MCAZ Medicines Control Authority of Zimbabwe

106 Baines Avenue
Tel: +263 242 736 981-7
708 255 / 792 165 / 0772 145 191/2/3
Email: mcaz@mcaz.co.zw
Website: www.mcaz.co.zw

P.O. Box 10559
Harare
Zimbabwe

REF: B/279/4/90/2023

27th March 2022

Theon Pharmaceuticals Ltd
Village-Saini Majra,
Tehsil-Nalagarh,
Distt.:Solan-174101(Himachal Pradesh),
INDIA

ATTENTION: Head Quality

Dear Sir/Madam

RE: INSPECTION OF A MANUFACTURING PREMISES – THEON PHARMACEUTICALS LTD VILLAGE-SAINI MAJRA, TEHSIL-NALAGARH, DISTT.:SOLAN-174101 (HIMACHAL PRADESH), INDIA

We refer to the inspection of the above-mentioned premises, to verify compliance with current Good Manufacturing Practices (cGMP) conducted from the 27th to 29th of October, 2022.

The summary of the inspection report was tabled at the 573rd meeting of the Registration Committee held on the 08th of March 2023. Based on the areas inspected, the people met, and the documents reviewed, and considering the findings of the inspection, the manufacturer, **Theon Pharmaceuticals Ltd Village-Saini Majra, Tehsil-Nalagarh, Distt.:Solan-174101(Himachal Pradesh), India** was found to be operating at an acceptable level of compliance with cGMP guidelines for the manufacture of general dry powder for injection and general oral dosage forms (tablets and capsules).

Based on the inspection, approval was given to **Theon Pharmaceuticals Ltd Village-Saini Majra, Tehsil-Nalagarh, Distt.:Solan-174101(Himachal Pradesh), India** to manufacture products for the Zimbabwean market from the approved blocks.

Please be advised that the facility will be due for another inspection three (3) years from the date of last inspection in line with MCAZ risk scheduling process. You will be expected to make the necessary arrangements and communicate with our offices for the routine inspection of your facility before the due date.

Yours faithfully,
MEDICINES CONTROL AUTHORITY OF ZIMBABWE

.....
C. Samatanga (Mrs.)
for: **DIRECTOR-GENERAL**

S. No.	Observations	Category	Compliance	Remarks	Inspectors/ comments	Accepted yes /No
1.0	**Good Practices in Production**					
--	1. There were pictures without instructions in the change rooms on entrance to the DPI warehouse.	Major	We acknowledge the observation. Pictorial without instructions has been revised/replaced with correct pictorial and displayed. No impact on the SOP as all instructs are defined. Displayed Pictorial pics are attached as **Attachment-1.** With respect to this observation, other areas are also verified and wherever gap found, changes has been done.	Closed	The picture showing the instructions is accepted.	Yes
--	2. There were non-GMP water taps in the wash room on entrance to the DPI warehouse.	Major	The taps provided in the first change room are of push type, later after hand wash there is automatic/sensor based hand dryer and then provided the automatic IPA dispenser with sensor. The Tap provided is for ease of hand wash of employees including workers. Fresh gloves are being provided to all employees working in process areas. Later there is isolators at filling and sealing stage having inbuilt gloves.	Closed	The taps need to be hands free type where the employees use elbows instead of hands. These taps are still easy to use. All the processes after handwashing are acceptable.	Yes
--	3. Though there was temperature and humidity monitoring in the RM warehouse, there was two-point	Major	We acknowledge the observation. In existing we are monitoring temp/RH after every 4 hour and there was no	Closed	The temporary corrective action to have procedures for minimum and	

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	monitoring without continuous monitoring.		procedure for monitoring of min. and max. value. SOP (No. QA/207) for monitoring of temperature, RH and differential pressure has been revised through change control no. CC/I/22/022 to introduce the format for Minimum and Maximum Temp./RH record (Para 5.5.1). Revised SOP and implemented format (QA-207/F08) is attached as **Attachment-2.** Further, for continuous monitoring of environmental conditions, proposal is to install the BMS system is in process.		maximum values of temperature and humidity recorded is acceptable however please indicate when you will have the BMS system running.	
--	4. There was no procedure for cancelling the previous maximum temperature reading on the thermometer in the RM warehouse.	Major	In continuation to the above point, we have elaborated procedure in the SOP that after recording of min and max. reading from digital thermo hygrometer, it will be reset to cancel previous readings (Para 5.5.1). Revised SOP is attached as **Attachment-2.**	Closed	The procedure to cancel the previous maximum temperature reading after taking recordings is accepted.	Yes
--	5. Labels were not numbered individually during receiving.	Major	We acknowledge the observation, as immediate action the numbered labels shall be implemented for all Zimbabwe market products. Instructions has been given to the purchase department.	Closed	May you please attach pictures of the labels that have been numbered as a result of the immediate	No

