Complete overview of differences between Guideline on GDP 2nd Edition, 2013 and Guideline on GDP 3rd Edition, 2018

Note that in relation to the following tables:

- Wherever possible, new or additions to texts are indicated by blue colour in the relevant text in the left hand column and existing clauses that have been removed are indicated by [square brackets and a purple colour].

- In general, the sentence 'Materials and/or Products and/or Cosmetics' which is dominantly in the Guideline on GDP 2nd Edition, 2013 will be replaced with 'Products/Cosmetics'.

- Chapter 5: Disposal of Materials/Products/Cosmetics of Guideline on GDP 2nd Edition, 2013 is incorporated into Chapter 4: Stock Handling and Stock Control of Guideline on GDP 3rd Edition, 2018.

- Chapter 6: Documentation and Chapter 14: Legal Documents of Guideline on GDP 2nd Edition, 2013 is incorporated into Chapter 11: Management of Records and Documentation of Guideline on GDP 3rd Edition, 2018.

- Chapter 7: Vehicles and Equipment of Guideline on GDP 2nd Edition, 2013 is incorporated into Chapter 3: Premises and Equipment and Chapter 5: Transportation of Guideline on GDP 3rd Edition, 2018.

- Chapter 8: Transportation and Goods in Transit of Guideline on GDP 2nd Edition, 2013 is incorporated into Chapter 5: Transportation of Guideline on GDP 3rd Edition, 2018.

- Chapter 15: Management of Cold Chain Products/Materials of Guideline on GDP 2nd Edition, 2013 is incorporated into Annex 1: Management of Time and Temperature Sensitive Products (TTSP) of Guideline on GDP 3rd Edition, 2018.

- Addition of Annex 2: Specific Provisions for Brokers and Annex 3: General Points to Consider for Audittee

INTRODUCTION

GUIDELINE ON GDP 3rd Edition, 2018	GUIDELINE ON GDP 2nd EDITION, 2013
Introduction Distribution is an important activity in the integrated supply-chain management. With the globalisation of the pharmaceutical industry, various individuals and organisations from locations around the world are generally responsible for handling, storage and distribution of such products. Therefore it is important to have adequate control over the entire supply chain from manufacture to delivery to the patient or end user. This guideline lays down the appropriate principles for those involved in the supply chain in conducting their activities while ensuring the maintenance of high standards of quality assurance and integrity of the distribution processes. Not all of the principles described will be relevant to every situation as it is recognised not all the principles are applicable to certain companies or environment. The principles should be adapted to meet individual company's needs where necessary. Alternative practices to those set out in the guideline that achieve an equivalent or better outcome can be adopted by companies provided that such alternative practices can be shown or demonstrated to achieve an outcome that is equivalent to or better than the provisions in the guideline. When the distribution chain is interrupted by manufacturing steps such as repackaging or relabeling, the principles of Good Manufacturing Practice (GMP) should be applied to these processes. This guideline is applicable to all organisations and individuals involved in any aspect of the storage and distribution of products/cosmetics including but not limited to the following:	Introduction [This guideline is used as a standard to justify status and as basis for the inspection of facilities such as manufacturers, importers and wholesalers. All manufacturers, importers and wholesalers of registered products/ notified cosmetics and its related materials are required to adopt proper distribution and store management procedures appropriate for the distribution and storage of registered products/ notified cosmetics and its related materials destined for the consumer. These procedures should include the management of personnel, premises, facilities and adequate documentary procedures that preserve the safety and quality of the material or product or cosmetic. Good Distribution Practice of **GDP** is defined as: **"The measure that need to be considered in the storage, transportation and distribution of any registered product/ notified cosmetic and its related materials such that the nature and quality intended is preserved when it reaches the consumer"]** [The GDP] also requires that products or cosmetics classified as dangerous drugs, scheduled poisons and psychotropic substances, under the Dangerous Drugs Act 1952 (Revised 1980), Poison Act 1952 (Revised 1989), Poisons (Psychotropic Substances) Regulations 1989 and the Control of Drugs and Cosmetics Regulations 1984 (Revised 2009), are stored and distributed in accordance with the requirements of the respective Acts and Regulations.

• Manufacturers of active pharmaceutical ingredients, drug products, radiopharmaceuticals, packaging materials, dietary supplements, biological and biotechnological products, and cell and gene therapy products. • Packaging operations by the manufacturer or a designated contractor for the Product Registration Holder. • Repackaging operations in which the products/cosmetics may be owned by an organisation other than the primary manufacturer. • Pharmacies including but not limited to retail, compounding and hospital. • Importers and exporters. • Wholesale distributors. • Distribution organisations involved in road, rail, sea and/or air services. • Third-party and fourth-party logistics providers, brokers and freight forwarders. • Health care professionals storing products prior to dispensing or administering to patients. This guideline also requires that products or cosmetics classified as dangerous drugs, scheduled poisons and psychotropic substances, under the Dangerous Drugs Act 1952 (Revised 1980), Poisons Act 1952 (Revised 1989), Poisons (Psychotropic Substances) Regulations 1989 and the Control of Drugs and Cosmetics Regulations 1984 (Revised 2009), are stored and distributed in accordance with the requirements of the respective Acts and Regulations.	

CHAPTER 1: QUALITY MANAGEMENT

GUIDELINE ON GDP 3rd Edition, 2018	GUIDELINE ON GDP 2nd EDITION, 2013
PRINCIPLE A quality system setting out responsibilities, processes and risk management principles in relation to the activities of importation, procurement, storage, transportation and distribution of products/cosmetics should be maintained. All relevant activities should be clearly defined in procedures and systemically reviewed. All critical steps of the processes and significant changes should be justified and where relevant validated. The quality system is the responsibility of the organization's management and requires their leadership and active participation and should be supported by personnel commitment.	-
1.1 Quality management system should include an appropriate organisational structure, procedures, processes and resources; and systematic actions necessary to ensure adequate confidence that a product/cosmetic will satisfy given requirements for quality. Totality of these actions is termed 'Quality System'. The Quality System should be fully documented and its effectiveness monitored.	1.1 [Within an organization, quality assurance serves as a management tool. In contractual situations quality assurance also serves to generate confidence in the supplier. There should be a documented quality policy describing the overall intentions and policies of the distributor regarding quality, as formally expressed and authorized by management.]
1.2 The quality system should ensure that: i. Products/Cosmetics are procured, held, supplied, imported, exported and distributed in a way that is compliant with the requirements of GDP; ii. Management responsibilities are clearly defined; iii. Products/Cosmetics are delivered to the right recipients within a satisfactory time period; iv. Records are made contemporaneously (simultaneously/ at same time);	1.2 [Quality management system should include an appropriate organizational structure, procedures, processes and resources; and systematic actions necessary to ensure adequate confidence that a product/ cosmetic will satisfy given requirements for quality. Totality of these actions is termed 'Quality System'.]

v. Deviations from established procedures are documented and investigated; vi. Appropriate corrective and preventive actions (commonly known as CAPA) are taken to correct deviations and prevent them in line with the principles of quality risk management.	
1.3 Quality system should also foster a safe, transparent and secure distribution system by establishing measures to ensure that products/cosmetics have a form of documentation that can be used to permit traceability of the products/cosmetics throughout distribution channels from the manufacturers, manufacturer's agents, wholesalers, importers, distributors and brokers to the retailers. Note: This is relocation of Clause 1.11 of Guideline on GDP 2nd Edition, 2013	1.3 [The quality system should include provisions that the holder of the marketing authorization labelled entity (if different from manufacturer) the appropriate national and/or international regulatory bodies, as well as other relevant competent authorities, should be informed immediately in case of confirmed or suspected counterfeit products and/or cosmetics. Such materials and/or products and/or cosmetics have to be stored in a secure segregated area and have to be clearly identified to prevent further distribution of sale.]
1.4 The quality system should extend to the control and review of any outsourced activities related to the procurement, holding, supply, import, storage, transport, distribution or export of products/cosmetics. These processes should include: i. Assessing the suitability and competence of the Contract Acceptor to carry out the activity and checking authorisation status, if required; ii. Defining the responsibilities and communication processes for the quality-related activities of the parties involved; iii. Monitoring and review of the performance of the Contract Acceptor, and the identification and implementation of any required improvements on a regular basis.	1.4 [All parties involved in the distribution of materials and/or products and/or cosmetics should share responsibility for the quality and safety of materials and/or products and/or cosmetics to ensure that they are fit for their intended use. There should be a procedure in place that describes pedigree documentation as well as the visual and/or analytical identification of potential counterfeit materials and/or products and/or cosmetics. The procedure should include provisions for notification, as appropriate for the holder of the marketing authorization labelled entity (if different from manufacturer) the appropriate national and/or international regulatory bodies, as well as other relevant competent authorities, when a potential counterfeit drug is identified.]
1.5 Authorised procurement and release procedures for all administrative and technical operations performed should be in place, to ensure that appropriate products/cosmetics are sourced from approved suppliers and distributed by approved entities. The approval should come from the	1.5 Where electronic commerce (e-commerce) is used, defined procedures and adequate systems should be in place to ensure traceability and confidence in the quality of materials and/or products and/or notified cosmetics. The provisions should

competent authority of the individual country where the legal entity is registered. There should be a written procedure in place to ensure and document traceability of the products/cosmetics received and distributed. Note: This is relocation of Clause 1.6 of Guideline on GDP 2nd Edition, 2013	guarantee the same degree of materials and/or products and/or notified cosmetics safety as it can be achieved in non e-commerce.
1.6 Where electronic commerce (e-commerce) is used, defined procedures and adequate systems should be in place to ensure traceability and confidence in the quality of products/cosmetics. The provisions should guarantee the same degree of products/cosmetics safety as it can be achieved in non e-commerce. Note: This is relocation of Clause 1.5 of Guideline on GDP 2nd Edition, 2013	1.6 Authorized procurement and release procedures for all administrative and technical operations performed should be in place, to ensure that appropriate materials and/or products and/or notified cosmetics are sourced from approved suppliers and distributed by approved entities. The approval should come from the competent authority of the individual country where the legal entity is registered. There should be a written procedure in place to ensure and document traceability of materials and/or products and/or cosmetics the products/ and/or notified cosmetics received and distributed based on batch numbers. [While it is understood that a differentiated approach may be necessary for different materials and/or products and/or cosmetics and regions, pedigree record and/track and trace technologies provide possible options to ensure traceability.]
1.7 Inspection and certification of compliance with a quality system (such as International Organisation for Standardisation (ISO) series, or national or international guidelines) by external bodies is recommended. Such certification, however, should not be seen as a substitute for compliance with the guideline. Note: This is relocation of Clause 1.8 of Guideline on GDP 2nd Edition, 2013	1.7 [All entities in the supply chain should be traceable as applicable, depending on the type of materials and/or products and/or cosmetics, and on the national policies and legislation. There should be written procedures and records to ensure traceability of the materials and/or products and/or cosmetics distributed.]
-	1.8 Inspection and certification of compliance with a quality system (such as International Organization for Standardisation (ISO)

	series, or national or international guidelines) by external bodies is recommended. Such certification, however, should not be seen as a substitute for compliance with the guideline.
-	1.9 [To support the avoidance of penetration of counterfeit materials and/or products and/or cosmetics into the supply chain pedigree procedures and records should be developed in order to allow the tracking and tracing of material and/or product and/or cosmetic in the supply chain. Each supplier should maintain and provide such pedigree records to the next recipient in the supply chain ending with the final recipient before purchase/ use by end user which is usually the patient or consumer.]
-	1.10 [If seal control programmes for transit shipment are in place, they should be managed properly (seals are issued in a tracked and sequential manner, seals are intact and numbers verified during transit and open receipt). There should be written procedures to control of incoming materials and/or products and/or cosmetics addressing a plausibility check, whether the materials and/or products and/or cosmetics might be counterfeit.]
-	1.11 Quality system should also foster a safe, transparent and secure distribution system by establishing measures to ensure that products and/or notified cosmetics have a form of documentation that can be used to permit traceability of the products and/or notified cosmetics throughout distribution channels from the manufacturers, manufacturer's agents, wholesalers, importers, distributors and brokers to the retailer.
-	1.12 [An ISO inspection is not a substitute for any national, federal or state regulation unless specifically stated by such regulatory agencies.]

