ANNEX A

LIST OF GDSP INSPECTION DEFICIENCIES

(This list is non-exhaustive and other observations may be added, removed or reclassified as appropriate).

Deficiencies	References	DD	DR	Classification
Quality Management				
Distribution, offering for sale, or selling of unregistered and substandard/counterfeit pharmaceutical products.	(WHO TRS 1025 Annex 7 18.32 & 20, Sec. 11 (a) of R.A. 3720 as amended by RA 9711 and Sec. 4 of Republic Act No. 8203)	✓	✓	Critical
Distributors or their agents distributed a pharmaceutical product outside a country or territory without appropriate marketing authorization.	(WHO TRS 1025 Annex 7 18.32, Sec. 11 (k) of RA 3720, as amended by RA 9711)	✓		Critical
Antibiotics/biological products were distributed and offered for sale without Batch notification/ Lot release in the market.	(Administrative Order No.2008-0033, Administrative Order 103 s. 2002, RA. 3720 Sec.11 (m))	✓		Critical
The distributor/drug retail outlet purchase the pharmaceutical products from entities that are not FDA license or without applicable authorizations to sell or supply such products.	(WHO TRS 1025 Annex 7 18.5, Sec. 11 (k) of RA 3720,as amended by RA 9711)	✓	✓	Critical
Offering for sale and/or presence of expired/damaged/recalled pharmaceutical products in the selling area together with other commercial stocks.	(Sec.11 (l) of R.A. 3720 as amended by RA 9711)		✓	Critical
Drug product/s requiring refrigeration are stored at ambient temperatures (e.g. room temperature).	(WHO TRS 1025 Annex 7 12.34)	✓	✓	Critical
There is no Quality System to ensure that GDP and GSP are implemented and that the quality of pharmaceutical product is maintained throughout the supply chain.	WHO TRS 1025 Annex7 5.1 & 5.3	✓		Major

There are no established or written procedures for procurement, storage, *distribution*, dispensing and other significant Standard Operating Procedures such as handling of complaints, product returns, recalls, suspected counterfeit/substandard/ falsified products; sanitation and pest control; handling of damaged and/or broken shipping containers; handling of spillage; transportation/ investigating and dealing with any failure to comply with storage requirements during the transportation; vehicle maintenance; disptach;as appropriate. There is also no evidence of implementation, in relation to all these SOPs.	(WHO TRS 1025 Annex 7 5.3,18.3 &12.12)	✓	✓	Major
The duties and responsibilities of personnel involved in the distribution/dispensing of pharmaceutical products are not specified and defined in the written job description.	(WHO TRS 1025 Annex 7 5.6)	✓	✓	Major
There is no authorized, written and established quality manual describing the establishment's quality system.	WHO TRS 1025 Annex 7 5.4	✓	✓	Others
There is no authorized and updated organizational structure that indicates the authority and interrelationships of personnel.	(WHO TRS 1025 Annex 7 5.5)	✓	✓	Others
Standard Operating Procedures are not consistently followed.		✓	✓	Others
The written job description is not duly signed by the senior management and the personnel involved in GDSP.	(WHO TRS 1025 Annex 7 5.6) (DS)	✓	✓	Others
Personnel				
There is no qualified personnel (Pharmacist) who is responsible for ensuring compliance with the establishment's operation with GDSP and fulfill other scope of pharmacy practice as described in Section IV of the RA 10918 or Philippine Pharmacy Act.	WHO TRS 1025 Annex7 16.2 & 16.7, R.A. 10918 Sec. 39, & AO 2020-0017	✓	✓	Major
The pharmacist in charge and any personnel involved in distribution/dispensing activities other than pharmacist lack relevant trainings and experiences on GDSP or any related activities as evident by the following: no established training	(WHO TRS 1025 Annex 7 16.2 & 16.7, R.A. 10918 Sec. 39, & AO 2020-0017)	✓	✓	Major

