality system should include appropriate procedures, processes and resources.

408

## 409 **6. QUALITY RISK MANAGEMENT**

410

411 6.1. There should be a system to assess, control, communicate and review risks identified at all  
412 stages in the supply chain. The evaluation of the risk should be based on scientific knowledge and  
413 experience with the process and ultimately linked to the protection of the patient.

414

415 6.2. Appropriate controls should be developed and implemented to address any risks identified.  
416 The effectiveness of the controls implemented should be evaluated at periodic intervals.

417

418 *(For further reading, see also WHO Guideline on Risk Management and ICH Q9, ISO 31000).*

419

## 420 **7. MANAGEMENT REVIEW**

421

422 7.1. There should be a system for periodic management review. The review should include:

423

- 424 • senior management;

- 425 • review of the quality system and its effectiveness by using quality metrics and key  
426 performance indicators;  
427 • identification of opportunities for continual improvement; and  
428 • follow-up on recommendations from previous management review meetings.  
429

430 7.2. Records should be maintained.  
431

## 432 **8. COMPLAINTS** 433

434 8.1. There should be a written procedure for the handling of complaints. A distinction should  
435 be made between complaints about a product or its packaging and those relating to distribution.  
436 In the case of a complaint about the quality of a product or its packaging, the original manufacturer  
437 and/ or marketing authorization holder should be informed as soon as possible.  
438

439 8.2. All complaints should be recorded and appropriately investigated. The root cause  
440 should be identified and the impact (e.g. on other batches or products) and risk assessed.  
441 Appropriate CAPA should be taken.  
442

443 8.3. Where required, the national regulatory authority should be informed and a recall  
444 initiated where appropriate.  
445

446 8.4. The relevant information, such as the results of the investigation of the complaint,  
447 should be shared with the relevant parties.  
448

449 8.5. Product quality problems or suspected cases of substandard or falsified products are  
450 identified and these should be handled according to the relevant procedures. The information  
451 should be shared with the appropriate national and/or regional regulatory authorities.  
452

## 453 **9. RETURNED GOODS** 454

455 9.1. Returned medical products should be handled in accordance with authorized  
456 procedures.

457 9.2. All returned goods should be placed in quarantine upon receiving. The status of  
458 the goods should be clear. Precautions should be taken to prevent access and distribution until  
459 a decision has been taken with regard to their disposition. The particular storage conditions  
460 applicable to the products should be maintained.

461

462 9.3. When handling returned goods, at least the following considerations should be  
463 taken:

464

- 465 • A risk-based process should be followed when deciding on the fate of the  
466 returned goods. This should include, but not be limited to, the nature of the  
467 product, storage conditions, condition of the product history, time-lapse since  
468 distribution, manner and condition of transport while being returned;
- 469 • the terms and conditions of the agreement between the parties; and
- 470 • examination of the returned goods, with decisions taken by suitably qualified,  
471 experienced and authorized persons.

472

473 9.4. Where products are rejected, authorized procedures should be followed, including safe  
474 transport.

475

476 9.5. Destruction of products should be done in accordance with international, national and  
477 local requirements regarding disposal of such products and with due consideration to the  
478 protection of the environment.

479

480 9.6. Records of all returned, rejected and destroyed medical products should be kept for a  
481 defined period.

482

## 483 **10. RECALLS**

484

485 10.1. There should be a written procedure to effectively and promptly recall medical products  
486 in compliance with national or regional requirements. A designated person(s) should be  
487 responsible for recalls.

488



489 10.2. The effectiveness of the procedure should be checked annually and updated as  
490 necessary.

491

492 10.3. The original manufacturer and/or marketing authorization holder, or other relevant contract  
493 party, should be informed in the event of a recall.

494

495 10.4. Information on a recall should be shared with the appropriate national or regional  
496 regulatory authority.

497

498 10.5. All recalled products should be transported and stored in secure, segregated conditions  
499 and clearly labelled as recalled products. The particular storage conditions applicable to the  
500 product should be maintained.

501

502 10.6. All customers and competent authorities of all countries to which a given product may  
503 have been distributed should be informed promptly of the recall of the product.

504

505 10.7. All records, including distribution records, should be readily accessible to the  
506 designated person(s) responsible for recalls. These records should contain sufficient  
507 information on products supplied to customers (e.g. name, address, contact detail, batch  
508 numbers, quantities, safety features - including exported products).