CHAPTER 2: PERSONNEL

GUIDELINE ON GDP 3rd Edition, 2018	GUIDELINE ON GDP 2nd EDITION, 2013
PRINCIPLE There must be sufficient competent personnel to carry out all the assigned tasks. Individual responsibilities should be clearly understood by the personnel and be recorded.	-
2.1 The company must have an organisation chart. Personnel in responsible positions should have specific duties recorded in written job descriptions and adequate authority to carry out their responsibilities. Their duties may be delegated to designated deputies of a satisfactory qualification level. There should be no gaps or unexplained overlaps in the responsibilities of those personnel concerned with the application of GDP. Note: This is relocation of Clause 2.3 of Guideline on GDP 2nd Edition, 2013	2.1 [Key personnel who perform supervisory and/or controlling store or warehouse functions should possess the necessary competency, knowledge and experience. They should also where necessary be in possession of the required professional and technical qualifications suitable for the tasks assigned to them.]
2.2 Besides the basic training on the theory and practice of GDP, newly recruited personnel should receive training appropriate to the duties assigned to them. Continuing training should also be given, and its practical effectiveness should be periodically assessed. Training programme should be available and approved. Training records should be kept. Note: This is relocation of Clause 2.6 of Guideline on GDP 2nd Edition, 2013	2.2 [The company should have an adequate number of personnel with the necessary qualifications and/or practical experience. The responsibilities placed on any individual should not be so extensive as to present any risk to quality.]
2.3 Personnel should receive training specific to their tasks given (e.g. evaluation of goods upon receiving, evaluation of complaints about	2.3 The company must have an organisation chart. Personnel in responsible positions should have specific duties recorded in

damage during process, return to saleable stock of returned used goods, products which require stringent handling conditions such as hazardous products, radioactive materials, products presenting special risks of abuse (including narcotics and psychotropic substances), fragile products and time and temperature sensitive products (TTSP).	written job descriptions and adequate authority to carry out their responsibilities. Their duties may be delegated to designated deputies of a satisfactory qualification level. There should be no gaps or unexplained overlaps in the responsibilities of those personnel concerned with the application of GDP.
2.4 In addition, training should include aspects of product identification and avoidance of falsified products/cosmetics entering the supply chain.	2.4 [Personnel employed in storage facilities should be certified healthy and fit for their assigned responsibilities. They should receive medical examination upon recruitment. After the first medical examination, examinations should be carried out periodically.]
2.5 Appropriate procedures relating to personnel hygiene and for appropriate clothing of personnel, relevant to the activities being carried out, should be established and observed. Personnel should be trained accordingly. Clothing should be adequate for the activities to be performed.	2.5 [Personnel employed in storage facilities should wear suitable protective or working garments, if necessary.]
-	2.6 Besides the basic training on the theory and practice of GDP, newly recruited personnel should receive training appropriate to the duties assigned to them. Continuing training should also be given, and its practical effectiveness should be periodically assessed. Training programme should be available and approved. Training records should be kept.
-	2.7 [Visitors or untrained personnel should, preferably, not to be taken into storage areas.]

CHAPTER 3: PREMISES AND EQUIPMENT

GUIDELINE ON GDP 3rd Edition, 2018	GUIDELINE ON GDP 2nd EDITION, 2013
CHAPTER 3: PREMISES AND EQUIPMENT	CHAPTER 3: PREMISES AND [FACILITIES]
PRINCIPLE Premise and equipment must be suitable and adequate as to ensure proper loading, unloading and storage, protection from contamination and distribution of products/cosmetics. In particular, the premises should be clean, dry and maintained within acceptable temperature limits.	[There should be defined and reserved areas or other control systems for the following activities: • Receipt, identification, storage and withholding from use of materials and/or products and/or cosmetics pending release; • Sampling of incoming materials, if necessary; • Holding rejected materials and/or products and/or cosmetics before disposal; • Storage of released materials and/or products and/or cosmetics; Packaging and labelling operations; • Quarantine storage before release of materials and/or products and/or cosmetics]
3.1 Premises should protect products/cosmetics from contamination and deterioration by light, moisture and temperature.	3.1 [Storage of materials and/or products and/or cosmetics should be carried out in buildings or parts of buildings that have been built for, or adapted to this purpose.]
3.2 Premises should have sufficient security to prevent unauthorised access and misappropriation of the goods. Visitors should be accompanied. Note: This is relocation of Clause 3.5 of Guideline on GDP 2nd Edition, 2013	3.2 [Buildings should protect materials and/or products and/or cosmetics from contamination and deterioration, including protection from excessive heat or undue exposure to direct sunlight. Adequate precautions should be taken against spillage or breakage.]
3.3 Premise must have a permanent address and be located at a site approved by the local authorities and/or other related Acts or	3.3 [The grounds should be established and maintained so as to minimize ingress into buildings of dust, soil or other contaminants

Regulations which must be adhered to by the licensee. Note: This is relocation of Clause 3.6 of Guideline on GDP 2nd Edition, 2013	and should be maintained in an orderly manner.]
3.4 Where premises are not directly operated by the company, a written contract should be in place. The contracted premises should have a separate authorisation of distribution.	3.4 [The foundation should be secure as possible against ground water and high enough to remain dry even under extreme rainfall and flood conditions.]
3.5 The receiving and dispatched areas should be appropriately designed. They should protect products/cosmetics from weather. The receiving areas should be designed and equipped to allow cleaning of the containers of incoming products/cosmetics, if necessary, before storage.	3.5 Buildings should have sufficient security to prevent unauthorised access and misappropriation of the goods.
3.6 There should be adequate storage areas to allow orderly and segregated storage of various categories of products/cosmetics: those in quarantine and released, rejected, returned or recalled. . These designated storage areas should be clearly marked and the access to the quarantine, rejected, returned or recalled area should be restricted to authorise personnel. Any system (e.g. Computerized and bar coding system) replacing the physical separation should be given equivalent assurance segregation and restriction in accessibility.	3.6 Premises must have a permanent address and be located at a site approved by the local authorities and/or other related Acts or Regulations which must be adhered to by the licensee.
3.7 The requirements under the regulations governing the storage of scheduled poisons, dangerous drugs and psychotropic substances must be taken into consideration. Note: This is relocation of Clause 3.9 of Guideline on GDP 2nd Edition, 2013	3.7 [Premises should be constructed, serviced and maintained regularly to protect stored materials and/or products and/or cosmetics, from all potentially harmful influences such as undue variations of temperature and humidity.]
3.8 Rest, wash and refreshment rooms for employee should be adequately	3.8 Storage facilities should be clean and free from accumulated waste

separated from the storage area. The presence of food, drink, smoking materials should be prohibited in the storage areas.	and vermin. A written sanitation programme should be available indicating the frequency of cleaning and the methods used to clean the premises and storage areas. There should also be a written programme for pest control. The pest control agents used should be safe, and there should be no risk of contamination of the materials and/or products and/or cosmetics. There should be appropriate procedures for cleanup of any spillage to ensure complete removal of any risk of contamination.
3.9 Products/cosmetics should be stored separately from non-medicinal products (medical devices, etc.).	3.9 [The storage facilities should be sufficiently large, and if necessary, have physically segregated zones for the orderly segregation of materials and/or products and/or cosmetics.] The requirements under the regulations governing the storage of scheduled poisons, dangerous drugs and psychotropic substances must be taken into consideration.
3.10 The premises should be designed or adapted to ensure that the required storage conditions are maintained. They should be suitably secure and of sufficient capacity to allow safe storage and handling of products/cosmetics. Storage areas should be provided with adequate lighting and ventilation to enable all operations to be carried out accurately and safely.	3.10 Appropriate and suitable storage conditions should be provided for hazardous, sensitive and dangerous products such as combustible liquids and solids, pressurized gases, highly toxic substances and radioactive materials / products subject to local legislations and appropriate security and safety measures.
3.11 Storage facilities should be clean and free from accumulated waste and dust. A written sanitation programme should be available indicating the frequency of cleaning and the methods used to clean the premises and storage areas. Cleaning record should be maintained. There should be appropriate procedures for the cleaning up if any spillage to ensure complete removal of any risk of contamination.	3.11 [Storage facilities should have sufficient lighting to allow store and warehouse operations to be carried out accurately and safely.]

3.12 Products/cosmetics should be stored off the floor and suitably spaced to permit cleaning and inspection. Pallet should be well maintained and kept in a good state of cleanliness.	3.12 [Materials and/or products and/or cosmetics requiring special storage conditions should be placed in separate areas constructed and equipped to provide the desired conditions.]
3.13 The storage area should be designed and equipped to prevent the entry of insects, rodents and other pests/animals. There should also be a written programme for pest control and appropriate record should be kept.	3.13 [Where controlled environmental storage conditions are required, these conditions should be continuously monitored and the appropriate action should be taken where necessary. Materials and/or products and/or cosmetics requiring dry or humidity controlled storage should be stored in areas where the relative humidity and temperature are maintained within prescribed limits by the use of proper equipment.]
3.14 Appropriate and suitable storage conditions should be provided for hazardous, sensitive and dangerous products such as combustible liquids and solids, pressurised gases, highly toxic substances and radioactive materials/products subject to local legislations and appropriate security and safety measures. Note: This is relocation of Clause 3.10 of Guideline on GDP 2nd Edition, 2013	3.14 [Bagged and boxed materials should be stored off the floor and suitably spaced to permit cleaning and inspection.]
3.15 Printed packaging materials are considered a critical conformity of the medicinal product and special attention should be paid to the safe and secure storage of these materials. Note: This is relocation of Clause 3.19 of Guideline on GDP 2nd Edition, 2013	3.15 [Materials and/or products and/or cosmetics should be stored in conditions which assure their quality, and appropriately rotated so that the oldest stock is used first. The First In/ First Out (FIFO) or First Expired/ First Out (FEFO) principle should be followed.]
3.16 Storage conditions for products/cosmetics should be in compliance with the instruction on the label. The storage area should be equipped with recorders or devices that will continuously monitor the storage conditions and record the relevant readings such as maximum and	3.16 [Rejected materials and/or products and/or cosmetics should be identified and controlled under a quarantine system designed to prevent their unintended use and distribution.]

minimum temperature and humidity of the day. Appropriate actions on the premises, equipment and/or products/cosmetics should be taken when the storage conditions are not met and these actions taken should be recorded.	
3.17 The records and devices for monitoring the storage conditions should be located in areas that are most likely to show fluctuations and/or the hottest and coldest locations where appropriate. This measuring equipment should be calibrated for the required operating range at defined intervals. Such calibrations records should be maintained.	3.17 [Materials and/or products and/or cosmetics should be re-evaluated as necessary to determine their compliance with specifications and suitability for use e.g after prolonged storage or exposure to temperature (heat) or humidity.]
3.18 An initial temperature mapping exercise should be carried out on the storage area before use, under representative conditions. Temperature monitoring equipment should be located according to the results of the mapping exercise, ensuring that monitoring devices are positioned in the areas that experience the extremes of fluctuations. The mapping exercise should be repeated for significant changes according to the results of a risk assessment exercise. Relevant document and records should be retained. Where current regulations state a period for retention of records, this should be followed.	3.18 [Precautions must be taken to prevent unauthorized persons entering controlled storage facilities.]
EQUIPMENT	-
3.19 All equipment impacting on storage and distribution of products/cosmetics should be designed, located, maintained and cleaned to a standard which suits its intended purpose. Planned maintenance should be in place for key equipment vital to the functionality of the operation.	3.19 Printed packaging materials are considered a critical conformity of the medicinal product and special attention should be paid to the safe and secure storage of these materials.
3.20 Adequate procedures and records of operations, repair, maintenance	3.20 [Receiving and dispatch bays should protect materials and/or

and calibration activities for key equipment should be in place including cleaning and safety precautions. Key equipment would include for example cold rooms/stores, monitored intruder alarm and access control system, refrigerators, thermohygrometers or other temperature and humidity recording devices, air handling units and any equipment used in conjunction with the onward supply chain.	products and/or cosmetics from the weather. Reception areas should be designed and equipped to allow containers of incoming materials to be cleaned where]
3.21 Equipment used to distribute or transport products/cosmetics should be suitable for their use and appropriately equipped to prevent exposure of the products/cosmetics to conditions that could affect their stability and packaging integrity, and prevent contamination of any kind.	3.21 [Records of temperature of the storage facilities must be measured at suitable predetermined intervals to show the maximum and minimum temperatures for the day. Where necessary humidity measurements should be performed.]
3.22 Where non-dedicated equipment is used, procedures must be in place to ensure that the quality of the products/cosmetics will not be compromised. Note: This is relocation of Clause 7.4 of Guideline on GDP 2nd Edition, 2013	3.22 [The instruments used for measuring and monitoring temperature and humidity should be calibrated and calibration record or calibration certificate should be recorded and retained.]
3.23 Equipment used for monitoring conditions within vehicles and containers, e.g. temperature and humidity, should be calibrated, at regular intervals. Note: This is relocation of Clause 7.10 of Guideline on GDP 2nd Edition, 2013	3.23 [Materials and/or products and/or cosmetics requiring dry or humidity controlled storage should be stored in areas where the relative humidity and temperature is maintain within prescribed limits.]
3.24 For time and temperature sensitive products (TTSP), qualified equipment (e.g. thermal packaging, temperature-controlled containers or temperature controlled vehicles) should be used to ensure correct transport conditions are maintained between the manufacturer, wholesale distributor and end user. The scope and	3.24 [It is recommended that temperature monitors be located in areas that are most likely to show fluctuations.]

	extent of such qualification and/or validation should be determined using a documented risk assessment approach. Validation and qualifications reports should be prepared summarising the results obtained and commenting on any observed deviations. Deviations should be documented and further actions decided to correct deviations and avoid their occurrence. Evidence of satisfactory validation and acceptance of a process or a piece of equipment should be produced and approved by appropriate personnel.	
3.25	Before a computerised system is brought into use, it should be demonstrated through appropriate validation or verification studies, that the system is capable of achieving the desired results accurately, consistently and reproducibly. A written, detailed descriptions of the system should be available (including diagram where appropriate). This should be kept up to date. The documents should describe principles, objectives, security measures, system scope, main features, how the computerised system is used and the ways it interacts with other system.	-
3.26	Data should only be entered into the computerised system or amended by persons authorised to do so. Data should be secured by physical or electronic means and protected against accidental or unauthorised modifications. Stored data should be checked periodically for accessibility. Data should be protected by backing up at regular intervals.	-
3.27	Procedures to be followed if the system fails or breaks down should be defined. This should include systems for the restoration of data.	-
	-	**[UNIFORM LABELLING RECOMMENDATION]**