S. No.	Observations	Category	Compliance	Remarks	Inspectors/ comments	Accepted yes /No
					corrective response to the observation.	
--	6. It was claimed that glove leak tests were being done, there was no procedure to show that glove leak tests had been carried out in the DPI filling section.	Major	We acknowledge the observation. In-house ORABS glove integrity test apparatus has been fabricated and implemented. SOP for physical inspection and leak test of ORABS gloves (SOP No. PD/077) has been prepared and implemented to handle the activity. Photograph of ORABS gloves tester and SOP is attached as **Attachment-3.** Training has been imparted to all concerned operators and supervisors.	Closed	The photographs are noted of. The documents to how that the glove leak tests were carried out will be reviewed in the next routine inspection.	YES
--	7. There was practice of individual carton weight verifications though there were no print outs for the weight verification from the balance.	Major	As per current procedure and practice, each carton is being verified by the qualified checkers and then weighing of cartons is in practice in presence of qualified packer before to insert in shipper or before to make the shrink wrap. Procedure to calculate the limit of cartons is also defined in the batch packing record. The limit to be defined is being verified by the production and IPQA. In-process checks procedure is in place. We have procedure in place for	Closed	Since the print outs may be too many for manual recording, online recording of the individual carton weights for weight verification may be more practical.	No

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			recording of final shipper weight in BPR, which is further being checked and verified by packing and QA persons. So, no impact observed. Weight print out of every carton is not feasible due to large batch size and difficulty to keep the prints in secure manner. For reference BPR is attached as **Attachment-4.** Precautionary, we are introducing the weight printout for the final pack i.e. shippers. To check the feasibility weighing balance vendor is called at site.			
--	8. Secondary packaging plastic wrapping for Ceftriaxone 1g was carried out at 130 degrees though the risk assessment tests had not been carried out to understand how this temperature affected the FG.	Major	We acknowledge the observation. Protocol based study has been performed to evaluate the risk of shrink wrapping temperature on the product. Though we are keeping/charging the stability samples with shrink wrap for which stability data and reports are available at site. Protocol based study has been performed. Protocol cum report (No. MIS/I/QA/01) is attached as **Attachment-5.**	Closed	The CAPA provided is satisfactory.	YES

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--	9. The magnifying glass used for punch set inspection was dusty even though there was evident from the log book that it had been used the previous day.	Major	We acknowledge the observation. The magnifying glass was found dusty, might be after usage it was not cleaned and placed in the kit. Training has been imparted to concerned persons to ensure cleaning after very usage. Further, SOP for handling, cleaning & storage of dies and punches (SOP No. PG/063) has been revised through change control number CC/G/23/001 to incorporate instruction for cleaning of dies and punches inspection kit (Para 5.10). Revised SOP and Training record is attached as **Attachment-6.**	Closed	Cleaning dies and magnifying glasses with a lint free cloth before and after use is acceptable. The training record is noted.	YES
--	10. There was no procedure for exclusion of materials in the sampling booth. Particle generating materials as cardboards were taken into the sampling booth. Menthol was packaged in a cardboard canister. Metformin was in a cardboard sack which was coated with a polybag on the inside.	Major	We acknowledge the observation. SOP for dispensing of raw materials (No. WG/009) has been revised through change control no. CC/G/22/078 to elaborate the procedure to ensure that raw material bags/containers which is generating foreign particles and getting torn shall be wrapped in poly bag before transfer in dispensing area and after dispensing activity same shall be replaced with fresh poly bag (Para 5.4.15).	Closed	Please outline the cleaning material to be used to clean packaging materials before transfer into the dynamic pass box. Wrapping particle generating material in a polybag before passing through the dynamic pass box is acceptable. However, how are you going to replace	YES