plan/program and no presented training records.				
There is an inadequate number of competent key personnel involved in distribution/dispensing of pharmaceutical products.	WHO TRS 1025 Annex7 16.1	✓	✓	Major
Job Descriptions of the personnel involved in the distribution/dispensing of pharmaceutical products are not consistent with the actual function.		✓	✓	Others
Quality Risk Management				
There is no established and written RMP following the FDA guidelines.	(RA 9711/ FC 2018-013, AO 2020-0017 & WHO TRS 1025 Annex 7 6.1-6.3)	✓	✓	Major
Lack of system to assess, control, communicate and review risks identified at all stages in the supply chain.	(WHO TRS 1025 Annex 7 6.1-6.3)		✓	Major
Complaints, Returns, Recall, and Falsified Medicines				
The company failed to conduct a full recall procedure for the defective pharmaceutical product.	(FDA Circular No. 2016-012 5.4.4, WHO TRS 1025 Annex 7 10.8)	✓		Critical
There are no records of progress of product recall and no final report was done to ensure effective and prompt recall of health products.	(WHO TRS 1025 Annex 7 10.8)	✓		Major
There is no procedure for mock recall.	FDA Circular No. 2016-012	✓		Major
There are no records on the received complaints, and returned health products.	(WHO TRS 1025 Annex 7 8.2)	✓	✓	Major
The received complaints (relative to the quality of the product), and suspected counterfeit health products are not investigated and reported to the MAH or the FDA.	(WHO TRS 1025 Annex 7 8.2)	✓	✓	Major
There is no secured, dedicated, labeled area for returned and recalled health products	(WHO TRS 1025 Annex 7 9.2)	✓	✓	Major

Premises, Equipment and Facilities				
Equipment (pharmaceutical refrigerator) or storage areas (cold storage room) for time- and temperature-sensitive pharmaceutical products(TTSPPs) are not maintained within acceptable temperature limits.	(WHO TRS 961 Annex 9 4.2)	✓	✓	Major
The equipment used is not suitable for its intended purpose and is not properly maintained.	(TRS 1025 Annex 7 Section 14.1)	✓	✓	Major
There were temperature deviations/excursions recorded but no CAPA was done.	(WHO TRS 961 Annex 9 9.1	✓	✓	Major
Equipment used for temperature monitoring was not calibrated.	(WHO TRS 1025 Annex 7 12.22, 12.37)	✓	✓	Major
Monitoring of temperature is not conducted.	(WHO TRS 961 Annex 9 4.18)	✓	✓	Major
Preventive maintenance on all temperature-controlled equipment are not implemented.	(TRS 961 Annex 9 Section 4.9)	✓	✓	Major
Contingency plan is not established and maintained to ensure Time and Temperature Sensitive Pharmaceutical products are protected from the event of power failure and equipment breakdown.	(TRS 961 Annex 9 Section 3.9.2)	✓	✓	Major
There is no designated area for returned, expired and damaged products. Returned and expired products were stored together with other commercial pharmaceutical products.	(WHO TRS 1025 Annex 7 10.5,12.8,12.26,12.32 &13.4)	✓	✓	Major
The area for pharmaceutical products under ambient conditions are not maintained within acceptable temperature limits as indicated in the product label.	(WHO TRS 1025 Annex 7 12.1, 12.22)	✓	✓	Major
Storage areas is not sufficient to allow orderly storage of the various categories of pharmaceutical products. In that pharmaceutical products were close to the wall, floor, and ceilings; thus, inspection and cleaning are not possible to be conducted.	(WHO TRS 1025 Annex 7 12.1,12.4, 12.20 & 12.23)	✓	✓	Major