	[Depending on the results of stability studies, some special label statements are recommended: • Store in well-closed container • Store in an airtight container • Store protected from light • Store protected from light and humidity • Store protected from heat • Store protected from freezing or do not freeze • Short-time storage at a temperature of X°C to Y°C If other labelling statements are made appropriate storage conditions should be provided and justified by supportive stability data. In certain cases a storage time at a higher temperature can be accepted provided it is justified and supported by suitable data generated under the proposed conditions. Special storage directions (e.g shipping and transportation) need to be requested from the manufacturer or supplier. In general, storage instructions should be labelled as follows: a. Related to container, e.g. store in a well-closed container b. Related to light and/or temperature, e.g. store protected from light c. Related to temperature, e.g. store at a temperature not exceeding X°C **The storage conditions for materials and/or products and/or cosmetics should follow the required storage specification of the materials and/or products and/or cosmetics.** **Where temperature is not stated (in terms of range) on the labels of the materials and/or products and/or cosmetics the following definitions should be followed:-**

	ON THE LABEL **MEANS** Freezer The temperature is thermostatically controlled between -20°C to -10°C Refrigerator The temperature is thermostatically controlled between 2°C to 8°C Cold place The temperature does not exceed 8°C Cool place The temperature is between 8°C and 15°C Room temperature The temperature is between 15°C and 30°C Warm The temperature is between 30°C and 40°C Excessive heat The temperature is above 40°C Do not store over 30°C The temperature is between 2°C and 30°C Do not store over 25°C The temperature is between 2°C and 25°C Do not store over 15°C The temperature is between 2°C and 15°C Do not store over 8°C The temperature is between 2°C and 8°C Do not store below 8°C The temperature is between 8°C and 25°C **Where storage conditions stated on the label means the following:-** **ON THE LABEL MEANS** Dry place No more than 75±5% relative humidity in

		normal storage conditions; to be provided to the user in a moisture-resistant container
	Protect from light	To be provided to the user in a light resistant container]

CHAPTER 4: STOCK HANDLING AND STOCK CONTROL

GUIDELINE ON GDP 3rd Edition, 2018	GUIDELINE ON GDP 2nd EDITION, 2013
PRINCIPLE All actions taken should ensure that the identity of the products/cosmetics is not lost and the distribution of products/cosmetics is performed according to the information on the outer packaging. The risk of falsified products/cosmetics entering the legal supply chain should be eliminated/minimised. All supplies of products/cosmetics must only be purchased from approved suppliers or companies that are authorised by the authorities. Where products/cosmetics are obtained from another wholesaler, the receiving wholesaler must verify that the supplier complies with the principles and guidelines of good distribution practices and that they hold a valid license issued by the authority. All products/cosmetics purchased from suppliers and distributed in the intended market by company must be appropriately authorised by the authority. All key operations should be fully described in the quality system in appropriate documentation.	-
RECEIVING	**4.1 RECEIVING [MATERIALS/ PRODUCTS/ COSMETICS]**
4.1 Upon receipt, each incoming delivery should be checked against the relevant documentation and physically verified by label description, type and quantity, against the relevant purchase order information including certificate of analysis and originated from approved suppliers. The consignment should be examined for uniformity and if necessary should be subdivided according to the supplier's lot numbers should the delivery comprise of more than one batch. Note: This is relocation of Clause 4.1.1 of Guideline on GDP 2nd Edition,	4.1.1 Upon receipt, each incoming delivery should be checked against the relevant documentation and physically verified by label description, type and quantity, against the relevant purchase order information. The consignment should be examined for uniformity and if necessary should be subdivided according to the supplier's lot numbers should the delivery comprise of more than one batch.

2013	
4.2 All containers should be carefully inspected for tampering, contamination and damage and if necessary the suspected container or the entire delivery should be quarantined or set aside for further investigation. Records should be retained for each delivery. Note: This is relocation of Clause 4.1.2 of Guideline on GDP 2nd Edition, 2013	4.1.2 All containers should be carefully inspected for tampering, contamination and damage and if necessary the suspected container or the entire delivery should be quarantined or set aside for further investigation. Records should be retained for each delivery.
4.3 Delivery order should include the description of the goods, quality (if applicable), quantity, supplier details, supplier's batch number, the date of receipt and assigned batch number. Where current regulations state a period for retention of records, this should be followed. Note: This is relocation of Clause 4.1.3 of Guideline on GDP 2nd Edition, 2013	4.1.3 [They] should include the description of the goods, quality (if applicable), quantity, supplier details, supplier's batch number, the date of receipt and assigned batch number. Where current regulations state a period for retention of records, this should be followed.
4.4 Products/cosmetics should remain in quarantine status until a given written release/rejected statement is issued by authorised personnel. Note: This is relocation of Clause 4.1.6 of Guideline on GDP 2nd Edition, 2013	4.1.4 [Security measures should be taken to ensure that rejected materials and/or products and/or cosmetics cannot be used and they should be stored separately from other products while awaiting destruction or return to the supplier. The method adopted should possess adequate safeguards to prevent uncontrolled or unsatisfactory materials from being used or released. Relevant records should be maintained.]
4.5 Products subject to specific storage requirements (e.g. narcotics, time and temperature sensitive products (TTSP) should be immediately identified and stored in accordance with the written procedure.	4.1.5 [Quarantine status can be achieved either through the use of separate storage areas or by means of documentary or electronic data processing systems.]
-	4.1.6 Materials and/or Products and/or cosmetics should remain in quarantine status until a given written release or is rejected

	by authorized personnel.
STOCK ROTATION AND CONTROL	**4.2 STOCK ROTATION AND CONTROL**
-	[Comprehensive records should be maintained showing all receipts and issues of materials and/or products and/or cosmetics according to batch number.]
4.6 Periodic stock reconciliation should be performed comparing the actual and recorded products/cosmetics quantity. All significant stock discrepancies should be subjected to investigation to check against inadvertent mix-ups and wrong issues of stock. Note: This is relocation of Clause 4.2.1 of Guideline on GDP 2nd Edition, 2013	4.2.1 Periodic stock reconciliation should be performed comparing the actual and recorded materials and/or products and/or cosmeticsquantity. All significant stock discrepancies should be subjected to investigation to check against inadvertent mix-ups and wrong issues of stock.
4.7 Issues should normally observe the principle of stock rotation (FIFO/FEFO) especially where expiry dated products/cosmetics are concerned. Note: This is relocation of Clause 4.2.2 of Guideline on GDP 2nd Edition, 2013	4.2.2 Issues should normally observe the principle of stock rotation [(first-in-first-out or first expiry first out)] especially where expiry dated materials and/or products and/or notified cosmetics are concerned.
4.8 Products/cosmetics with broken seals, damaged packaging or suspected of possible contamination must not be sold or supplied. Note: This is relocation of Clause 4.2.3 of Guideline on GDP 2nd Edition, 2013	4.2.3 Materials and/or Products and/or cosmetics with broken seals, damaged packaging or suspected of possible contamination must not be sold or supplied.
4.9 All stocks should be checked regularly for expired products/cosmetics. All due precautions should be observed to preclude issue of expired products/cosmetics. Note: This is relocation of Clause 4.3.1 of Guideline on GDP 2nd Edition,	4.2.4 [Goods bearing an expiry date must not be received or supplied after their expiry date or too close to their expiry date that this date is likely to occur before the goods are used by the consumer.]

2013	
4.10 All labels and containers of products/cosmetics should not be altered, tampered or changed. Acts and regulations relating to labels and containers should be adhered to at all times. Note: This is relocation of Clause 4.2.5 of Guideline on GDP 2nd Edition, 2013	4.2.5 All labels and containers of materials and/or products and/or cosmetics should not be altered, tampered or changed. Acts and regulations relating to labels and containers should be adhered to at all times.
4.11 Products/cosmetics in cartons/bulk packs should be adequately labelled with at least the product name, batch number and expiry date or retest date.	4.2.6 [Partly used containers of materials and/or products and/or cosmetics should be securely re-closed to prevent spoilage and/or contamination during subsequent storage. Damaged containers should not be issued but should be brought to the attention of the authorized personnel.]
4.12 Repacking (including relabeling) of products/cosmetics must be carried out only by company who hold an appropriate license or approval from authority, unless the activities are exempted from these requirements.	4.2.7 [Materials and/or products and/or cosmetics should be protected from excessive climatic conditions during storage and transit, such as heat, moisture and direct sunlight. They should be stored separately from other materials and/or products and/or cosmetics in conditions which satisfy the requirements for the materials and/or products and/or cosmetics, so that the shelf life declaration may be maintained.]
RETURNED AND REJECTED	**4.3 [CONTROL OF EXPIRED STOCK]**
4.13 All returned and rejected products/cosmetics should be placed in quarantine and be clearly marked as such. They should be stored separately in restricted area. Note: This is relocation of Clause 4.4.1 of Guideline on GDP 2nd Edition, 2013	4.3.1 All stocks should be checked regularly for expired products/ cosmetics. All due precautions should be observed to preclude issue of expired products.

4.14	Returned products/cosmetics must be handled according to a written, risk based process taking into account the product concerned, any specific storage requirements and the time elapsed since the product/cosmetic was originally dispatched. Returns should be conducted in accordance with national legislation, and contractual arrangements between the parties. A record/list of returned goods must be maintained.	-
4.15	The fate of returned and rejected products/cosmetics should be determined after sufficient evaluation by trained and competent person authorised to do so. Note: This is relocation of Clause 4.4.2 of Guideline on GDP 2nd Edition, 2013	-
4.16	Provision should be made for the appropriate and safe transport and storage of returned or rejected products/cosmetics in accordance with the relevant storage and other requirements. Note: This is relocation of Clause 4.4.3 of Guideline on GDP 2nd Edition, 2013	-
4.17	Products/cosmetics returned to saleable stock should be placed such that the stock rotation system operates effectively.	-
4.18	Stolen products/cosmetics that have been recovered cannot be returned to saleable stock and sold to end user.	-
4.19	All action taken should be approved and recorded. Note: This is clause 4.4.4 of Guideline on GDP 2nd Edition, 2013	-
4.20	Any counterfeit products/cosmetics found in the distribution network should be physically segregated from other products/cosmetics to avoid	-

any confusion. They should be clearly labelled as 'Not for sale' or with other similar phrases/words. The regulatory authority and the holder of the marketing authorisation of the original product should be informed immediately.	
4.21 Records of returned products/cosmetics should be maintained. For each return, documentation should include: a. Name and address of the consignee returning the products/cosmetics. b. Name or designation of products/cosmetics, batch number and quantity returned c. Reasons for return d. Use or disposal of the returned products/cosmetics and record of the assessment performed.	-
-	**4.4 RETURNED AND REJECTED PRODUCTS**
-	4.4.1 All returned and rejected products should be placed in quarantine and be clearly marked as such. They should be stored separately in restricted area.
-	4.4.2 The fate of returned and rejected products/ cosmetics should be determined after sufficient evaluation by trained and competent person authorized to do so
-	4.4.3 Provision should be made for the appropriate and safe transport and storage of returned or rejected products/ cosmetics in accordance with the relevant storage and other requirements.
-	4.4.4 All action taken should be approved and recorded.
DISTRIBUTION	**4.5 DISTRIBUTION**
4.22 Controls should be in place to ensure the correct product/cosmetic is	4.5.1 The allocation of shipping materials should be carried out only

picked. The product should have an appropriate remaining shelf life when it is picked.	after receipt of a sales order. Rules for distribution procedures should be established depending on the nature of the products, and after taking into account any special precautions to be observed.
4.23 The allocation of shipping materials should be carried out only after receipt of a sales order. Rules for distribution procedures should be established depending on the nature of the products, and after taking into account any special precautions to be observed. Note: This is relocation of Clause 4.5.1 of Guideline on GDP 2nd Edition, 2013	4.5.2 [The shipping container should offer adequate protection from all external influences and should be indelibly and clearly labelled. When necessary, devices which allow monitoring during transportation should be used.]
4.24 Import and export activities should be conducted in accordance with national legislation and with international guidelines or standards when appropriate. This is also the case if the wholesalers or importers are holding products in a free zone. Wholesalers should take the appropriate measures in order to prevent products not authorised for the internal market and intended for export from reaching the internal market.	4.5.3 [In the event of materials and/or products and/or cosmetics shipment, special care should be used when using dry ice in containers. In addition to safety issues, it must be ensured that the materials and/or products and/or cosmetics do not come into contact with the dry ice, as it may have adverse effects on the quality of the materials and/or products and/or cosmetics.]
4.25 Deliveries should be made only to wholesale dealers or persons who are authorised to supply the products/cosmetics.	4.5.4 [Distribution documents should comply to national relevant national regulations, and at least includes: a. Date of distribution b. Customer's name and address c. Product and/or cosmetic description, e.g. name, dosage form and strength (if appropriate), batch number and quantity.]
4.26 A written procedure on the delivery of the products/cosmetics to end users should be available.	-