S. No.	Observations	Category	Compliance	Remarks	Inspectors/ comments	Accepted yes /No
			Revised SOP is attached as **Attachment-7.** Further, list of materials identified which are having such packaging issue and matter shall be discussed with respective vendors to improve or change the packing.		the polybag in the dispensing booth without foreign material shedding off from the packaging material.	
--	11. Some received goods` packaging material in the RM storage area was damaged. Medicines with damaged packaging materials included Azithromycin and Menthol. Cast iron on canisters for PVPK-30 USP/BP was rusting. The product had been received on the 18th of October, 2022 which was evident that it was already rusted on receiving. Four containers of the product had been received. The product was supplied by Omen Medicare but manufactured by Boai Maj Ltd. from China. There was no policy on management of products bought from brokers. API transport validation had also not been carried out. API products were being received without data loggers.	Major	We acknowledge the observation. Though, we have well defined procedure is in place to check the containers/packs integrity at the time of receipt of material and then to mention such discrepancy in the available checklist format. The materials which were identified in the audit with damaged or dented, it was might be during the handling of the materials later after receipt. Though the inside polybags of the containers were intact and in good shape. So, there is no risk with the material quality. We acknowledge that the cast iron lid of the PVPK-30 canister was rusted which as an immediate action has been replaced with the good lid. During review of SOP, it is found that specific instructions are not mentioned to handle such materials with damaged, torn or rusty	Closed	There may be need to improve handling of received materials so that fragile polybags are not damaged from the outside. Separating damaged and rusty packaged materials from the good, packaged materials awaiting for QA to communicate with the supplier is acceptable. The checklist to be used during receiving is noted. Training record is also noted.	YES

S. No.	Observations	Category	Compliance	Remarks	Inspectors/ comments	Accepted yes /No
			condition, So, respective SOP for receipt and storage of raw materials (No. WG/004) has been revised through change control no.CC/G/23/005 and incorporated specific instructions in procedure at para 5.3.7 and in check list format WG-004/F02 at sr. no. 4, 5 &16. Revised SOP is attached as **Attachment-8.** Further, retraining has been imparted to whole warehouse team to ensure such discrepancies in material receiving checklist and to ensure evaluation for such defects. Training record is attached as **Attachment-8.** Further, list of materials identified which are having such packaging issue and matter is under discussion with respective vendors to improve or change the packing. In continuation to the observation for API products were being received without data loggers, we have revised our SOP for verification of incoming vehicle bringing materials (No. WG/002) through change control no. CC/G/23/005 and incorporated		The corrective action to download data from data loggers before unloading materials from the delivery van is acceptable.	

S. No.	Observations	Category	Compliance	Remarks	Inspectors/ comments	Accepted yes /No
			procedure that temperature sensitive material or material which requires controlled temperature shall be received in refrigerated van with data logger (para 5.3.6, 5.3.7 & 5.3.8). W.R.T revision in procedure format for vehicle inspection report (No. WG-002/F02) has been also revised. Revised and effective SOP is attached as **Attachment-9.**			
--	12. Temperature and humidity were monitored twice. RM stock was controlled using ERP software. The window system was not active and no evidence was provided of the effect of using the ERP system on an inactivated window system.	Major	We acknowledge the observation. After Windows 10 update, it happened due to some bug or glitch. After troubleshooting, it has been fixed. But there is no any impact on ERP system. Reference Attached **as Attachment-10**.	Closed	The picture showing activated Windows 10 properties is acceptable	YES
--	13. Powder particles were accumulating on packaging materials for Glimepiride IP and Doxycycline IP. Damaged and folded aluminum canisters were also present in the storage area. The damaged packaging was for Metoprolol IP. It was not clear how QA handle situations of this nature. Glucosamine packaging materials had black residues on the sides of the outer covering.	Major	We acknowledge the observation. Though, we have well defined procedure is in place to check the containers/packs integrity at the time of receipt of material and then to mention such discrepancy in the available checklist format. The materials which were identified in the audit with damaged or dented, it was might be during the handling of the materials later after receipt. Though the inside polybags of the containers were intact and in good	Closed	There may be need to improve handling of received materials so that fragile polybags are not damaged from the outside. Separating damaged and rusty packaged materials from the good packaged materials awaiting	YES

S. No.	Observations	Category	Compliance	Remarks	Inspectors/ comments	Accepted yes /No
			shape. So, there is no risk with the material quality. We acknowledge that the cast iron lid of the PVPK-30 canister was rusted which as an immediate action has been replaced with the good lid. During review of SOP, it is found that specific instructions are not mentioned to handle such materials with damaged, torn or rusty condition, So, respective SOP for receipt and storage of raw materials (No. WG/004) has been revised through change control no.CC/G/23/005 and incorporated specific instructions in procedure at para 5.3.7 and in check list format WG-004/F02 at sr. no. 4, 5 &16. Revised SOP is attached as **Attachment-8.** Further, retraining has been imparted to whole warehouse team to ensure such discrepancies in material receiving checklist and to ensure evaluation for such defects. Training record is attached as **Attachment-8.** Further, list of materials identified which are having such packaging issue and matter is under discussion		for QA to communicate with the supplier is acceptable. The checklist to be used during receiving is noted. Training record is also noted.	