509

510 10.8. The progress of a recall process should be recorded and a final report issued which  
511 includes a reconciliation between delivered and recovered quantities of products.

512

## 513 **11. SELF-INSPECTION**

514

515 11.1. The quality system should include self-inspections. These should be conducted to  
516 monitor implementation and compliance with the principles of regulations, GSP, GDP and  
517 other appropriate guidelines.

518

519 11.2. Self-inspections should be conducted periodically according to an annual schedule.

520

521 11.3. The team conducting the inspection should be free from bias and individual members should  
522 have appropriate knowledge and experience. Audits by independent third parties may be beneficial.

523

524 11.4. The results of all self-inspections should be recorded. Reports should contain all  
525 observations made during the inspection and presented to the relevant personnel as well as  
526 management.

527

528 11.5. Necessary CAPAs should be taken and the effectiveness of the CAPAs should be  
529 reviewed.

530

## 531 **12. PREMISES**

532

### 533 *General*

534

535 12.1. Premises should be suitably located, designed, constructed and maintained to ensure  
536 appropriate operations such as receiving, storage, picking, packing and dispatch of medical  
537 products.

538

539 12.2. There should be sufficient space, lighting and ventilation to ensure required  
540 segregation, appropriate storage conditions and cleanliness.

541

542 12.3. Sufficient security should be provided and access should be controlled.

543

544 12.4. Appropriate controls and segregation should be provided for products requiring specific  
545 handling or storage such as radio-active materials, products containing hazardous substances,  
546 and products to be stored under controlled temperature and relative humidity conditions.

547

548 12.5. Receiving and dispatch bays should be separate and should protect products from  
549 weather conditions.

550

551 12.6. Activities relating to receiving and dispatch such be done in accordance with authorized  
552 procedures. Areas should be suitably equipped for the operations.

553 12.7. Premises should be kept clean. Cleaning equipment and cleaning agents should not  
554 become possible sources of contamination.

555

556 12.8. Premises should be protected from the entry of birds, rodents, insects and other animals.  
557 A rodent and pest control programme should be in place.

558

559 12.9. Toilets, wash, rest and canteen facilities should be separate from other areas. Food,  
560 eating, drinking, and smoking should be prohibited in all areas where medical products are  
561 stored or handled.

562 *Receiving*

563

564 12.10. Each incoming delivery should be checked against the relevant documentation  
565 to ensure that the correct product is delivered from the correct supplier. This may  
566 include, e.g. the purchase order, each container, label description, batch number,  
567 product and quantity.

568

569 12.11. The consignment should be examined for uniformity of the containers and, if  
570 necessary, should be subdivided according to the supplier's batch number should the  
571 delivery comprise more than one batch. Each batch should be dealt with separately.

572

573 12.12. Each container should be carefully checked for possible contamination,  
574 tampering and damage. Any suspect containers or, if necessary, the entire delivery  
575 should be quarantined for further investigation.

576

577 12.13. Receiving areas should be of sufficient size to allow cleaning of incoming  
578 containers.

579

580 12.14. When required, samples should be taken only by appropriately trained and  
581 qualified personnel and in strict accordance with written sampling procedure and  
582 sampling plans. Containers from which samples have been taken should be labelled  
583 accordingly.

584

585 12.15. Following sampling, the goods should be subject to quarantine. Batch  
586 segregation should be maintained during quarantine and all subsequent storage.

587

588 12.16. Materials and products requiring storage under controlled conditions of  
589 temperature and relative humidity should be handled as a priority.

590

591 12.17. Materials and products should remain in quarantine until an authorized release  
592 or rejection is obtained.

593

594 12.18. Measures should be taken to ensure that rejected materials and products cannot  
595 be used. They should be stored separately from other materials and products while  
596 awaiting destruction or return to the supplier.

597

598 *Storage areas*

599

600 12.19. Precautions should be taken to prevent unauthorized persons from entering  
601 storage areas.

602

603 12.20. Storage areas should be of sufficient capacity to allow the orderly storage of  
604 the various categories of materials and products, such as starting and packaging  
605 materials, intermediates, finished products, products in quarantine, and released,  
606 rejected, returned or recalled products.