4.27 A system should be in place by which the distribution of each batch of products/cosmetics can be readily identified to permit its recall.	-
4.28 For all suppliers, a document (e.g. Deliver order) must be enclosed stating the date, name of products/cosmetics, batch number, quantity supplied, name and address of supplier, name and delivery address of the consignee (actual physical storage premise, if different) and applicable transport and storage conditions. Records should be kept so that the actual location of products/cosmetics can be known.	-
DISPOSAL	-
4.29 Products/cosmetics intended for destruction should be appropriately identified, segregated accordingly and handled in accordance with written procedure.	-
4.30 Destruction of products/cosmetics should be carried out in accordance with the national legislative and regulatory requirements and with due consideration to protect the environment.	-
4.31 Disposal records should be maintained for a defined period. Note: This is relocation of Clause 5.2 of Guideline on GDP 2nd Edition, 2013	-

CHAPTER 5: TRANSPORTATION

GUIDELINE ON GDP 3rd Edition, 2018	GUIDELINE ON GDP 2nd EDITION, 2013
CHAPTER 5: TRANSPORTATION	**[CHAPTER 5: DISPOSAL OF PRODUCTS/ MATERIALS/ COSMETICS]**
PRINCIPLE It is the responsibility of all manufacturers, importers and wholesalers of products/cosmetics to protect their products against breakage, adulteration, theft and to ensure that temperature conditions are maintained within acceptable limits during transport. Regardless of the mode of transport, it should be possible to demonstrate that the products/cosmetics have not been exposed to conditions that may compromise their quality and integrity. A risk-based approach should be utilised when planning transportation.	-
5.1 Vehicles used to distribute or transport products/cosmetics should be suitable for their use and appropriately equipped to prevent exposure of the products/cosmetics to conditions that could affect their stability and packaging integrity, and prevent contamination of any kind. Note: This is relocation of Clause 7.1 of Guideline on GDP 2nd Edition, 2013	5.1 [Disposal of materials and/or products and/or cosmetics should be carried out, according to proper destruction procedures, approved by appropriate authorities such as States Enforcement Offices, National Pharmaceutical Control Bureau, the Ministry of Natural Resources and Environment and local authorities.]
5.2 Dedicated vehicles should be used, where possible, when handling products/cosmetics. Where non-dedicated vehicles are used, procedures must be in place to ensure that the quality of the products/cosmetics will not be compromised. Appropriate cleaning should be performed, checked and recorded.	5.2 Disposal records should be maintained.

Note: This is relocation of Clause 7.3 and 7.4 of Guideline on GDP 2nd Edition, 2013	
5.3 There should be procedures in place for the operation and maintenance of all vehicles involved in the distribution process, including cleaning and safety precautions. There should also be written programme for pest control. Cleaning and fumigation agents should not have an adverse effect on products and/ cosmetics quality. Note: This is relocation of combination of Clause 7.5 and 7.7 of Guideline on GDP 2nd Edition, 2013	-
5.4 Risk assessment of delivery routes should be used to determine where temperature controls are required. Equipment used for monitoring conditions within vehicles and containers, e.g. temperature and humidity, should be calibrated, at regular intervals.	-
5.5 Vehicles and containers should be of sufficient capacity to allow orderly storage of the various categories of products/cosmetics during transportation. Note: This is relocation of Clause 7.11 of Guideline on GDP 2nd Edition, 2013	-
5.6 Measures should be in place to prevent unauthorized persons from entering and/or tampering with vehicles, as well as to prevent the theft or misappropriation thereof. Note: This is relocation of Clause 7.13 of Guideline on GDP 2nd Edition, 2013	-
5.7 Products/cosmetics should be secured in such a manner to prevent or provide evidence of unauthorized access. Shipments should be secured	-

and include the appropriate documentation to ensure that identification and verification of compliance with regulatory requirements is facilitated at ocean ports, truck borders, airports, custom warehouses and third party logistic providers. Note: This is relocation of Clause 8.1 of Guideline on GDP 2nd Edition, 2013	
5.8 Products/cosmetics should be stored and transported in accordance with procedures in such a way that: the identity of the products/cosmetics is not lost; the products/cosmetics does not contaminate and is not contaminated by other products/cosmetics; adequate precautions are taken against spillage, breakage, misappropriation and theft; and temperature and relative humidity conditions are maintained accordingly. Note: This is relocation of Clause 8.2 of Guideline on GDP 2nd Edition, 2013	-
5.9 Measures should be established to ensure that products/cosmetics have a form of documentation that can be used to permit traceability of the products /cosmetics throughout the distribution activity. Note: This is relocation of Clause 8.3 of Guideline on GDP 2nd Edition, 2013	-
5.10 Written procedures should be in place for investigating and dealing with any excursions of storage requirements, e.g. temperature excursions. Note: This is relocation of Clause 8.5 of Guideline on GDP 2nd Edition, 2013	-
5.11 Transportation and storage of products/cosmetics comprising highly active and radioactive materials, other dangerous drugs and substances presenting special risks of abuse, fire or explosion (e.g. combustible liquids, solids and pressurized gases) should be stored	-

	in safe, dedicated and secure areas and transported in safe, dedicated and secure containers and vehicles. In addition, applicable international agreements and national legislation should be complied with. Note: This is relocation of Clause 8.6 of Guideline on GDP 2nd Edition, 2013	
5.12	Packaging materials and transportation containers should be of suitable design to prevent damage of products/ cosmetics during transport. If there are seal control programs, such programs should be in place and managed properly (e.g. seals are issued and tracked in a sequential manner, seals are intact and numbers verified during transit and upon receipt). Note: This is relocation of Clause 8.11 of Guideline on GDP 2nd Edition, 2013	-
5.13	Containers should bear labels providing sufficient information on handling and storage requirements and precautions to ensure that the products/cosmetics are properly handled and secured at all times. The containers should enable identification of the contents of the containers and the source.	-
5.14	Damage to containers and any other event or problem that occurs during transit must be recorded and reported to the relevant department, entity or authority and investigated. Note: This is relocation of Clause 8.13 of Guideline on GDP 2nd Edition, 2013	-
5.15	Where possible, mechanisms should be available to allow for the segregation during transit of rejected, recalled and returned products/ cosmetics as well as those suspected to be counterfeits. Where feasible, such goods must be securely packaged, clearly labelled,	-

	and be accompanied by appropriate supporting documentation. Note: This is relocation of Clause 7.12 of Guideline on GDP 2nd Edition, 2013	
5.16	Where transportation is performed by a third party, the contract should in place covering the requirements of Chapter 10. Transportation providers should be made aware by manufacturers, manufacturer's agents, wholesalers, importers, distributors and brokers of the relevant transport conditions applicable to the consignment. Where the transportation route includes unloading and reloading or transit storage at a transportation hub, particular attention should be paid to temperature monitoring, cleanliness and the security of any intermediate storage facilities.	-
5.17	Company is responsible to ensure the competency of the transportation provider elected. Besides that, it is the responsibility of the company to ensure that the elected transportation provider reports the incident or deviation, if any, which occurred during the transportation or distribution process.	-

CHAPTER 6: PRODUCTS/COSMETICS COMPLAINTS

GUIDELINE ON GDP 3rd Edition, 2018	GUIDELINE ON GDP 2nd EDITION, 2013
CHAPTER 6: PRODUCTS/COSMETICS COMPLAINTS	**[CHAPTER 6: DOCUMENTATION]**
PRINCIPLE All complaints must be recorded and handled carefully according to written procedures. Records should be made available to competent authorities. An assessment of returned products/cosmetics should be performed by designated personnel before any approval for resale.	[Documentation should be made available at all times.]
6.1 Complaints should be recorded with all the original details. A distinction should be made between complaints related to the quality of the products/cosmetics and those related to distribution. In the event of a complaint about the quality of the products/cosmetics and a potential product/cosmetic defect, the manufacturer and/or product registration holder of the product/cosmetic should be informed without delay. Any products/cosmetics distribution complaint should be thoroughly investigated to identify the origin of or the reason for the complaint.	**6.1 [WRITTEN INSTRUCTIONS** Written instructions should describe the different operations which may affect the quality of the materials and/or products and/or cosmetics or of the distribution activity: • Receipt and checking of deliveries, • Storage, cleaning and maintenance of the premises (including pest control), • Recording of the storage conditions, • Security of stocks on site and of consignments in transit, • Withdrawal from saleable stock • Records, including records of clients' orders, • Returned materials and/or products and/or cosmetics, recall plans, etc These procedures should be approved, signed and dated by the authorized person.] Records should be made at the time each operation is taken and in such a way that all significant activities or events are traceable.

	Records should be clear and readily available. The retention of documentation relating to the distribution of materials and/or products and/or cosmetics should comply with the national requirements. 6.1.1 If records are computerized, only authorized persons should be able to enter or modify data in the computer. Access should be restricted by passwords or other means. Users should have a unique identifier (User ID) for their personal and sole use so that activities can subsequently be traced to the responsible individual. 6.1.2 Records electronically stored should be protected by back-up transfer on paper or other means, at regular intervals. It is particularly important that the data, including audit trail, are readily available throughout the period of retention. Back-up data should be stored as long as necessary at a separate and secure location.
6.2 Procedures shall be developed within the company for the handling of all written and oral complaints regarding a possible product/cosmetic defect. There should also be a record for each individual product/cosmetic complaint.	6.2 **[INVENTORY SYSTEM]** (Applicable for all registered products and/or notified cosmetics) These should include (e.g see Appendix 1):- • Stock Card Serial No. • Name of Materials or Products or Cosmetics • Strength and Packing size of materials and products and cosmetics • DCA Registration No. / Notification No./ Product Identification Number • Date of Transaction • Invoice No./ Delivery No.

	• Quantity Received • Quantity Supplied • Batch No. (where applicable) • Stock Balance • Initial/ Signature Entries of incoming goods should be clearly identified and a separate stock card is required for each material and/or product and/or cosmetic as well as each strength of the same material and/or product and/or cosmetic.]
6.3 The procedure shall ensure that the complaints received are investigated and followed through and that all corrective actions are taken to prevent repeated complaints. The investigation should also cover distribution condition and the condition under which the product/ cosmetic is used. The complainant shall be provided with a response after the completion of the investigation.	6.3 **[LABELLING OF CONTAINERS/ PACKAGING MATERIALS** 6.3.1 All containers or packaging materials should be clearly and indelibly labeled with at least the name and/or of the material and/or product and/or cosmetic, and the lot number of the batch. 6.3.2 Written information should exist for each stored material and/or product and/or cosmetic indicating recommended storage conditions, along with any precautions to be observed and retest dates. Pharmacopoeial requirements and other current national regulations concerning labels and containers should be respected at all times.] 6.3.3 For manufacturers/importers, each hologram label should be recorded according to its usage in a logbook. Any hologram labeling activity that is done by a third party, delivery/ distribution record of the hologram should be recorded in a logbook for traceability purpose.
6.4 A person should be designated/appointed to handle complaints. This person must have the authority to initiate investigations and to decide	-

on the measures to be taken. The contact details of the designated/appointed person should be included in the procedure.	
6.5 If a product/cosmetic defect is discovered or suspected in a batch, consideration should be given to determine whether other batches are also affected. Note: This is relocation of Clause 9.6.3 of Guideline on GDP 2nd Edition, 2013	-

CHAPTER 7: PRODUCTS/COSMETICS RECALL

GUIDELINE ON GDP 3rd Edition, 2018	GUIDELINE ON GDP 2nd EDITION, 2013
CHAPTER 7: PRODUCTS/COSMETICS RECALL	**[CHAPTER 7: VEHICLES AND EQUIPMENT]**
PRINCIPLE The Control of Drugs and Cosmetics Regulations 1984, requires every licensed manufacturer, importer and wholesaler to have a procedure (Product Recall Procedure), which sets out in a step-wise manner the various actions to be taken to ensure the prompt recall of defective products/cosmetics. Such procedures should be reviewed regularly and updated.	-
DEFINITION Product recall is a process taken by the manufacturer, importer and wholesaler to remove or withdraw a particular materials/ products/ cosmetics from all links of distribution. The removal or withdrawal may be due to critical quality defects discovered or serious adverse drug reactions reported which might cause health risks to users of the products/cosmetics. Note: This is relocation of Clause 10.2 of Guideline on GDP 2nd Edition, 2013	7.1 Vehicles and equipment used to distribute or transport products and/or cosmetics should be suitable for their use and appropriately equipped to prevent exposure of the products and/or notified cosmetics to conditions that could affect their stability and packaging integrity, and prevent contamination of any kind.
DECISION FOR RECALL The decision for recall shall be made when there is or may caused potential risk to the user of the products/cosmetics by reason of faulty production or on medical grounds: • Voluntarily undertaken by the manufacturers and distributors.	7.2 [Vehicles and equipments must aim to minimize the risk of errors and permit effective cleaning and/or maintenance, to avoid contamination, accumulation of dust or dirt and/or any adverse effect on the quality of materials and/or products and/or cosmetics being distributed.]