S. No.	Observations	Category	Compliance	Remarks	Inspectors/ comments	Accepted yes /No
			with respective vendors to improve or change the packing.			
--	14. There were some products stored on plastic planks on gang ways the RM storage area. Temperature mapping studies were not provided for the additional area. Additionally, different products were packed too close together that there was no space to move in between the columns. Metformin and Tranexamic Acid were stored too close.	Major	We acknowledge the observation. During audit it was found that some material were stored on the pallets in warehouse rather on the rack. But we are not agreed that the mapping study was not provided. The mapping study is available and it also cover whole area where the material was placed. Mapping study is attached as **Attachment-11.** We have also reviewed the SOP and found that location design for data loggers is also defined in the SOP. But we are agreed that the materials should be placed only on the racks rather it is on the pellets in between the racks or sides. Retraining has been imparted to whole warehouse and IPQA team to ensure proper placement of materials on its designated racks. Training record is attached as **Attachment-12.**	Closed	The revalidation report for temperature and humidity mapping TMR/O/PG/001-01 shows that temperature mapping was carried out in the RM storage areas however the report does not indicate how much of the storage area was covered in the study. The CAPA provided does not address the observation of products being packed too close.	YES

S. No.	Observations	Category	Compliance	Remarks	Inspectors/ comments	Accepted yes /No
			Material placed in between the racks has been properly arranged and placed on the racks.			
--	15. There was use of the same material codes for API and raw materials. This then meant there was a risk of using non dossier approved APIs for certain jurisdiction. A case in point was Ceftriaxone that had 3 vendors and all of them had the same material code IRMC00008. It was further noted that it was not clear from the materials picking list how the warehouse personnel would differentiate these materials.	Major	We acknowledge the observations. IRMC00008 has been dedicated for Vendor Sterile India which is being offered for Zimbabwe market. Validation and stability is performed with same vendor code. Similar approach shall be followed for other regulatory markets. Accordingly respective BMR has been revised through CC/I/22/028. Revised BMR and Vendor code list is attached as **Attachment-15 & 13.**	Closed	Assigning a unique material code per supplier is acceptable. The practice will be evaluated during the next routine inspection.	YES
--	16. Whereas there was a practice to ensure that residual contents in a canister would be used in the next BMR, this instruction could not be demonstrated from a BMR perspective.	Major	We acknowledge the observation. We have been incorporated to handle the loose container in campaign batch through MRN and remain loose quantity handle procedure in revised BMR (Para. 3.6 &3.7) BMR has been revised through change control no. CC/I/22/028. Revised BMR (No. BMR/CFXM/007/01) is attached as **Attachment-15.**	Closed	The instructions for using quantity from previously opened canisters and recording of any left over quantities in BMR CFXM/007/01 is acceptable. There is need to train personnel on this revised procedure.	YES

S. No.	Observations	Category	Compliance	Remarks	Inspectors/ comments	Accepted yes /No
--	17. For the BMR of ceftriaxone, it was noted that one operator had inspected all the vials post washing. This was despite the production manager indicating there was a practice of rotating these operators with provision for rest.	Major	We acknowledge the observation. We have been incorporated the procedure/instruction of post washing visual inspection in respective BMR (Para. 15.2) Also, we have followed the SOP No, PD/058, Title- Procedure of cleaning and operation of visual inspection machine. The respective SOP is already implemented and we have maintained the record of time break for visual inspectors, Format No.- PD-058/F01-03 BMR has been revised through change control no. CC/I/22/028. Revised BMR (No. BMR/CFXM/007/01) is attached as **Attachment-15.**	Closed	Incorporating the procedure in BMR with column for checker details is accepted. However, there is need to identify the root cause of this practice so that it may not be repeated in the future.	YES
--	18. From the BMR it was noted that the environmental conditions during line clearance would be written as OK in the BMR without recording the actual values.	Major	We acknowledge the observation. We have incorporated the provision to record Temp/RH monitoring during line clearance of all manufacturing stages in revised BMR. BMR has been revised through change control no. CC/I/22/028. Revised BMR (No. BMR/CFXM/007/01) is attached as **Attachment-15.**	Closed	Recording the observed humidity and temperature on stages in the BMR is accepted.	YES