607

608 12.21. Storage areas should be appropriately designed, constructed, maintained or  
609 adapted. They should be kept clean and dry and there should be sufficient space and  
610 lighting.

611

612 12.22. Storage areas should be maintained within acceptable temperature limits.  
613 Where special storage conditions are required on the label (e.g. temperature, relative  
614 humidity), these should be provided, controlled, monitored and recorded.

615

616 12.23. Materials and products should be stored off the floor and suitably spaced to  
617 permit ventilation, cleaning and inspection. Suitable pallets should be used and kept  
618 in a good state of cleanliness and repair.

619

620 12.24. A written sanitation programme should be available indicating the frequency  
621 of cleaning and the methods to be used to clean the premises and storage areas.

622

623 12.25. There should be a written programme for pest control. The pest-control agents  
624 used should be safe and there should be no risk of contamination of the materials and  
625 products.

626

627 12.26. There should be appropriate procedures for the clean-up of any spillage to  
628 ensure complete removal of any risk of contamination.

629

630 12.27. Where the status is ensured by storage in separate areas, these areas must be  
631 clearly marked and their access restricted to authorized personnel. Any system  
632 replacing physical separation and labelling or demarcation should provide equivalent  
633 security. For example, computerized systems can be used provided that they are  
634 validated to demonstrate security of access.

635

636 12.28. Where required, a separate sampling area should be in place. If sampling is  
637 performed in the storage area, it should be conducted in such a way that there is no  
638 risk of contamination or cross-contamination. Adequate cleaning procedures should  
639 be in place for the sampling areas.

640

641 12.29. Certain materials and products such as highly active and radioactive materials,  
642 narcotics and other hazardous, sensitive and/or dangerous materials and products, as  
643 well as substances presenting special risks of abuse, fire or explosion (e.g. combustible  
644 liquids and solids and pressurized gases), should be stored in a dedicated area that is  
645 subject to appropriate additional safety and security measures.

646

647 12.30. Materials and products should be handled and stored in such a manner as to  
648 prevent contamination, mix-ups and cross-contamination.

649

650 12.31. Materials and products should be stored in conditions which assure that their  
651 quality is maintained and stock should be appropriately rotated. The “first expired/first  
652 out” (FEFO) principle should be followed.

653

654 12.32. Rejected materials and products should be identified and controlled under a  
655 quarantine system designed to prevent their use until a final decision is taken on their  
656 fate.

657

658 12.33. Narcotic products should be stored in compliance with international  
659 conventions, and national laws and regulations on narcotics.

660

661 12.34. Broken or damaged items should be withdrawn from usable stock and  
662 separated.

663

664 12.35. There should be appropriate procedures for the clean-up of any spillage to ensure  
665 complete removal of any risk of contamination.

666

667 *Storage conditions*

668

669 12.36. The storage conditions for materials and medical products should be in  
670 compliance with the labelling, which is based on the results of stability testing.

671

672 12.37. Heating, ventilation and air conditioning systems (HVAC) should be  
673 appropriately designed, installed, qualified and maintained to ensure that the required  
674 storage conditions are maintained.

675

676 12.38. Where required, mapping studies for temperature and relative humidity, as  
677 appropriate, should be done to show uniformity across the storage facility. (*Ref: WHO*  
678 *Technical Report Series No. 961, Annex 9, Model guidance for the storage and transport*

679 *of time- and temperature-sensitive pharmaceutical products*). This applies, for example, to  
680 areas, refrigerators and freezers.

681

682 12.39. Temperature and relative humidity, as appropriate, should be controlled and  
683 monitored at regular intervals. Data should be recorded and the records should be  
684 reviewed. The equipment used for monitoring should be calibrated and be suitable for  
685 their intended use. All records pertaining to mapping and monitoring should be kept  
686 for a suitable period of time and as required by national legislation.

687

688 12.40. Temperature and relative humidity, as appropriate, should be controlled and  
689 monitored at regular intervals. Data should be recorded and the records should be  
690 reviewed. The equipment used for monitoring should be calibrated and be suitable for  
691 their intended use. All records pertaining to mapping and monitoring should be kept  
692 for a suitable period of time and as required by national legislation.

693

694 *Note: See annexure 1 for recommended storage conditions.*

695

### 696 **13. STOCK CONTROL AND ROTATION**

697

698 13.1. Periodic stock reconciliation should be performed at defined intervals by comparing  
699 the actual and recorded stocks.