Storage areas are not kept clean and with evidence of accumulated dirt, visible dust, and presence of rodents, insects, and other animals.	(WHO TRS 1025 Annex 7 12.7)	✓	✓	Major
There is no adequate lighting provided in all areas in the establishment.	(WHO TRS 1025 Annex 7 12.2, & 12.21)	✓	✓	Others
There are no precautions taken to prevent unauthorized persons from entering the storage area.	(WHO TRS 1025 Annex 7 12.19)	✓	✓	Others
Stock Control and Rotation				
Stock discrepancies are not investigated and no appropriate CAPA was taken to prevent recurrence.	(WHO TRS 1025 Annex 7 13.2)	✓	✓	Major
There are no records for periodic stock reconciliation.	(WHO TRS 1025 Annex 7 13.1, 13.4)	✓	✓	Others
Documentation				
Falsification and misrepresentation of the Marketing authorization of pharmaceutical products and other documents issued by the FDA such as Lot release, batch notification, Certificate of Product Registration and License to Operate.	(Republic Act No. 10951 Art. 172)	✓	✓	Critical
The documentation was not compliant with Good Documentation Practice due to the presence of unsigned and untraceable corrections, and some records had been made in pencil. (e.g. Temperature monitoring record)	(WHO TRS 1025 Annex 7 17.5)	✓	✓	Major
Standard Operating Procedures and any related documents are not complete, signed, dated and controlled and do not follow a uniform format (e.g. No document Number and poor records retrieval).	(WHO TRS 1025 Annex 7 17.1 & 17.3)	✓	✓	Major
There were considerable gaps in temperature records.	(WHO TRS 961 Annex 9 9.3.1)	✓	✓	Major
Records relating to the storage of pharmaceutical products are not readily available upon request such as temperature monitoring record/logbook	(WHO TRS 1025 Annex 7 13.1, 17.1 & 17.9)	✓	✓	Major

and stocks inventory.				
All records of all receipts of pharmaceutical products from suppliers are not provided/presented (e.g. Sales Invoices and Delivery Receipts)	(WHO TRS 1025 Annex 7 17.10)	✓	✓	Major
Documents are not reviewed and updated based on existing processes.	(WHO TRS 1025 Annex 7 17.2)	✓	✓	Others
Self-Inspection				
The management failed to conduct an evaluation of the self-inspection report and corrective action were not address within the defined timeline.	(WHO TRS 1025 Annex7 11.5)	✓	✓	Major
Self-inspection had not been performed as defined in the procedure.	(WHO TRS 1025 Annex7 11.1 & 11.2)	✓	✓	Major
The results of self-inspections are not recorded.	(WHO TRS 1025 Annex7 11.4)	✓	✓	Others
Activities and Operations				
Temperature monitoring during transport of time- and temperature- sensitive pharmaceutical products (TTSPPs) is not conducted.	(WHO TRS 961 Annex9 6.4.2, 6.5.1)	✓		Major
Shipping containers used for transportation of TTSPPs are not capable of maintaining the temperature range needed as stated in the product label.	(WHO TRS 961 Annex9 6.8.3)	✓		Major
Shipping containers of cold-chain pharmaceutical products do not bear labels providing sufficient information on handling and storage conditions and precautions to ensure that the products are properly handled and secure at all times.	(WHO TRS 961 Annex9 6.4.2, 6.9)	✓		Others
Temperature-controlled vehicles directly owned and/or operated are not qualified before it becomes operational.	(WHO TRS 961 Annex9 6.6)	✓		Others
Equipment used for temperature monitoring was not calibrated and not suitable for its intended use.	(WHO TRS 1025 Annex 7 12.22, 12.37)	✓		Others

There is no temperature monitoring device in the temperature-controlled road vehicles used for the transport of TTSPPs that ensures that it is transported within the product's temperature profile.	(WHO TRS 1025 Annex7 18.24, WHO TRS 961 Annex9 16.4.2)	✓		Others
Temperature excursion during transport were not investigated.	(WHO TRS 961 Annex9 9.1)	✓		Major
Contract/ Outsourced Activities				
There are no written contract/agreement defining the responsibilities of each party including compliance with the guideline and the principle of GDSP and relevant warranty clauses with Suppliers, sub- distributors and 3rd Party Warehousing.	(WHO TRS 1025 Annex7 19.2)	✓		Others
The quality agreement between the suppliers and sub distributors is not duly notarized, signed by appropriate parties, and does not define the responsibilities of all entities and the conditions of subcontracting compliant with GDSP guidelines.	(WHO TRS 1025 Annex7 19.2)	✓		Others
Authorized distributors or third-party warehousing and transportation logistics were not audited periodically.	(WHO TRS 1025 Annex7 19.3)	✓		Others