S. No.	Observations	Category	Compliance	Remarks	Inspectors/ comments	Accepted yes /No
--	19. The Non-Viable Particle counts and the Viable Particle Counts were not attached to the BMR. It was not clear how these were then reviewed as part of batch release.	Major	We acknowledge the observation. We have been implemented to attach NVPC report in BMR during line clearance and after completion of filling activity. Also, started to attach the VPC report before release the batch. Provision has been mentioned in the BMR at Para 12.0. BMR has been revised through change control no. CC/I/22/028. Revised BMR (No. BMR/CFXM/007/01) is attached as **Attachment-15.** To ensure the viable count report with batch record, SOP for release of Finished Product (No. QA/049) has been revised through change control no. CC/Q/23/002 and incorporated check point in batch release checklist at point 9 (Format no. QA-049/F01). Revised SOP is attached as **Attachment-14** and shall be effective after training.	Closed	Including the procedures to Ensure that the NVPC have been performed and there are in the acceptable range and the media sterile plates are available for exposing n area to monitor VPC in line clearance of the BMR are acceptable.	YES

S. No.	Observations	Category	Compliance	Remarks	Inspectors/ comments	Accepted yes /No
--	20. It was noted from the BMR that there was provision to collect 105 samples for QC analysis, it was not evident from which part of the production run these had been sampled as the sampling times were not indicated.	Major	We acknowledge the observation. We have been incorporated the provision of finish sample, control sample & reference sample collection from initial, middle & end interval in revised BPR (Para 15). BPR has been revised through change control no. CC/I/22/028. Revised BPR (No. BPR/CFXM/007) is attached as **Attachment-15.**	Closed	--	YES
--	21. There was no monitoring or recording of interventions during the batch filling process. This was despite the fact that these had been challenged during media fill studies.	Major	We acknowledge the observation. We have been incorporated the provision of interventions during manufacturing in respective BMR (Para 16). BMR has been revised through change control no. CC/I/22/028. Revised BMR (No. BMR/CFXM/007/01) is attached as **Attachment-15.**	Closed	Incorporating the procedure to record machine breakdowns and stoppage during the filling process as part of the BMR is accepted.	YES
--	22. There was no provision to record in the BMR any deviations that would have occurred during the manufacturing process.	Major	We acknowledge the observation. We have incorporated the provision of deviations & change control recording in respective BMRs and BPRs. BMR and BPR has been revised through change control no. CC/I/22/028. Revised BMR and	Closed	In accordance to section 24, recording of deviations and the deviation approval or remarks in the BMR is accepted.	YES

S. No.	Observations	Category	Compliance	Remarks	Inspectors/ comments	Accepted yes /No
			BPR are attached as **Attachment-15 & 4.**			
--	23. The SOP for assigning shelf-life or for calculating shelf life of the finished product could not be produced during the inspection.	Major	We acknowledge the observation. SOP for Product Stability Studies Program (No. QA/026) has been revised through change control no. CC/Q/22/045 and incorporated procedure for shelf life assigning as per reference ICH guideline (Para 5.13.4). Annexure for estimation of shelf life has been introduced. Revised SOP is attached as **Attachment-16.**	Closed	Incorporating the procedure for estimating shelf life in accordance to the decision tree for data evaluation for retest/shelf life estimation is accepted. The practice based on this methos will be evaluated in the net routine inspection. Please attach relevant training records.	YES
--	24. The User privileges for the system that stores master copies could not be produced during the inspection.	Major	We acknowledge the observation. User privileges has been provided to the users systems maintaining master documents. List is attached as **Attachment-17.** Holistically, user privileges are also verified for employees in quality assurance who perform the issuance, BOM revision and updation, artwork review, spec/STP approval, etc.	Closed	User privileges list is noted.	Yes

S. No.	Observations	Category	Compliance	Remarks	Inspectors/ comments	Accepted yes /No
--	Cross Contamination 25. During the production tour, it was noted that the dispensary was said to be in a clean state. Upon request for dismantling of the return grills for the RLAF, it was noted that there were thick stains of powder that demonstrated that the inner side of the grills were not being cleaned. On request of the type cleaning procedure for the room, it was noted that it was not explicit that these grills had to be dismantled and hence cleaned during products change over. This meant there was high potential of products cross contamination in the RLAF.	Major	We acknowledge the observation. To investigate the matter, incident is logged. During review, it was found that the dispensing booth of another area was properly cleaned and there were no such stains were available. During investigation, it is also found that the personnel involved in the cleaning and verification activity are trained and aware about the procedure. So, the personnel negligence in this matter cannot be ruled out. Also during review of method factor and measurement factor, found that procedure for dismantling of grill and to clean the same is not defined in the respective SOP, method factor can also be not ruled out. As a CAPA, SOP for operation and cleaning of dispensing area has been revised and incorporated the suggested procedure. Training has been imparted for the revised procedure. Revised SOP and training record is attached as **Attachment-18.**	Closed	Cleaning the filter grills with a lint free cloth mopped with 705 IPA solution during Grade B cleaning is accepted. The training record is noted.	YES
--	**Batch release**	Major	a & b. We acknowledge the observation. To investigate the matter, incident (IN/I/22/005) is logged. During review and	Closed	a. The immediate correction to impart all	YES