700

701 13.2. The root cause for stock discrepancies should be identified and appropriate CAPAs  
702 taken to prevent recurrence.

703

704 13.3. Damaged containers should not be issued unless the quality of the material  
705 has been shown to be unaffected. Where possible, this should be brought to the  
706 attention of the person responsible for quality. Any action taken should be  
707 documented.

708

709 13.4. All stocks should be checked regularly for obsolete, to be retested, and  
710 expired materials and products.

711 **14. EQUIPMENT**

712

713 14.1. Equipment, including computerized systems should be suitable for their intended  
714 use. These should be appropriately designed, located, installed, qualified and maintained.

715

716 14.2. Computerized systems should be capable of achieving the desired output and results.

717

718 14.3. Where electronic commerce (e-commerce) is used, i.e. electronic means are used for  
719 any of the steps, defined procedures and adequate systems should be in place to ensure  
720 traceability and confidence in the supply chain and products concerned.

721

722 14.4. Electronic transactions (including those conducted via the Internet) relating to the  
723 distribution of medical products should be performed only by authorized persons according  
724 to defined and authorized access and privileges.

725

726 14.5. Where GXP systems are used, these should meet the requirements of 21 CFR 211  
727 Part 11, EU chapter 11 and WHO guidelines on computerized systems.

728

729 14.6. Data should meet ALCOA principles. Procedures should be followed, and records  
730 maintained for the back-up and restoration of data.

731

732 **15. QUALIFICATION AND VALIDATION**

733

734 15.1. The scope and extent of qualification and validation should be determined  
735 using a documented risk assessment approach.

736

737 15.2. Premises, utilities, equipment and instruments, processes and procedures  
738 should be considered. The scope and extent of qualification and validation in case of  
739 any significant changes should be identified.

740

741 15.3. Qualification and validation should be done following procedures and  
742 protocols. The results and outcome of the qualification and validation should be



743 recorded in reports. Deviations should be investigated and the completion of the  
744 qualification and validation should be concluded and approved by responsible  
745 personnel.

746

747 **16. PERSONNEL**

748

749 16.1. There should be an adequate number of personnel.

750

751 16.2. Personnel should have appropriate educational qualification, experience and training  
752 relative to the activities undertaken.

753

754 16.3. Personnel should have the authority and resources needed to carry out their duties and  
755 to follow the quality systems, as well as to identify and correct deviations from the established  
756 procedures.

757

758 16.4. There should be arrangements in place to ensure that management and personnel are  
759 not subject to commercial, political, financial and other pressures or conflict of interest that  
760 may have an adverse effect on the quality of service provided or on the integrity of  
761 pharmaceutical products.

762

763 16.5. Safety procedures relating to all relevant aspects including the safety of personnel and  
764 property, environmental protection and product integrity, should be in place.

765

766 16.6. Personnel should receive initial and continued training in accordance with a written  
767 training programme. The training should cover the requirements of GSP, GDP (as applicable),  
768 as well as on-the-job training. Other topics may include product security, product identification,  
769 the detection of falsified products.

770

771 16.7. Personnel dealing with hazardous pharmaceutical products (such as highly active  
772 materials, radioactive materials, narcotics, and other hazardous, environmentally sensitive  
773 and/or dangerous pharmaceutical products, as well as products presenting special risks of  
774 abuse, fire or explosion) should be given specific training.

775 16.8. Personnel should be trained in, and observe high levels of, personal hygiene  
776 and sanitation.

777

778 16.9. Records of all training, attendance and assessment should be kept.

779

780 16.10. Personnel handling products should wear garments suitable for the activities that they  
781 perform. Personnel dealing with hazardous pharmaceutical products, including products  
782 containing materials that are highly active, toxic, infectious or sensitizing, should be provided  
783 with protective garments as necessary.

784

785 16.11. Appropriate procedures relating to personnel hygiene, relevant to the activities to be  
786 carried out, should be established and observed. Such procedures should cover health, hygiene  
787 and clothing of personnel.

788

789 16.12. Procedures and conditions of employment for employees, including contract and  
790 temporary staff, and other personnel having access to medical products, must be designed and  
791 administered to assist in minimizing the possibility of such products coming into the possession  
792 of unauthorized persons or entities.