• As directed by the Director of Pharmaceutical Services, Ministry of Health. Unless the Director of Pharmaceutical Services, Ministry of Health has already specified the degree and level of a particular products/ cosmetics recall, the degree and level will be decided by the Product Recall Committee based on risks involved. The Product Recall Committee shall compromise of personnel who are responsible for the execution and coordination of recall. The persons responsible shall handle all aspects of the recalls with the appropriate degree of urgency. Note: This is relocation of combination Clause 10.3 and 10.5 of Guideline on GDP 2nd Edition, 2013	
DEGREE AND LEVEL OF RECALL The following criteria are used to classify the degree and level of recall. **DEGREE OF RECALL** The degree of recall is classified according to the severity of quality defects and adverse reactions of the products/cosmetics. Degree I – Products/Cosmetics with major health risks that might caused serious injuries or death. Should be under an embargo within 24 hours. Degree II – Products/Cosmetics with minor health risks or are substandard. Should be under an embargo within 72 hours. Degree III – Products/Cosmetics with other reasons for recall. Should be under an embargo within 30 days or as specified. **LEVEL OF RECALL** The level of recall depends on the nature of problem, extent of the	7.3 Dedicated vehicles and equipment should be used, where possible, when handling products/ cosmetics.

product/cosmetic's distribution and degree of hazard involved. Level A: To all consumers (end users) Level B: To all points of sales (e.g. Hospitals, Pharmacies, Clinics, Specialists Centres) Level C: To all sub-distributors (wholesalers)	
GENERAL	7.4 Where non-dedicated vehicles and equipment are used, procedures must be in place to ensure that the quality of the products/ cosmetics will not be compromised. Appropriate cleaning should be performed, checked and recorded.
7.1 A person or committee should be designated for the co-ordination and execution of all product recalls. The contact details of the designated person or committee should be included in the procedure.	7.5 There should be procedures in place for the operation and maintenance of all vehicles involved in the distribution process, including cleaning and safety precautions.
7.2 In the event of a product/cosmetic recall, all end users to whom the products/cosmetics have been distributed shall be informed with the appropriate degree of urgency. The notification of recall should include: • The name of the product/ cosmetic, its strength (if necessary) and pack size. • The products/cosmetics batch number, the nature of the defect. • Whether the recall should be carried out at the consumer level (end users), all points of sale or sub-distributors (wholesalers and retail) level. • The action to be taken. • The urgency of the action (with reasons, indication of health risk, as appropriate).	7.6 [Vehicles, containers and equipment should be kept clean, dry and free from accumulated waste. Organizations in charge of the distribution must ensure that vehicles are cleared up on regular basis.]

7.3 The local regulatory authority should be informed of all product/cosmetics recalls. If the products/cosmetics are exported, the overseas counterparts and/or regulatory authorities must be informed of the recall.	7.7 Vehicles, containers and equipment should be kept free from rodents, vermin, birds and other pests. There should also be written programme for pest control. Cleaning and fumigation agents should not have an adverse effect on products and/or notified cosmetics quality.
7.4 Where products/cosmetics recall affects a particular batch, consideration should also be given to determine whether other batches are also affected.	7.8 [Special attention should be given to the design, use, cleaning and maintenance of all equipment used for the handling of materials and/or products and/or cosmetics which are not in a protective shipping carton or case.]
7.5 The storage conditions applicable to products/cosmetics which are subjected to recall should be maintained during storage and transit until a decision has been made regarding the products/cosmetics. Note: This is relocation of Clause 10.9 of Guideline on GDP 2nd Edition, 2013	7.9 [Where special storage conditions (e.g. temperature and/or relative humidity), different from or limiting, the expected environmental conditions, are required during transit these should be provided, checked, monitored and recorded. All monitoring records should be kept as required by national requirements.]
7.6 The progress of recall process should be recorded for a final report including reconciliation of the recalled products/cosmetics and a final report of the executed products/cosmetics recall will be forwarded to the local regulatory authority.	7.10 Equipment used for monitoring conditions within vehicles and containers, e.g. temperature and humidity, should be calibrated, at regular intervals.
-	7.11 Vehicles and containers should be of sufficient capacity to allow orderly storage of the various categories of products/ cosmetics during transportation.
-	7.12 Where possible, mechanisms should be available to allow for the segregation during transit of rejected, recalled and returned materials and/or products and/or cosmetics as well as those suspected to be counterfeits. Where feasible, such

	goods must be securely packaged, clearly labelled, and be accompanied by appropriate supporting documentation.
-	7.13 Measures should be in place to prevent unauthorized persons from entering and/or tampering with vehicles, as well as to prevent the theft or misappropriation thereof.

CHAPTER 8: COUNTERFEIT PRODUCTS/COSMETICS

GUIDELINE ON GDP 3rd Edition, 2018	GUIDELINE ON GDP 2nd EDITION, 2013
CHAPTER 8: COUNTERFEIT PRODUCTS/COSMETICS	**[CHAPTER 8: TRANSPORTATION AND GOODS IN TRANSIT]**
PRINCIPLE Any counterfeit products/cosmetics found in the distribution network should be physically segregated from other products/cosmetics to avoid any confusion. They should be clearly labelled. All relevant activities in relation to such products/cosmetics should be documented and records retained. The sale and distribution of suspected counterfeit products/cosmetics should be suspended immediately. A consistent approach by all partners in the supply chain is required in order to be successful in the fight against falsified products/cosmetics.	-
GENERAL	-
8.1 The regulatory authority and the product registration holder of the original products/cosmetics should be informed immediately. A procedure should be in place to this effect. It should be recorded with all the original details and investigated. Note: This is relocation of Clause 12.2 of Guideline on GDP 2nd Edition, 2013	8.1 Products/cosmetics should be secured in such a manner to prevent or provide evidence of unauthorized access. Shipments should be secured and include the appropriate documentation to ensure that identification and verification of compliance with regulatory requirements is facilitated at ocean ports, truck borders, airports, custom warehouses and third party logistic providers.
8.2 Upon confirmation as counterfeit products/cosmetics, a formal decision should be taken on removal of such products/cosmetics from the market, ensuring that it does not re-enter the supply chain, including retention of any samples necessary for public health, regulatory, or legal needs and arrangements for its disposal. All related decisions should be	8.2 Products/cosmetics should be stored and transported in accordance with procedures in such a way that: the identity of the products/cosmetics is not lost; the products/cosmetics does not contaminate and is not contaminated by other products/cosmetics; adequate precautions are taken against

appropriately documented.	spillage, breakage, misappropriation and theft; and temperature and relative humidity conditions are maintained accordingly.
-	8.3 Measures should be established to ensure that products/ cosmetics have a form of documentation that can be used to permit traceability of the products/cosmetics throughout the distribution activity.
-	8.4 [Where special conditions are required during transportation that are different from or limited by the given environmental conditions (e.g. temperature, humidity) these should be provided, monitored and recorded.]
-	8.5 Written procedures should be in place for investigating and dealing with any excursions of storage requirements, e.g. temperature excursions.
-	8.6 Transportation and storage of products/ cosmetics comprising highly active and radioactive materials, other dangerous drugs and substances presenting special risks of abuse, fire or explosion (e.g. combustible liquids, solids and pressurized gases) should be stored in safe, dedicated and secure areas and transported in safe, dedicated and secure containers and vehicles. In addition, applicable international agreements and national legislation should be complied with.
-	8.7 Materials and/or products containing narcotics and other dependence-producing substances should be transported in safe and secure containers and vehicles and be stored in safe and secure areas, and where it is a mandatory requirement transported in safe and secure containers and vehicles. In addition, applicable international agreements and national legislation should be complied with.

-	8.8 [Spillages should be cleaned as soon as possible to prevent possible contamination, cross-contamination and hazards. Written procedures should be in place for the handling of such occurrences.]
-	8.9 [Physical or other equivalent (e.g. electronic) segregation should be provided for the storage and distribution during transit or rejected, expired, recalled or returned materials and/or products and/or cosmetics and suspected counterfeits. The materials and/or products and/or cosmetics should be appropriately identified, secured, packaged, clearly labelled and be accompanied by appropriate supporting documentation.]
-	8.10 Products/ cosmetics containing toxic and/or flammable substances should be stored and transported in suitably designed, separate and closed containers, taking into account national legislation and international agreements.
-	8.11 Packaging materials and transportation containers should be of suitable design to prevent damage of products/ cosmetics during transport. If there are seal control programs, such programs should be in place and managed properly (e.g. seals are issued and tracked in a sequential manner, seals are intact and numbers verified during transit and upon receipt).
-	8.12 [Third party drivers should be segregated from the warehouse and only allowed in the shipping/ receiving area. They should also identify themselves and present paperwork to identify that they are authorized for the load. Subcontracting carriers is not recommended. If subcontracting occurs, they must uphold the same standards as the contracted carriers.]
-	8.13 Damage to containers and any other event or problem that occurs during transit must be recorded and reported to the

	relevant department, entity or authority and investigated.
-	8.14 [Materials and/or products and/or cosmetics in transit must be accompanied by appropriate documentation. For each importation, the Certificate of Analysis (CoA) for each batch of product and/or cosmetic must be kept by the importer.]

CHAPTER 9: OUTSOURCED ACTIVITIES

GUIDELINE ON GDP 3rd Edition, 2018	GUIDELINE ON GDP 2nd EDITION, 2013
CHAPTER 9: OUTSOURCED ACTIVITIES	**[CHAPTER 9: PRODUCT/COSMETIC COMPLAINTS]**
PRINCIPLE Any activities performed, referenced in the GDP guideline and delegated to another party should be correctly defined, agreed and controlled in order to avoid misunderstandings which could affect the integrity of the products/cosmetics. There must be a written contract between the Contract Giver and the Contract Acceptor which clearly established the duties of each party.	-
GENERAL	-
9.1 The Contract Giver is responsible for assessing the competence of the Contract Acceptor to successfully carry out the work required and for ensuring by means of the contract and through audits that the principles and guidelines of GDP are followed. Audits toward contract acceptor by the contract giver should be permitted at any time.	**9.1 [PRINCIPLE** 9.1.1 A complaint is defined as a situation whereby when a customer or any other (outside party) has reported a material (e.g. active pharmaceutical ingredients) or product and/or cosmetic defect or adverse reactions with any of the company's marketed materials or products or cosmetics. This is valid regardless of whether: • The report is written or verbal • The sample of affected product is attached 9.1.2 A report on a product and/or cosmetic defect which has been identified within the company on a marketed product and/or cosmetic batch is also considered a complaint.]

9.2 The Contract Acceptor should have adequate premises and equipment, procedures, knowledge and experience and competent personnel to carry out the work ordered by the Contract Giver.	**9.2 [CLASSIFICATION OF COMPLAINTS** 9.2.1 Complaints can be classified as: • Medical (e.g. adverse reactions) • Pharmaceutical (e.g. precipitation, lack of efficacy) • Technical (e.g. damaged packaging or labelling defects)]
9.3 The Contract Acceptor should not pass to a third party any of the work entrusted to him under the contract without the Contract Giver's prior evaluation and approval of the arrangements and an audit of the third party by the Contract Giver or the Contract Acceptor. Arrangements made between the Contract Acceptor and any third party should ensure that the wholesale distribution information is made available in the same way as between the original Contract Giver and Contract Acceptor.	**9.3 [PROCEDURE FOR COMPLAINTS** 9.3.1 The procedure for dealing with complaints shall ensure that: • That complaints received are given proper due attention and promptness • That measures are taken to prevent repeated complaints • That made when adequate information is available, a decision is made whether to make a recall and if so, the degree to which a recall is to be made 9.3.2 Follow-up of complaints will contribute to a higher and more uniform product or cosmetic quality as well as prevent further defects, improve quality and client satisfaction.]
9.4 Depending on the nature of activities performed, the Contract Acceptor should understand that he might subject to inspection by Regulatory Authority. Note: This is relocation of Clause 13.4 of Guideline on GDP 2nd Edition,	**9.4 [PERSONS RESPONSIBLE** Within each company, 2 persons responsible with adequate knowledge shall be assigned the task of dealing with complaints. The person responsible must also have the authority to decide on

2013	measures to be taken. The required particulars for the responsible persons are as follows:- **PERSON RESPONSIBLE I** **PERSON RESPONSIBLE II** Name (as in Passport/ IC): Name (as in Passport/ IC): Passport/ IC No: Passport/ IC No: Position: Position: Home Address: Home Address: Telephone No: Telephone No: • Office Office • Residence Residence]
-	**9.5 [REPORTING** 9.5.1 Procedures shall be developed within the company for the receipt of reports on complaints at anytime. It is important that complaints reach the persons responsible. 9.5.2 All complaints reported should be recorded and properly documented.]
-	**9.6 [INVESTIGATION** 9.6.1 The persons responsible should initiate the investigation immediately. 9.6.2 The investigation shall be documented. 9.6.3 If a material and/or product and/or cosmetic defect is

	discovered or suspected in a batch, consideration should be given to determine whether other batches are also affected. 9.6.4 The investigation should also cover: • Distribution condition • Condition under which the material and/or product and/or cosmetic is used]
-	**9.7 [CORRECTIVE AND PREVENTIVE ACTION** 9.7.1 The persons responsible shall ensure that all the corrective and preventive actions are taken following the outcome of the investigation. All corrective and preventive actions should be recorded, reported and implemented. 9.7.2 If a recall has been decided, some of the procedures stated in the Product Recall Procedure shall be applied. 9.7.3 The company's management shall discuss possible steps to prevent future defects and take over any responsibility for further handling of the complaint from the persons responsible.]
-	**9.8 [RESPONSE TO COMPLAINANT** 9.8.1 The persons responsible should acknowledge the complainant within 24 hours after receipt of complaint(s). 9.8.2 The persons responsible shall provide response to the complainant within an agreed timeframe after completion of the investigation. 9.8.3 If the person who complains is informed of the outcome of

	the investigation over the telephone, the date and information provided shall be noted.]
-	**9.9 [DOCUMENTATION** 9.9.1 Each individual complaint and its relevant attached documents shall be filed. 9.9.2 A final report shall be prepared and kept in the Complaint File. One copy of the final report shall be forwarded to the relevant parties. 9.9.3 Complaint file should contain: • Written procedures describing the actions to be taken in the handling of all written and oral complaints regarding the materials and products and/or cosmetics (procedures for dealing with complaints). • A written record of each individual complaint and as well as the completed investigation report.]