S. No.	Observations	Category	Compliance	Remarks	Inspectors/ comments	Accepted yes /No
	26. The batch release process was not in a state of control a evidenced by the following; a. The Ceftriaxone batch under review was released by Neha Mishra on the 18/10/2022 at 0843hrs. This was despite the fact that she was not one of the authorized personnel on the premises. b. Furthermore, it was noted that the batch release certificate was generated on 18/10/2022 at 0843hrs whilst the sterility incubation period had only ended on 18/10/2022 at 1653hrs. c. Furthermore the person who had released the batch had only joined the facility in June 2022 and from her training records, she had not been trained on all key SOPs. Cases in point were key SOPs such as the one for release of finished goods.		investigation, found that the concerned person (Ms. Neha) training record for batch release was not available. But she was trained with the release procedure. During review, the probable root cause found that due to immediate left of concerned authorized person for batch release, the responsibility was taken care by Ms. Neha as she had the sufficient experience (5-6 years) for the particular activity in previous organization with same dosage form. At the time of joining she was assigned for the role of QMS activities and her training records for particular SOPs were in place. The root cause for this observation found that responsibility assigned without knowing the training of respective person by the HOD. As an immediate action, instructions given to stop the rights of release by Ms. Neha. Training has been imparted to the concerned person. Reviewed the ERP rights of the concerned persons deputed for the		batch release responsibilities to the HOD is accepted. b. The explanation of the root cause is noted however what is the corrective action to make sure that a similar situation will not be repeated in the near future.	

S. No.	Observations	Category	Compliance	Remarks	Inspectors/ comments	Accepted yes /No
			activities w.r.t their training record and assigned responsibilities. Release rights has been given to HOD only with having appropriate experience for the activity. Holistically, same has been also ensured in another blocks. b. We acknowledge the observation that the batch was released in the morning but results were reported at 16:53. When discussed with the concerned person, she respond that she had verbal communication that sterility test has been completed but she had not ensured the results from test report. Negligence from the work is the root cause of this observation. Identified the list of products which are being released by the concerned person and reviewed respective batch records/chemical and sterility reports/ release note and other relevant records as per review and release checklist. No any significant abnormalities are found in the testing data and batch records. All has been compiled in proper manner and are in place.			

S. No.	Observations	Category	Compliance	Remarks	Inspectors/ comments	Accepted yes /No
			Further, conditional release SOP for batch release is also in place in case of batch release for transit purpose. Training has been imparted to all concerned person for batch review and release before the release of product. Investigation report with supporting documents are attached as Attachment as **Attachment-19.** Job description. Authorized person list for release List of documents reviewed, released by Ms. Neha			
2.			Closed			
--	1. Though duct leakage tests were carried out initially during qualification, they were not performed regularly as part of preventive maintenance.	Major	We acknowledge the observation. SOP for Preventive Maintenance of Equipment (ER/001) has been revised through change control no. CC/G/23/003 and incorporated checkpoint to verify the duct leakage (Format No. ER-001/F54). Revised checklist is attached as **Attachment-20.** Also Leakage verification has been performed and wherever leakage observed has been arrested.	**HVAC**	Checking the leakages in ducting, duct joints, gaskets and insulation physically at operation and rest if any as shown on checklist number PM/048-01 is accepted.	Yes