793

794 16.13. Codes of practice and punitive procedures should be in place to prevent and address  
795 situations where persons involved in the storage and distribution of medical products are  
796 suspected of, or found to be implicated in, any activities relating to the misappropriation,  
797 tampering, diversion or falsifying of any product.

798

## 799 **17. DOCUMENTATION**

800

801 17.1. Documentation includes all procedures and records, whether in paper or electronic  
802 form. Documents should be appropriately designed, completed, reviewed, authorized,  
803 distributed and kept as required. Documents should be readily available.

804

805 17.2. Written procedures should be followed for the preparation, review, approval, use of and  
806 control of all documents relating to the policies and activities for storage and distribution of  
807 medical products process.

808

809 17.3. Documents should be laid out in an orderly fashion and be easy to complete, review  
810 and check. The title, scope, objective and purpose of each document should be clear.

811

812 17.4. The contents of documents should be accurate, legible, traceable, attributable and  
813 unambiguous.

814

815 17.5. All documents should be completed, signed and dated as required by authorized  
816 person(s) and should not be changed without the necessary authorization.

817

818 17.6. Documentation should be prepared and maintained in accordance with the national  
819 legislation and principles of good documentation practices (*see WHO Technical Report*  
820 *Series No. 996, Annex 5, Guidance on good data and record management practices*).

821

822 17.7. The distributor must establish and maintain procedures for the identification,  
823 collection, indexing, retrieval, storage, maintenance, disposal of and access to all applicable  
824 documentation.

825

826 17.8. Documents should be reviewed regularly and kept up-to-date. When a document has  
827 been revised, a system should exist to prevent inadvertent use of the superseded version.

828

829 17.9. All records must be readily retrievable and be stored and retained using facilities that  
830 are safeguarded against unauthorized access, modification, damage, deterioration and/or loss  
831 of documentation.

832

833 17.10. Records should contain at least the following information:

834

- 835 • date;
- 836 • name of the product;

- 837 • quantity received, or supplied; and
- 838 • name and address of the supplier.

839

840 17.11. Comprehensive records should be maintained for all receipts, materials and  
841 products stored, and issues or distribution. They should include, for example, the  
842 description of the goods, quantity, names and addresses (such supplier, customer),  
843 batch number(s), date of receipt/dispatch and expiry date.

844

845 17.12. All containers should be clearly labelled with at least the name of the  
846 material/product, the batch number, the expiry date or retest date, and the specified  
847 storage conditions. Unauthorized abbreviations, names or codes should not be used.

848

## 849 **18. ACTIVITIES AND OPERATIONS**

850

851 18.1. All activities and operations relating to procurement, storage and distribution of  
852 medical products should be conducted in accordance with national legislation, GSP, GDP and  
853 associated guidelines.

854

855 18.2. Storage and distribution of medical products should be done by persons so authorized,  
856 in accordance with national legislation.

857

858 18.3. Activities and operations should be performed in accordance with documented  
859 procedures.

860

### 861 *Receiving*

862

863 18.4. Materials and products should be procured from appropriately authorized suppliers.

864

865 18.5. Deliveries should be examined for damage, seal intactness, signs of tampering,  
866 labelling, completeness of order and other related aspects, at receipt.

867

868 18.6. Containers and consignments not meeting acceptance criteria for receiving should be  
869 separated, quarantined and investigated. This includes suspected falsified products.

870

871 18.7. Materials and products requiring specific storage conditions, or access control (e.g.  
872 narcotics) should be processed without delay and stored in accordance with their requirements.

873

874 *Storage*

875

876 18.8. There should be sufficient space for the safe and secure storage of medical products  
877 (*see section xxx above*).

878

879 18.9. Appropriate controls should be implemented to prevent contamination and/or mix ups  
880 during storage.

881

882 18.10. Storage areas should be clean and kept free from litter, birds, dust and pests.

883

884 18.11. Controls and procedures should be in place to prevent and handle spillage and  
885 breakage.

886

887 18.12. Materials and products should be stored under the conditions specified on the label, e.g.  
888 controlled temperature and relative humidity when necessary. When specific storage  
889 conditions are required, the storage area should be qualified and operated within the specified  
890 limits. The storage conditions should be monitored and records maintained. The records  
891 should be reviewed and trends and out of limit results investigated.