CHAPTER 10: SELF INSPECTION

GUIDELINE ON GDP 3rd Edition, 2018	GUIDELINE ON GDP 2nd EDITION, 2013
CHAPTER 10: SELF INSPECTION	**[CHAPTER 10: PRODUCT/COSMETIC RECALL]**
PRINCIPLE The quality system should include self-inspections. These should be conducted in order to monitor implementation and compliance with the principles of GDP and to trigger necessary corrective and preventive measures. Note: This is relocation of Clause 11.1 of Guideline on GDP 2nd Edition, 2013	-
GENERAL	-
10.1 Self-inspections should be conducted covering all aspects of GDP and compliance with the regulations, guidelines and procedures within a defined time frame.	**10.1 PRINCIPLE** The Control of Drugs and Cosmetics Regulations 1984, requires every licensed manufacturer, importer and wholesaler to have a procedure (Product Recall Procedure), which sets out in a step-wise manner the various actions to be taken to ensure the prompt recall of defective products. Such procedures should be reviewed regularly and updated.
10.2 Self-inspections should be conducted in an independent and detailed way by a designated, competent person, according to an approved written procedure. Note: This is relocation of Clause 11.2 of Guideline on GDP 2nd Edition,	**10.2 DEFINITION** Product recall is a process taken by the manufacturer, importer and wholesaler to remove or withdraw a particular materials/ products/ cosmetics from all links of distribution. The removal or withdrawal may be due to critical quality defects

2013	discovered or serious adverse drug reactions reported which might cause health risks to users of the products/ cosmetics.
10.3 The results of all self-inspections should be recorded. Reports should contain all observations made during the inspection and, where applicable, proposals for corrective measures. There should be an effective follow-up program. Management should evaluate the inspection report, and corrective actions taken and recorded. Note: This is relocation of Clause 11.3 of Guideline on GDP 2nd Edition, 2013	**10.3 DECISION FOR RECALL** The decision for recall shall be made when there is or may caused potential risk to the user of the products and/or notified cosmetics by reason of faulty production or on medical grounds: • Voluntarily undertaken by the manufacturers and distributors. • As directed by the Director of Pharmaceutical Services, Ministry of Health.
-	**10.4 DEGREE AND LEVEL OF RECALL** The following criteria are used to classify the degree and level of recall. **10.4.1 DEGREE OF RECALL** The degree of recall is classified according to the severity of quality defects and adverse reactions of the products and/or notified cosmetics. Degree I – Products/ cosmetics with major health risks that might caused serious injuries or death. Should be under an embargo within 24 hours. Degree II – Products/ cosmetics with minor health risks or are substandard. Should be under an embargo within 72 hours. Degree III – Products/ cosmetics with other reasons for recall. Should be under an embargo within 30 days or as specified.

	10.4.2 LEVEL OF RECALL The level of recall depends on the nature of problem, extent of the product or cosmetic's distribution and degree of hazard involved. Level A: To all consumers (end users) Level B: To all points of sales (e.g. Hospitals, Pharmacies, Clinics, Specialists Centres) Level C: To all sub-distributors (wholesalers)
-	**10.5 DECISION ON THE DEGREE AND LEVEL OF RECALL** Unless the Director of Pharmaceutical Services, Ministry of Health has already specified the degree and level of a particular products and/or notified cosmetics recall, the degree and level will be decided by the Product Recall Committee based on risks involved. The Product Recall Committee shall compromise of personnel who are responsible for the execution and coordination of recall. The persons responsible shall handle all aspects of the recalls with the appropriate degree of urgency.
-	**10.6 [ORGANISATION OF PRODUCT RECALL** Two persons responsible for the recall activities shall be appointed. Once a decision is made, the responsible persons appointed are to initiate and undertake the material and/or product and/or cosmetic recall as well as to follow-up on any matters arising from such recall. The distribution records should be maintained and made readily available to the persons responsible for recalls. They should also contain sufficient information on wholesalers and customers supplied

	directly. The required particulars for the persons responsible are as follows: **PERSON RESPONSIBLE I** **PERSON RESPONSIBLE II** Name (as in Passport/ IC): Name (as in Passport/ IC): Passport/ IC No: Passport/ IC No: Position: Position: Home address: Home address: Telephone no: Telephone no: • Office Office • Residence Residence • Mobile Mobile]
-	**10.7 [NOTIFICATION OF RECALL** Notification of recall should be extended to all parties involved. The notification of recall should include: • The name of the material and/or product and/or cosmetic, its strength (if necessary) and pack size • The materials and/or products and/or cosmetics batch number, the nature of the defect • The action to be taken • The urgency of the action (with reasons, indication of health risk, as appropriate)]
-	**10.8 [DISSEMINATION OF PRODUCT RECALL NOTICES** **10.8.1 Level A: To the consumers (end users)**

	This recall level is carried out when necessary as an attempt to stop all use of a material and/or product and/or cosmetic and to recover stock that has reached the end user. **When there is imminent danger, the public are warned by media release which is meant to urgently alert the public by radio, television and the press.** **10.8.2 Level B: To all points of sale** All wholesalers will be identified and required to provide a list of all points of sale. These points can be established through a distribution record. **Recall notices will be sent to all point of sales. At the same time, representatives from the company will be sent to these points of sale to retrieve the stocks.** **10.8.3 Level C: To wholesalers and stockists** Consumers are not at any risk from administering the materials and/or products and/or cosmetics. **The wholesalers and stockists will be contacted by the company representatives so that arrangement can be made to retrieve all the stocks concerned from the wholesalers and stockists.]**
-	**10.9 [ORGANIZING THE RETURN OF THE RECALLED PRODUCT** All affected stocks of the recalled materials and/or products and/or cosmetics will be stored separately and sealed appropriately in a different section of the warehouse to prevent any mix-up.

	A centre which collects and stores all returned stocks of the recalled materials and/or products and/or cosmetics need to be named. Details such as date returned, name and address of customer, batch number, expiry date, quantity and nature of materials and/or products and/or cosmetics shall be noted down by this centre as records. Depending on the degree of the product recall, the most effective and appropriate mode of transportation of such recalled materials and/or products and/or cosmetics will be decided and agreed upon.] The storage conditions applicable to a material and/or product and/or cosmetic which is subjected to recall should be maintained during storage and transit until a decision has been made regarding the material and/or product and/or cosmetic.
-	**10.10 [FATE OF THE RECALLED MATERIAL AND/OR PRODUCT AND/OR COSMETIC** All available records and information on the returned stocks will be collected for evaluation of recall situation. A report of the affected stocks will be presented to the product recall committee and the fate of the material and/or product and/or cosmetic shall be made. The recalled material and/or product and/or cosmetic shall be destroyed if the conditions under which the material and/or product and/or cosmetic, its container, carton or labeling as a result of storage or transportation, casts doubt on its safety, identity and quality. Upon approval from the relevant authorities, proper destruction with appropriate precautionary measures shall be

	taken to ensure total elimination of affected stock. The destruction should be carried out and witnessed by authorized personnel. Details, such as mode and place of material and/or product and/or cosmetic destruction, the date and quantity shall be noted down and retained.]
-	**10.11 [FINAL REPORT OF RECALLED PRODUCT** A final report of the executed material and/or product and/or cosmetic recall will be prepared and forwarded to the National Pharmaceutical Control Bureau.]

CHAPTER 11: MANAGEMENT OF RECORDS AND DOCUMENTATION

GUIDELINE ON GDP 3rd Edition, 2018	GUIDELINE ON GDP 2nd EDITION, 2013
CHAPTER 11: MANAGEMENT OF RECORDS AND DOCUMENTATION	**[CHAPTER 11: SELF INSPECTION]**
PRINCIPLE Policies and procedures should be in place to ensure: • All records are kept in accordance with legislative requirements. • All records are maintained in accordance with the general requirements of this guideline and other relevant guideline by the national regulatory authority. • Prevent errors from verbal communication and permits the tracking of relevant operations during the receipt, storage and distribution of products/cosmetics.	-
Management of Documentation	-
11.1 Documentation comprises all written procedures, instructions, contracts, records and data. It may be in electronic or paper form. All documents should be approved, signed and dated by the appropriate authorized persons and not be changed without authorisation.	11.1 The quality system should include self-inspections. These should be conducted in order to monitor implementation and compliance with the principles of GDP and to trigger necessary corrective and preventive measures.
11.2 Documents should be: • Clear, concise, comprehensible and readily available to those that need to use them; • Numbered, dated, have a title, name and position of the person responsible for the documents; • Include detailed instructions on the subject and a date for	11.2 Self-inspections should be conducted in an independent and detailed way by a designated, competent person, according to an approved written procedure.

review.	
Management of Records	11.3 The results of all self-inspections should be recorded. Reports should contain all observations made during the inspection and, where applicable, proposals for corrective measures. There should be an effective follow-up programme. Management should evaluate the inspection report, and corrective actions taken and recorded.
11.3 Accurate record of all receipts and sales transactions must be kept.	-
11.4 Records should be made at the time each operation is taken in such a way that all significant activities or events are traceable. Records should be clear and readily available. The retention of documentation relating to distribution of products/ cosmetics should comply with national requirements. Note: This is relocation of Clause 6.1 of Guideline on GDP 2nd Edition, 2013	-
11.5 If records are computerised, only authorised persons should be able to enter or modify data in the computer. Access should be restricted by passwords or other means. Users should have a unique identifier (User ID) for their personal and sole use so that activities can subsequently be traced to the responsible individual. Note: This is relocation of Clause 6.1.1 of Guideline on GDP 2nd Edition, 2013	-
11.6 Records electronically stored should be protected by back-up transfer on paper or other means, at regular intervals. It is particularly important that the data, including audit trail, are readily available throughout the period of retention. Back-up data should be stored as long as necessary at a separate and secure location.	-

	Note: This is relocation of Clause 6.2 of Guideline on GDP 2nd Edition, 2013	
11.7	In accordance with the requirements specified by the regulatory authority, manufacturers/importers must record the usage of each hologram label used. In the case of any hologram labeling activity that is done by third party, the delivery/distribution record of hologram usage must be kept/recorded for traceability purpose.	-
11.8	Where applicable, full Material Safety Data Sheet (MSDS) and Certificate of Analysis (CoA) of products/cosmetics should be available.	-
11.9	All relevant legal records and documentations should comply to the current legislations referring to: a. Poisons Act 1952 and its regulations b. Sale of Drugs Act 1952 c. Control of Drugs and Cosmetic Regulations 1984 d. Dangerous Drugs Act 1952 e. Dangerous Drugs Regulations 1952 Note: This is relocation of Chapter 14 of Guideline on GDP 2nd Edition, 2013	-
11.10	**Wholesale Records** *Records of Transactions (Regulation 27),* *Control of Drugs and Cosmetics Regulations 1984:* Applicable for all registered products/cosmetics other than scheduled poisons, psychotropic substances and dangerous drugs.	-

	Entries to be made in 'Records of Transactions (For Licensed Wholesaler)'. These records should include:- • Date of Sale/ Supply • Name and address of supplier/ purchaser • Name, quantity and strength of products/cosmetics received/sold • Registration Reference of the products/cosmetics • Batch No. • Invoice No/Delivery Order No. Note: This is relocation of Clause 14.5 of Guideline on GDP 2nd Edition, 2013	
11.11	**Importation Records** *Records of Transactions (Regulation 27),* *Control of Drugs and Cosmetics Regulations 1984:* Applicable to all registered products/ cosmetics other than scheduled poisons, psychotropic substances and dangerous drugs. Entries to be made in 'Records of Transactions (For Licensed Importer)'. These records should include:- • Date of Importation • Name and address of supplier/purchaser • Name, quantity and strength of products/cosmetics imported/supplied • Invoice No./Bill Landing No./Airway Bill No. • Date of Sale/Supply • Name and address of purchaser • Registration reference of the products/cosmetics	-

• Batch No. • Invoice No./Delivery No. Note: This is relocation of Clause 14.6 of Guideline on GDP 2nd Edition, 2013	

ANNEX 1: MANAGEMENT OF TIME AND TEMPERATURE SENSITIVE PRODUCTS (TTSP)