S. No.	Observations	Category	Compliance	Remarks	Inspectors/ comments	Accepted yes /No
--	2. There were no tamper proof seals on the adjusting screws of all the magnehelic gauges of the AHUs. Additionally, there were no alert and action limits defined on the magnehelic gauges in the whole facility.	Major	SOP for operation and cleaning of AHUs (No. ER/054) has been revised through change control no.CC/G/23/003 and incorporated procedure to affix the tamper proof seal (Para 5.2.4) after damper adjustment. Also alert and action limit based on trend has been elaborated in the procedure at Para 5.2.5. Revised SOP is attached as **Attachment-21.**	Closed	The procedures to affix tamper proof seals and action and alert limits on all magnehelic gauges as instructed in SOP ER/054-06is accepted.	YES
--	3. The magnehelic gauge (MB/MHG/013) between the sterility room (Grade B) and the microbiology laboratory (Grade D) was not zeroing when the pass box door was opened. Additionally the pass box door was not flash fit. The metal grill on the return of the pass box had been removed during the inspection.	Major	As discussed during the audit, dynamic pass box concern has been rectified as vent pipe was squeezed but both doors were not opening at a time. Same we had assured during inspection also. Moreover sterility testing area is at positive pressure with respect to outside area. Flow of air shall always from higher cleaning level to lower. Metal grill has been immediately placed and same was apprised during audit. Supportings photographs are attached as **Attachment-22.**	Closed	The photographs are noted but the root cause of the observation has not been identified. Identifying the root cause will enable you to come up with a corrective action so that this similar situation will not be repeated.	No
--	4. There was no BMS at the facility to monitor key parameters such as	Major	We acknowledge the observation. Presently we have installed	Closed	The correction procedure to install	YES

S. No.	Observations	Category	Compliance	Remarks	Inspectors/ comments	Accepted yes /No
	pressure differential, temperature and humidity in the production areas.		calibrated digital thermo hygrometers in all process and storage areas. The monitoring of the environmental condition is after every 4 hrs. Temperature mapping of all storage areas for consecutive 3 days and with seasonal mapping is available at site. HVAC qualification and re-qualification is being performed at regular defined intervals and wherever required necessary actions are being taken. Viable monitoring of the areas is being performed as per the frequency defined in SOP and sufficient trend is in place. Pressure gauges monitoring of AHUs procedure is in place and whenever any excursion, procedure is defined to take the necessary action. Manual controlling with all supporting documents are in place. Environmental monitoring provision is also provided in the respective batch records and also being ensured at the time of line clearance and as per frequency defined in batch records. Doer and checker provision is provided.	31/07/23	calibrated digital thermohygrometers in all storage and process areas is accepted. Please ensure that these can record the maximum and minimum temperature and humidity recordings.	

S. No.	Observations	Category	Compliance	Remarks	Inspectors/ comments	Accepted yes /No
			Though, for continuous monitoring purpose and for auto controlling, we have started worked and quotations has been received. TCD: 30/06/23.			
--	5. It was further noted that there was no online particle counters in the dry powder section to be used during machine set up and during line clearance. Handheld devices were being used. There was no provision of recording potential interventions to account for any excursions from these manual systems and NVPC counts were only being done for 10 minutes not during the machine setup and up to the time when the filling process started.	Major	This is in continuation of observation, organization possess portable particle counter in which 1 cubic meter air is sampled from each location before start of activity, which means the NVPC activity is performed after machine part set up and before immediate start of activity. Moreover NVPC activity is also getting monitored at the end of activity before any cleaning, so if this remain with in limit so chances of any particle contamination is ellimaited as it matches the particle concentration of 3520 particles for 0.5 micron in both cases though it is before activity or after activity as limit for Grade A. Passive air sampling is a continuous process as exposure takes place till completion of activity, plates are kept from before activity after cleaning and get retrieved and replaced on a constant and recommended time interval. As we have no abrupt observation so level of area cleanliness with respect	Open	The CAPA provide does not address to the observation of not recording interventions from using handheld devices for particle counting. Monitoring NVPC activity at the end of the activity before cleaning and using that figure to assimilate the NVPC during the filling process is accepted.	Yes

S. No.	Observations	Category	Compliance	Remarks	Inspectors/ comments	Accepted yes /No
			to viable and non-viable criteria is assured.			
--	6. The PAO certificate for the aerosol used during HEPA leakage tests could not be produced during inspection.	Major	The certificate was represented during the documentation review. Might be missed to note during the discussion. For reference, certificate is attached as **Attachment-23.**	Closed	The certificate of analysis is noted.	Yes
--	7. For the grade B area recovery studies for the DPI area, the T_0 concentration was 1020for 0.5 micron particles and 12 for 5 micron particles. This was against the spec limit of 3520 for 0.5 microns and 29 for 5 micron particles. This then the 100:1 approach could not be demonstrated during the recovery studies.	Major	We acknowledge the observation. This might be happened due to overlook of the respective guidelines. SOP for requalification of AHU is reviewed and found compliant w.r.t procedure defined in ISO 14644. Training has been imparted to all concerned team of qualification and engineering. Training record is attached as **Attachment-24.** Requalification for recovery test shall be performed again as per the procedure. TCD: 15/02/23.	Closed 15/02/23	The training record has been noted. The requalification report will be reviewed in the next routine inspection.	Yes
--	8. The beta lactam containment control strategy could not be produced during the inspection.	Major	We would like to inform that the containment study has been performed for Beta block w.r.t General block.	Open	The validation report for detection of penicillin contamination in environment and general block	YES