892

893 18.13. Stock should be rotated and the FEFO policy should be implemented.

894

895 18.14. Computerized systems used for stock management should be validated.

896

897 18.15. Materials and products reaching their expiry date should be separated from usable  
898 stock and not be supplied.

899

900 *Repackaging and relabelling*

901

902 18.16. Repackaging and relabelling of materials and products are not recommended. Where  
903 they do occur, they should only be performed by entities appropriately authorized to do so and  
904 in compliance with the applicable national, regional and international requirements, and in  
905 accordance with GMP.

906

907 18.17. Procedures should be in place for the controlled disposal of original packaging to  
908 prevent re-use.

909

910 *Distribution and transport*

911

912 18.18. Materials and products should be transported in accordance with the conditions stated  
913 on the labels. There should be no risk to the quality of the material or product during transport  
914 and distribution.

915

916 18.19. Product, batch and container identity should be maintained at all times.

917

918 18.20. All labels should remain legible.

919

920 18.21. Distribution records should be sufficiently detailed to allow for a recall when required.

921

922 18.22. A copy of the original certificate of analysis from the manufacturer should be provided  
923 to the customer.

924

925 18.23. Drivers of vehicles should be identified and present appropriate documentation to  
926 demonstrate that they are authorized to transport medical products.

927

928 18.24. Vehicles should be suitable for their purpose, with sufficient space and appropriately  
929 equipped to protect materials and products.

930

931 18.25. The design and use of vehicles and equipment must aim to minimize the risk of errors  
932 and permit effective cleaning and/or maintenance to avoid contamination, build-up of dust or  
933 dirt and/or any adverse effect on the quality of the products.

934

935 18.26. Where feasible, consideration should be given to adding technology, such as global  
936 positioning system (GPS) electronic tracking devices and engine-kill buttons to vehicles, which  
937 would enhance the security and traceability of vehicles with products.

938

939 18.27. Where possible, dedicated vehicles and equipment should be used for medical  
940 products. Where non-dedicated vehicles and equipment are used, procedures should be in place  
941 to ensure that the quality of the products will not be compromised. Defective vehicles and  
942 equipment should not be used. These should either be labelled as such or removed from  
943 service.

944

945 18.28. There should be procedures in place for the operation and maintenance of all vehicles  
946 and equipment.

947

948 18.29. There should be written programmes and records for cleaning and pest control.  
949 Records should be kept. The cleaning and fumigation agents used should not have any adverse  
950 effect on product quality.

951

952 18.30. Equipment chosen and used for the cleaning of vehicles should not constitute a source  
953 of contamination. Agents used for the cleaning of vehicles should be approved by  
954 management.

955

956 18.31. Appropriate environmental conditions should be provided, checked, monitored and  
957 recorded. All monitoring records should be kept for a minimum of the shelf life of the product  
958 distributed plus one year, or longer, if required by national legislation. Records of monitoring  
959 data should be made available for inspection by the regulatory or other oversight body.

960

961 18.32. Instruments used for monitoring conditions, e.g. temperature and humidity, within  
962 vehicles and containers should be calibrated at regular intervals.

963 18.33. Where possible, mechanisms should be available to allow for the segregation during  
964 transit of rejected, recalled and returned products as well as those suspected as falsified. Such  
965 goods should be securely packaged, clearly labelled and be accompanied by appropriate  
966 supporting documentation.

967

968 18.34. Measures should be in place to prevent unauthorized persons from entering and/or  
969 tampering with vehicles and/or equipment, as well as to prevent the theft or misappropriation  
970 thereof.

971

972 18.35. Shipment containers should have no adverse effect on the quality of the products and  
973 should offer adequate protection to materials and products. Containers should be labelled  
974 indicating, e.g. handling and storage conditions, precautions, contents and source, safety  
975 symbols as appropriate.

976

977 18.36. Special care should be taken when using dry ice in shipment containers due to safety  
978 issues and possible adverse effects on the quality of products.

979

980 18.37. Written procedures should be available for the handling of damaged and/or broken  
981 shipment containers. Particular attention should be paid to those containing potentially toxic  
982 and hazardous products.

983

984 *Dispatch*

985

986 18.38. Products should only be sold and/or distributed to persons or entities that are  
987 authorized to acquire such products in accordance with the applicable national legislation.  
988 Written proof of such authorization must be obtained prior to the distribution of products to  
989 such persons or entities.