GUIDELINE ON GDP 3rd Edition, 2018	GUIDELINE ON GDP 2nd EDITION, 2013
ANNEX 1: MANAGEMENT OF TIME AND TEMPERATURE SENSITIVE PRODUCTS (TTSP)	**[CHAPTER 15: MANAGEMENT OF COLD CHAIN PRODUCTS/MATERIALS]**
PRINCIPLE Policies and procedures should be available to ensure that the activities of receipt, storage and distribution are done without compromising on the quality, efficacy, safety and integrity of time and temperature sensitive products (TTSP) according to the manufacturer's recommended conditions as per the approved product's label by the authority as well as the product stability data.	-
GENERAL	-
1. List of products including the cold chain storage temperature specifications should be provided for reference to personnel who handle the receipt of goods.	15.1 List of products should be provided with cold chain storage temperature specifications for reference by personnel who handle the receipt of goods and related store personnel.
2. Regular and appropriate training should be provided for all personnel (including drivers) involved in the handling of TTSP to ensure the quality of TTSP are maintained. The training should also cover on applicable pharmaceutical legislations and regulations; SOPs and safety issues and response to emergencies. Training records and effectiveness checks on training provided should be available upon request.	15.2 Written procedures should be available and appropriate training should be provided for all staff involved in the handling, receipt, storage, packing and delivery operations for cold chain products/materials to ensure the quality of cold chain products/materials is maintained.
3. Net storage capacity of the storage facilities should be sufficient to accommodate peak TTSP stock levels under correct temperature conditions and in a manner which enables efficient and correct stock management operations to take place.	15.3 Cold chain product storage facilities should be qualified prior to prevail that it is capable of storing the product in accordance with the specifications given situation. Qualification and validation records must be kept and cold chain products

	storage facilities must be able to operate at all time in accordance to the qualifying conditions.
4. TTSP storage facilities should be qualified prior to prevail that it is capable of storing the product in accordance with the specifications given situation. Qualification and validation records must be kept and TTSP storage facilities must be able to operate at all time in accordance to the qualifying conditions. Note: This is relocation of Clause 15.3 of Guideline on GDP 2nd Edition, 2013	15.4 Written procedures should be established to ensure that the cold chain products / materials received are distributed under storage conditions comply with the directions on the label of products based on product stability testing results. Companies can use the temperature 'data logger' or other temperature recording devices to verify that the desired temperature has been maintained during the delivery of each consignment received. In addition, simulation studies can be conducted to validate the delivery conditions, taking into account the possibility of the worst situation.
5. Household-style unit refrigerators and freezers are only acceptable if they have been independently tested and found to comply with the temperature control requirements of a recognized standard for pharmaceutical refrigerators or freezers.	15.5 Cold chain products should be identified immediately after receipt and stored under the storage conditions that comply with the directions on the product label. Written procedures should be provided to ensure that the activities of receipt, storage and distribution are done without compromising on the quality, efficacy and safety of the products/cosmetics.
6. Controlled or hazardous TTSP should be stored in dedicated, separated and securely locked facilities/areas that comply fully with all legislative and regulatory requirements.	15.6 Inspection upon receipt of products / materials should be done to prevent signs of aggression, destruction and non-conformance along the cold chain storage and distribution, as well as physical damage to the packaging materials, labels and quantity of the product compared to the information in the purchase order. These inspections shall be conducted under the recommended storage conditions as on the product label.
7. Cold room, freezer room, refrigerator and freezer must be fitted with an alarm system to alert personnel if any occurrence of temperature beyond specifications. Action and warning limits should be established. Periodic testing program on the alarm system should be established to ensure the alarm system is functioning.	15.7 All cold chain products (e.g. removed, quarantined) must be stored under the storage conditions stated on the label other than the product which will be disposed off.

Note: This is relocation of Clause 15.12 of Guideline on GDP 2nd Edition, 2013	
8. Alternative power systems should be established for cold rooms to ensure cold room temperatures remain and the temperature/humidity detector will continue functioning in the event of power failure. Periodic testing program on alternative power systems should be established to ensure that it works. Alternative plan to provide alternative areas where storage temperature equivalent should be provided if no alternative power systems can be provided. Note: This is relocation of Clause 15.13 of Guideline on GDP 2nd Edition, 2013	15.8 [Temperature and humidity (if needed) for cold room or refrigerator must be monitored and recorded continuously using temperature and humidity sensors.]
9. Calibration and temperature monitoring functions of all equipment, including alarms and other related equipment, must be inspected at least annually. Note: This is relocation of Clause 15.14 of Guideline on GDP 2nd Edition, 2013	15.9 Maximum and minimum temperatures should be recorded, either electronically or manually at least once in the last 24 hours, with continuous review of records. Records must be kept for at least one year.
10. Periodic maintenance program for air conditioning systems in a cold room and freezer must be established and implemented. Note: This is relocation of Clause 15.11 of Guideline on GDP 2nd Edition, 2013	15.10 Suitability of locations for placing temperature sensors in a cold room used for storage of cold chain products should be subjected to temperature mapping study. Mapping studies should be conducted in accordance with written procedures and storage conditions determined before operation.
11. Verification upon receipt of products should be done to ensure there are no signs of tampering and non-conformance (such as deviation of temperature profile from the manufacturer's recommendation as per the approved product's label by the authority, physical damage to products, packaging materials, etc.). Note: This is relocation of Clause 15.6 of Guideline on GDP 2nd Edition, 2013	15.11 Periodic maintenance programmes for air conditioning systems in a cold room and freezer must be established and implemented.

12. All TTSP (e.g. rejected, quarantined) must be stored under the storage conditions stated on the label other than the product which will be disposed off. If the storage temperature is found to have deviated from the storage specifications, manufacturer for the products should be contacted to confirm the suitability of the use of products and the decision recorded. Note: This is relocation of combination of Clause 15.7 & 15.24 of Guideline on GDP 2nd Edition, 2013	15.12 Cold room or freezer must be fitted with an alarm system to alert staff if any occurrence of temperature beyond specifications. Action and warning limits should be established. Periodic testing programme on the alarm system should be established to ensure the alarm system is functioning.
13. Maximum and minimum temperature and humidity (if needed) for all temperature controlled rooms, cold rooms, freezer rooms, refrigerators and freezers must be monitored and recorded continuously using temperature and humidity monitoring devices. Note: This is relocation of combination of Clause 15.9 of Guideline on GDP 2nd Edition, 2013	15.13 Alternative power systems should be established for cold rooms to ensure cold room temperatures remain and the temperature/humidity detector will continue functioning in the event of power failure. Periodic testing programme on alternative power systems should be established to ensure that it works. Alternative plan to provide alternative areas where storage temperature equivalent should be provided if no alternative power systems can be provided.
14. Suitability of locations for placing temperature sensors in all temperature controlled rooms, cold rooms, freezer rooms, refrigerators and freezers used for storage of TTSP should be subjected to temperature mapping study. Mapping studies should be conducted in accordance with written procedures and storage conditions determined before operation. Note: This is relocation of Clause 15.10 of Guideline on GDP 2nd Edition, 2013	15.14 Calibration and temperature monitoring functions of all equipment, including alarms and other related equipment, must be inspected at least annually.
15. Container systems used for delivery of TTSP should be fully qualified to show that it is 'fit for purpose' and capable of maintaining the temperature profile defined for each product during transportation/distribution, can minimize product degradation due to temperature sensitivity and can meet the product stability profile requirements stated by the pharmaceutical manufacturer. Documented	15.15 Written procedures should be available to explain the packing materials required, packing configuration of transportation container for cold chain products / materials and labels to identify these products as products that require special storage /shipping conditions. Packaging operations for cold chain products should be recorded and should have the second

evidence of such assurance and compliance should be demonstrated and available upon request.	person conformance to ensure that the packaging operations carried out in accordance following written procedures
16. Packaging operations for TTSP should be verified in accordance with written procedures. Packaging for TTSP should be mapped and continuously monitored. Note: This is relocation of Clause 15.15 of Guideline on GDP 2nd Edition, 2013	15.16 [Outer packing/shipping contacting cold chain products/materials should be labelled: • "Cold but not freezing" for medicines that require maintenance of temperature in the range of +2°C to +8°C, or • "Refrigerate the contents of the package" for medicine transported in packaging that needs to be removed before the medicines to be placed in the refrigerator, or • "Keep Frozen" for medicines that require maintenance in the range of temperature below 0°C.]
17. There should be a system in place to control the reuse of temperature protection components (e.g. ice/water blankets, water/gel packs, phase change materials, insulated packaging, etc) to ensure that incompletely components are not used in error.	15.17 Medicines labelled "Keep Frozen" should be transported in such a manner to ensure that it remains frozen.
18. Necessary precaution steps should be implemented when using dry ice during transportation in order to avoid a direct contact with the product and consequently caused coagulation of products. Note: This is relocation of Clause 15.19 of Guideline on GDP 2nd Edition, 2013	15.18 [Packing and handling of cold chain medicines should put a warning to acknowledge the recipient that it is a cold chain medicines and receiver must put the medicines in appropriate storage facilities as soon as possible.]
19. TTSP should be clearly labelled and identifiable from other products in the same delivery. In cases where TTSP are to be air freighted, the package(s) should be labelled according to the International Air Transport Association (IATA) regulations.	15.19 Necessary precaution steps should be implemented when using dry ice during transportation in order to avoid a direct contact with the product and consequently caused coagulation of products / materials.
20. Procedures must be implemented to handle the returned products and also the products that have been stored under out of the specified storage condition during the reception, storage and distribution of	15.20 Refrigerated vehicles or containers to transport cold chain products should be mapped and monitored.

products. Note: This is relocation of Clause 15.23 of Guideline on GDP 2nd Edition, 2013	
21. TTSP should be transported under validated conditions to ensure that the relevant temperature range is maintained according to the directions on the label of the products. In addition, simulation studies can be conducted to validate the delivery conditions, taking into account the possibility of the worst situation. Note: This is relocation of Clause 15.4 of Guideline on GDP 2nd Edition, 2013	15.21 Delivery route planning for cold chain products should be created to prevent the risk of exposure to the cold chain products beyond the control of the ambient temperature. Cold chain medicines should be clearly identified from other items in the same distribution activities.
22. Refrigerated vehicles or containers to transport TTSP should be mapped and continuously monitored. Note: This is relocation of Clause 15.20 of Guideline on GDP 2nd Edition, 2013	15.22 [For each delivery, evaluation and validation of methods of delivery temperature control system to be used must consider the time required for delivery, weather conditions and any future risk exposure.]
23. Delivery route planning for TTSP should be created to prevent the risk of exposure to the products beyond the control of the ambient temperature. TTSP should be clearly identified from other items in the same distribution activities. Note: This is relocation of Clause 15.21 of Guideline on GDP 2nd Edition, 2013	15.23 Procedures must be implemented to handle the returned products and also the products / materials that have been stored under out of the specified storage condition during the reception, storage and distribution of products / materials.
24. Products labelled "Keep Frozen" should be transported in such a manner to ensure that it remains frozen. Note: This is relocation of Clause 15.17 of Guideline on GDP 2nd Edition, 2013	15.24 If the storage temperature is found to have deviated from the storage specifications, manufacturer for the products / materials should be contacted to confirm the suitability of the use of products / materials and the decision recorded.

ANNEX 2: SPECIFIC PROVISIONS FOR BROKERS

GUIDELINE ON GDP 3rd Edition, 2018	GUIDELINE ON GDP 2nd EDITION, 2013
This section is applicable or relevant to brokers, agents, traders, dealers or distributors. A 'broker' is a person involved in activities in relation to the sale or purchase of medicinal products, except for wholesale distribution, that do not include physical handling and that consist of negotiating independently and on behalf of another legal or natural person. It is also applicable to those brokers that may trade and/or take possession, distribute or store an API or intermediate. They must have a permanent address and contact details. They must notify the regulatory authority of any changes to those details without unnecessary delay. All requirements in this guideline also apply to brokers. 1. The quality system of a broker should be defined in writing, approved and kept up to date. It should set out responsibilities, processes and risk management in relation to their activities. 2. Any companies involved in the brokering activities should have personnel trained particularly in the issues concerning falsified products, handling of complaints and recall. All relevant activities should be clearly defined in procedures and systemically reviewed and record accordingly. 3. Brokers that deal in API or intermediate should maintain complete traceability of products/materials that are distributed. Such documents include name and address of the original manufacturer, purchase orders, transportation documentation, manufacturer's batch number,	-

transportation and distribution records as well as original Certificate of Analysis from the manufacturer. 4. Original Certificates of Analysis issued by the manufacturer or authenticated copies of the original Certificates of Analysis for each batch of intermediates or APIs should be provided to the customers upon request. 5. The general provisions on documentation in Chapter 11 apply.	

[CHAPTER 12: COUNTERFEIT MATERIALS/PRODUCTS/COSMETICS]

GUIDELINE ON GDP 3rd Edition, 2018	GUIDELINE ON GDP 2nd EDITION, 2013
-	**[CHAPTER 12: COUNTERFEIT MATERIALS/PRODUCTS/COSMETICS]**
-	12.1 Any counterfeit products/ cosmetics found in the distribution network should be physically segregated from other products/ cosmetics to avoid any confusion. They should be clearly labelled. All relevant activities in relation to such products should be documented and records retained. The sale and distribution of a suspected counterfeit product should be suspended immediately.
-	12.2 The regulatory authority and the holder of the marketing authorization of the original products and/or notified cosmetics should be informed immediately.

[CHAPTER 13: CONTRACT ACTIVITIES]

GUIDELINE ON GDP 3rd Edition, 2018	GUIDELINE ON GDP 2nd EDITION, 2013
-	**[CHAPTER 13: CONTRACT ACTIVITIES]**
-	13.1 [Any activities performed, referenced in the GDP guideline and delegated to another party, should be agreed upon in a contract.]
-	13.2 [There should be a written and approved contract or formal agreements between the Contract Giver and Contract Acceptor that addresses and defines in detail the responsibilities and GDP requirements for each party.]
-	13.3 [The contract should permit the Contract Giver to visit the facilities of the Contract Acceptor.]
-	13.4 Depending on the nature of activities performed, the Contract Acceptor should understand that he might subject to inspection by Regulatory Authority.