990

991 18.39. Dispatch and transportation should be undertaken only after the receipt of a valid order  
992 which should be documented.

993

994 18.40. There should be documented, detailed procedures for the dispatch of products.



995 18.41. Records for the dispatch of products should be prepared and should include  
996 information such as, but not limited to, date of dispatch; complete business name and address  
997 (no acronyms), type of entity responsible for the transportation, telephone number, names of  
998 contact persons; status of the addressee (e.g. retail pharmacy, hospital or community clinic); a  
999 description of the products including, e.g. name, dosage form and strength (if applicable);  
1000 quantity of the products, i.e. number of containers and quantity per container (if applicable);  
1001 applicable transport and storage conditions; a unique number to allow identification of the  
1002 delivery order; and assigned batch number and expiry date (where not possible at dispatch, this  
1003 information should at least be kept at receipt to facilitate traceability).

1004

1005 18.42. Records of dispatch should contain enough information to enable traceability of the  
1006 product. Such records should facilitate the recall of a batch of a product, if necessary, as well  
1007 as the investigation of falsified or potentially falsified products. In addition, the assigned batch  
1008 number and expiry date of pharmaceutical products should be recorded at the point of receipt  
1009 to facilitate traceability.

1010

1011 18.43. Vehicles and containers should be loaded carefully and systematically, where  
1012 applicable on a first-out/last-in basis, to save time when unloading, prevent physical damage  
1013 and reduce security risks. Extra care should be taken during loading and unloading of cartons  
1014 to avoid damage.

1015

1016 18.44. Products should not be supplied or received after their expiry date, or so close to the  
1017 expiry date that this date is likely to be reached before the products are used by the consumer.

1018

1019 18.45. Products and shipment containers should be secured to prevent or provide evidence of  
1020 unauthorized access. Vehicles and operators should be provided with additional security, as  
1021 appropriate, to prevent theft and other misappropriation of products during transportation.

1022

1023 18.46. Products should be stored and transported in accordance with procedures such that:

1024

- 1025 • the identity of the product is not lost;
- 1026 • the product does not contaminate and is not contaminated by other products;

- 1027 • adequate precautions are taken against spillage, breakage, misappropriation and  
1028 theft; and  
1029 • appropriate environmental conditions are maintained, e.g. using cold chain for  
1030 thermolabile products.

1031

1032 18.47. Written procedures should be in place for investigating and dealing with any failure  
1033 to comply with storage requirements, e.g. temperature deviations. If a deviation has been  
1034 noticed during transportation by the person or entity responsible for transportation, this should  
1035 be reported to the distributor and recipient. In cases where the recipient notices the deviation,  
1036 it should be reported to the distributor.

1037

1038 18.48. Transportation of products containing hazardous substances, or narcotics and other  
1039 dependence-producing substances, should be transported in safe, suitably designed, secured  
1040 containers and vehicles. In addition, the requirements of applicable international agreements  
1041 and national legislation should be met.

1042

1043 18.49. Spillages should be cleaned up as soon as possible to prevent possible contamination,  
1044 cross-contamination and hazards. Written procedures should be in place for the handling of  
1045 such occurrences.

1046

1047 18.50. Damage to containers and any other event or problem that occurs during transit must  
1048 be recorded and reported to the relevant department, entity or authority, and investigated.

1049

1050 18.51. Products in transit must be accompanied by the appropriate documentation.

1051

## 1052 **19. OUTSOURCED ACTIVITIES**

1053

1054 19.1. Any activity relating to the storage and distribution of a medical product which is  
1055 delegated to another person or entity should be performed by parties appropriately authorized,  
1056 in accordance with national legislation, and the terms of a written contract.

1057

1058 19.2. There should be a written contract between the parties. The contract should define the  
1059 responsibilities of each party (contract giver and contract acceptor) and at least the following:

1060

- 1061 • compliance with this guideline and the principles of GSP and GDP;
- 1062 • relevant warranty clauses;
- 1063 • responsibilities of the contractor for measures to avoid the entry of substandard and  
1064 falsified products into the distribution chain;
- 1065 • training of personnel;
- 1066 • conditions of subcontracting subject to the written approval of the contract giver; and
- 1067 • periodic audits.

1068

1069 19.3. The contract giver should assess the competence of the contract acceptor before  
1070 entering into an agreement.

1071

1072 19.4. The contract giver should provide all relevant information relating to the  
1073 material/products to the contract acceptor.

1074

1075 19.5. The contract acceptor should have adequate resources (e.g. premises, equipment,  
1076 personnel, knowledge, experience, vehicles as appropriate) to carry out the work.

1077

1078 19.6. The contract acceptor should refrain from performing any activity that may adversely  
1079 affect the materials or products handled.

1080

## 1081 **20. SUBSTANDARD AND FALSIFIED PRODUCTS**

1082

1083 20.1. The quality system should include procedures to assist in identifying and handling  
1084 materials and products that are suspected to be substandard and or falsified.

1085

1086 20.2. Where these materials and products are identified, the holder of the marketing  
1087 authorization, the manufacturer and the appropriate national and/or international regulatory  
1088 bodies, as well as other relevant competent authorities, should be informed.

1089

1090 20.3. Such products should be stored in a secure, segregated area and clearly identified to  
1091 prevent further distribution or sale. Access should be controlled.

1092

1093 20.4. Records should be maintained reflecting the investigations and action taken, such as  
1094 disposal of the material or products. Falsified materials and products should not re-enter the  
1095 market.

1096

## 1097 **21. INSPECTION OF STORAGE AND DISTRIBUTION FACILITIES**

1098

1099 21.1. Storage and distribution facilities should be inspected by inspectors so authorized in  
1100 terms of national legislation. This should be done at determined periodic intervals.

1101

1102 21.2. Inspectors should have appropriate educational qualifications, knowledge and  
1103 experience.

1104

1105 21.3. An inspection should normally be conducted by a team of inspectors.

1106

1107 21.4. Inspectors should assess compliance with national legislation, GSP, GDP and related  
1108 guidelines (GxP) as appropriate.

1109

1110 21.5. Inspections should cover the premises, equipment, personnel, activities, quality  
1111 system, qualification and validation, and other related aspects as contained in this guideline.

1112

1113 21.6. An inspection report should be prepared and provided to the inspected entity within  
1114 30 days from the last day of the inspection. Observations may be categorized based on risk  
1115 assessment.

1116

1117 21.7. CAPA for observations listed as non-compliances in the inspection report, with the  
1118 national legislation and guidelines, should be submitted for review by the inspectors within the  
1119 defined period as stated by the inspectors.

1120

1121 21.8. Inspections should be closed with a conclusion after the review of the CAPAs.

1122 **References and further reading**

1123

1124 *[Note from Secretariat: the references included in the text will be added here in the final*  
1125 *version. Proposals for further reading references are invited.]*

1126

1127

1128

1129

1130 **ANNEXURE 1. RECOMMENDED STORAGE CONDITIONS**

1131

1132 *Note: Appropriate conditions should be provided for materials and products during storage*  
1133 *and distribution. Conditions should be maintained as stated on their labels from the*  
1134 *manufacturers and suppliers, during storage and distribution. Where possible, actual limits*  
1135 *should be provided by the manufacturers, such as “store below 25°C”. Vague statements such*  
1136 *as “store at ambient conditions” should be avoided.*

1137

1138 Table 1. Recommended limits for descriptive storage conditions<sup>1</sup>

Label description	Recommended limits
Store at controlled room temperature	20 to 25°C
Store in a cool place	8 to 15°C
Store in a refrigerator	2 to 8°C
Store in a freezer	-25 to -10°C
Store in a dry place	No more than 60% relative humidity
Protect from moisture	No more than 60% relative humidity
Store under ambient conditions	Storage in dry, well-ventilated premises at temperatures of 15 –30°C. Extraneous odours, other indications of contamination, and intense light must be excluded.
Do not store over 30°C	2 to 30°C
Do not store over 25°C	2 to 25°C
Do not store over 15°C	2 to 15°C
Do not store over 8°C	2 to 8°C
Do not store below 8°C	8 to 25°C
Protect from light	To be provided in light resistant containers. Light level not exceeding 300 lux.
Chilled	Refrigerated

1139 <sup>1</sup>These limits are recommended values, based on pharmacopoeia limits and guidelines

1140

1141

\*\*\*