[CHAPTER 14: LEGAL DOCUMENTS]

GUIDELINE ON GDP 3rd Edition, 2018	GUIDELINE ON GDP 2nd EDITION, 2013
-	All relevant legal records and documentations should comply to the current legislations referring to: a. Poisons Act 1952 and its regulations b. Sale of Drugs Act 1952 c. Control of Drugs and Cosmetic Regulations 1984 d. Dangerous Drugs Act 1952 e. Dangerous Drugs Regulations 1952
-	**14.1 [RECEIVING RECORDS FOR DANGEROUS DRUGS** *Records of Transactions of Registered Products (Regulation 27),* *Control of Drugs and Cosmetics Regulations 1984;* *Second Schedule Dangerous Act 1952 (Revised 1980);* *Form of Register Part 1 Regulations 15 (1) (a):* 14.1.1 Entries to be made in the 'Register' in case of drugs or preparation obtained. 14.1.2 These records should include:- • The Class of Drugs and preparations to which the entries relate to be specified at the head of each page in the register INN Name • Name, strength and packing size of the product Date on which supply was received • Name and address of person or firm from whom obtained

	Amount obtained • Form in which obtained (Name, strength and packing size of products) • MAL Registration No. • Invoice Number or Delivery Oder Batch Number • Total Stock]
-	**14.2 [SUPPLY RECORDS FOR DANGEROUS DRUGS** *Records of Transactions of Registered Products (Regulation 27),* *Control of Drugs and Cosmetics Regulations 1984;* *Second Schedule Dangerous Act 1952 (Revised 1980);* *Form of Register Part II Regulations 15 (1) (a):* 14.2.1 Entries to be made in the 'Register' in case of drugs or preparation obtained. 14.2.2 These records should include:- • The Class of Drugs and preparations to which the entries relate to be specified at the head of each page in the register INN Name • Name, strength and packing size of the product Date on which supply was received • Name and address of person or firm from whom obtained Amount obtained • Form in which obtained (Name, strength and packing size of products) • MAL Registration No. • Invoice Number or Delivery Oder Batch Number • Total Stock]
-	**14.3 [SUPPLY REGISTER FOR PSYCHOTROPIC SUBSTANCES**

	Regulations 20 & 22 Poisons (Psychotropic Substances) Regulations 1989; Records of Transactions of Registered Products (Regulation 27), Control of Drugs and Cosmetics Regulations 1984: 14.3.1 These records should include:- • The INN Name • Name, strength and packing (quantity) of product • Name and address of supplier/ purchaser • Date of Sale/ Supply/ Received • Purpose of which required • Quantity Supplied/ Received • Total Stock • MAL Registration No. • Batch No. • Invoice No/ Import or Export Authorization • No. Bill Landing No./ Airway Bill No. • Reference to purchaser's signed order **A SEPARATE REGISTER IS REQUIRED FOR EACH PRODUCT AND EACH STRENGTH OF THE SAME PRODUCT** 14.3.2 Entries for incoming registered products should be clearly identified.]
-	**14.4 [POISON WHOLESALE RECORD** Section 15(3), Poisons Act 1952 (Revised 1989); Records of Transactions of Registered Products (Regulation 27), Control of Drugs and Cosmetic Regulations 1984: 14.4.1 Entries to be made in 'Poisons Wholesale Sales Book'. 14.4.2 These records should include: • INN Name

	• Name, strength and packing size of products • Name of purchaser • Name and address of purchaser • Date of Sale • Name of poison sold • Quantity of poison sold • Purpose for which required • Signature of Purchaser or refer to signed order • MAL Registration No. • Batch No. • Invoice No./ Bill Landing Np./ Airway Bill No. • Reference to purchaser's signed order 14.4.3 Entries for incoming registered products should be clearly identified.]
-	**14.5 Wholesale Records** *Records of Transactions of Registered Products (Regulation 27), Control of Drugs and Cosmetics Regulations 1984:* Applicable for all registered products and/or cosmetics other than scheduled poisons, psychotropic substances and dangerous drugs. Entries to be made in 'Records of Transactions (For Licensed Wholesaler)'. These records should include:- • Name, strength of products or cosmetics • Date of Sale/ Supply • Name and address of supplier/ purchaser • Registration Reference of the product • (MAL Registration No.) or cosmetic (Notification No.) • Quantity Received/ Sold

	• Packing Size • Batch No. • Invoice No/ Delivery Order No. Entries for incoming registered products and/or notified cosmetics should be clearly identified.
-	**14.6 Importation Records** *Records of Transactions of Registered Products (Regulation 27), Control of Drugs and Cosmetics Regulations 1984:* Applicable to all registered products and/or cosmetic other than scheduled poisons, psychotropic substances and dangerous drugs. Entries to be made in 'Records of Transactions (For Licensed Importer)'. These records should include:- • INN Name (if applicable) • Name, strength and packing size of products/ cosmetics • Date of Importation • Name and address of supplier/ purchaser • Quantity imported/ supplied • Invoice No./ Bill Landing No./ Airway Bill No. • Date of Sale/ Supply • Name and address of purchaser • PBKD Registration No./ Notification No. • Batch No. • Packing Size • Invoice No./ Delivery Entries for incoming registered products and/or notified cosmetics should be clearly identified.

GLOSSARY OF TERMS

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Active Pharmaceutical Ingredient (API) Any substance or mixture of substances intended to be used in the manufacture of a drug product and that when used in the production of a drug becomes an active ingredient of the drug product. Such substances are intended to furnish pharmacological activity or other direct effects in the diagnosis, cure, mitigation, treatment or prevention of diseases, or to affect the structure and function of the body.	Active Pharmaceutical Ingredient (API) Any substance or mixture of substances intended to be used in the manufacture of a drug product and that when used in the production of a drug becomes an active ingredient of the drug product. Such substances are intended to furnish pharmacological activity or other direct effects in the diagnosis, cure, mitigation, treatment or prevention of diseases, or to affect the structure and function of the body.
Authorities Refer to government bodies or agencies such as local authorities, state health department as well as Ministry of Natural Resources & Environment given lawful approval or recognition on particular responsibilities.	Authorities Refer to government bodies or agencies such as local authorities, state health department as well as Ministry of Natural Resources & Environment given lawful approval or recognition on particular responsibilities.
Counterfeit product or cosmetic Product or cosmetic which is deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products/cosmetics and may include products/ cosmetics with the correct ingredients or with wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging.	Counterfeit product or cosmetic Product or cosmetic which is deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products/ cosmetics and may include products/ cosmetics with the correct ingredients or with wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging.
Consignment	Consignment

The delivery batch of materials and products or cosmetics supplied at one time in response to a particular request or order.	The delivery batch of materials and products or cosmetics supplied at one time in response to a particular request or order.
Contamination The undesired introduction of impurities of a chemical or microbiological nature, or of foreign matter during manufacturing, sampling, packaging or repackaging, storage or transport.	Contamination The undesired introduction of impurities of a chemical or microbiological nature, or of foreign matter during manufacturing, sampling, packaging or repackaging, storage or transport.
Cosmetic Means: a. Any substance or preparation intended to be placed in contact with the various external parts of the human body (including epidermis, hair system, nails, lips and external genital organs) or with the teeth and mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfume them, changing their appearance or correcting body odours, protecting them or keeping them in good condition. b. A cosmetic product currently notified in accordance with the provisions of the Sale of Drugs Act 1952 and the Control of Drugs and Cosmetics Regulations 1984.	Cosmetic Any substance or preparation intended to be placed in contact with the various external parts of the human body (including epidermis, hair system, nails, lips and external genital organs) or with the teeth and mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfume them, changing their appearance or correcting body odours, protecting them or keeping them in good condition.
Cross-contamination Contamination of a material or product or cosmetic with another material or product or cosmetic.	Cross-contamination Contamination of a material or product or cosmetic with another material or product or cosmetic.
	[Excipient

	Any substances in the drug product other than the API.]
	[Finished product A product that has undergone all stages of production including packaging in its final container and labeling.]
-	[First Expired/ First Out (FEFO) principle concept A distribution procedure that ensures the approved stock that has a nearer expiry date is distributed and/or utilized before an approved and identical stock item with later expiry is distributed and/or utilized.]
-	[First In/ First Out (FIFO) principle concept A distribution procedure that ensures the oldest approved stock is distributed and/or utilized before a new approved and identical stock item is distributed and/or utilized.]
Good Distribution Practice (GDP) The measures that need to be considered in the storage, transportation and distribution of any registered product/ notified cosmetic and its related materials such that the nature and quality intended is preserved when it reaches the consumer.	-
Intermediate (API Intermediate) A material produced during the processing step of an API which must undergo further molecular change or purification before it becomes an API.	Intermediate (API Intermediate) A material produced during the processing step of an API which must undergo further molecular change or purification before it becomes an API.

Labelling The term 'labelling' designates all labels and other written, printed or graphic matter upon, or in, any package or wrapper in which it is enclosed, except any outer shipping container. A shipping container, unless such container is also essentially the immediate container or the outside of the consumer package, is exempt from labeling requirements.	Labelling The term 'labelling' designates all labels and other written, printed or graphic matter upon, or in, any package or wrapper in which it is enclosed, except any outer shipping container. A shipping container, unless such container is also essentially the immediate container or the outside of the consumer package, is exempt from labeling requirements.
License Any license issued under Regulation 12 of the Control of Drugs and Cosmetics Regulations 1984.	License Any license issued under Regulation 12 of the Control of Drugs and Cosmetics Regulations 1984 (Revised 2009).
Manufacturer Includes: a. the making or assembling of the products/cosmetics; b. the enclosing or packing of the product in any container in a form suitable for administration or application, and the labeling of the container; and c. the carrying out of any process in the course of any or the foregoing activities.	Manufacturer Includes: a. the making or assembling of the product/ cosmetic; b. the enclosing or packing of the product in any container in a form suitable for administration or application, and the labeling of the container; and c. the carrying out of any process in the course of any or the foregoing activities.
Manufacturer's Agent Representatives or companies acting as agents empowered by the manufacturer to sell or solicit sales for the manufacturer's products in a defined territory.	-

-	[Material A general term used to denote raw materials, starting materials, intermediates, excipients and packaging materials and labeling materials.]
-	[Notified Cosmetic A cosmetic product currently notified in accordance with the provisions of the Sales of Drugs Act 1952 (Revised 1989) and the Control of Drugs and Cosmetics Regulations 1984 (Revised 2009).]
Packaging material Any material employed in the packaging of a material or product or cosmetic, including any other packaging used for transportation or shipment. Packaging materials are referred to as primary or secondary according to whether or not they are intended to be in direct contact with the product.	Packaging material Any material employed in the packaging of a material or product or cosmetic, including any other packaging used for transportation or shipment. Packaging materials are referred to as primary or secondary according to whether or not they are intended to be in direct contact with the product.
Printed packaging material Packaging material which is a imprinted with text or numbers or a combination of both.	Printed packaging material Packaging material which is a imprinted with text or numbers or a combination of both.
Product Means: a. a drug in a dosage unit or otherwise, for use wholly or mainly by being administered to one or more human beings or animals for medicinal purpose; or	Product Means: a. a drug in a dosage unit or otherwise, for use wholly or mainly by being administered to one or more human beings or animals for medicinal purpose;or

b. a drug to be used as an ingredient of a preparation for medicinal purpose. c. raw materials, starting materials, intermediates, excipients, packaging materials and labeling materials. d. Applicable to Active Pharmaceutical Ingredients (if applicable)	b. a drug to be used as an ingredient of a preparation for medicinal purpose. c. raw materials, starting materials, intermediates, excipients, packaging materials and labeling materials. d. Applicable to Active Pharmaceutical Ingredients (if applicable)
-	[Raw material A product currently registered in accordance with the provisions of the Control of Drugs and Cosmetics Regulations 1984 (Revised 2009).
Return product/cosmetic Product or cosmetic sent back from the customer to the supplier.	Return product/ cosmetic Product or cosmetic sent back from the customer to the supplier.
Storage A term used to describe the safe keeping of products or cosmetic such as starting materials and finished products received from supplier, semi-finished products or cosmetics in process and finished products awaiting dispatch and products or cosmetics awaiting distribution to retailers and products or cosmetics (rejected, recalled and damaged) awaiting disposal.	Storage A term used to describe the safe keeping of materials and products or cosmetic such as starting materials and finished products received from supplier, semi-finished products or cosmetics in process and finished products awaiting dispatch and products or cosmetics awaiting distribution to retailers and products or cosmetics (rejected, recalled and damaged) awaiting disposal.
Supplier A person providing products or cosmetics on request. Supplier may be agents, brokers, distributors, manufacturers or traders.	Supplier A person providing products or materials or cosmetics on request. Supplier may be agents, brokers, distributors, manufacturers or traders.

Temperature Room temperature: 15 - 25°C or up to 30°C depends on climatic condition Cool temperature: 8 - 15°C Cold temperature: 2 - 8°C Frozen temperature: ≥ - 20°C	-
Wholesale A sale to any person who intends to sell again and any sale by a licensed wholesaler.	-