S. No.	Observations	Category	Compliance	Remarks	Inspectors/ comments	Accepted yes /No
			Same was also represented during the audit. During the study all inlets and surrounding has been captured for the study. Further, we would also like to inform that the Beta lactam block is more than the 50 meters apart from the general block, which meets the territory requirements of separate facility. Containment study report is attached as **Attachment-25.**		PDR/O/PG/02-00 shows that all test parameters from swab testing and active air sampling were within specified limits.	
2.0			Closed			
--	1. It was noted that onsite audits were only being done for local manufacturer. Offshore manufacturers were being passed on desktop audits.	Major	We acknowledge the observation. The vendor audits are being performed on risk based approach. Off shore vendor approval are being done based desktop review and based on accreditation of the manufacturing unit from its territory. Further, we are making a contract with an agency to perform the vendor audits of off shore manufacturers. Accordingly SOP for vendor qualification (No. QA/021) has been revised through change control no. CC/Q/23/002 (Para 5.2.33).	**Materials Management** 30/06/23	The correction to engage a third party to carry out onsite audits of shore manufacturers is accepted. Please attach the technical agreement with the agency and the revised SOP.	YES

S. No.	Observations	Category	Compliance	Remarks	Inspectors/ comments	Accepted yes /No
--	2. During the facility tour, the warehouse rejected materials logbook had no entries in 2022 and it was reported that there had not been any rejects in the year. When inspectors visited the QC laboratory, it was noted a number of materials had been rejected in 2022 for OOS and these had not been logged in the rejected materials log book. Cases in point of material were Aceclofenac IP from Attis Remedica on the 29/4/22, Methylcobalamin IP, Aceclofenac Attis IP on the 06/06/2022 and Mefenamic acid from Parkleton Private rejected on the 18/07/2022.	Major	We acknowledge the observation. Investigation has been carried out and It has been concluded that the root cause of the reported incident is person negligence during the handling of rejected material (Not complies during the analysis with respect to may test like description, assay, RS) due to the lack of awareness and training on the Out of specification results (SOP No. QA/035). Training has been imparted to all concern .Investigation report and training attendance sheet is attached as **Attachment-26.**	Open	The investigation report for OOS not logged for the rejected raw materials enlisting risk cause identification using the 6M methods, impact assessment on other batches, vendor approval and training is accepted. The training record is noted.	YES
--	3. Out of specification reports for all these rejected materials could not be produced during the inspection as the manufacturer indicated that these were not being logged. The OOS logbook only indicated that one material had failed in the year under review.	Major	We acknowledge the observation. Investigation has been carried out and It has been concluded that the root cause of the reported incident is person negligence during the handling of rejected material (Not complies during the analysis with respect to may test like description, assay, RS) due to the lack of awareness and training on the Out of specification results (SOP No. QA/035). Training has been imparted to all concern .Investigation report and training attendance sheet is attached as **Attachment-26.**	Closed	The investigation report for OOS not logged for the rejected raw materials enlisting risk cause identification using the 6M methods, impact assessment on other batches, vendor approval and training is accepted. The training record is noted.	YES

S. No.	Observations	Category	Compliance	Remarks	Inspectors/ comments	Accepted yes /No
--	4. Whereas the SOPs for Vendor qualification provided for annual vendor ratings, it was noted that the approach to this rating was not define anywhere. There was no definition of the steps taken for each cumulative ratings. During the audit all the vendor ratings could not be produced.	Major	We acknowledge the observation. SOP for vendor qualification (No. QA/021) has been revised through change control no. CC/Q/23/002 to elaborate the procedure for annual vendor rating at Para 5.4. Revised SOP is attached as **Attachment-27.**	Closed	Rating vendors on a scale from 0 to 5 that is from worst to excellent after receiving ever consignment and then calculating the average score annually is accepted. Basing reinspection of vendors on average annual score and APQR results will be evaluated during the next routine inspection.	
--	5. There was no SOP for intelligence monitoring of vendors.	Major	We acknowledge the observation. SOP for vendor qualification (No. QA/021) has been revised through change control no. CC/Q/23/002. Vendor assessment questionnaire format has been revised to evaluate the quality system review of vendors like complaints, Recall and any not of standard issues from regulatory bodies at point no. 17.2.14,17.2.15,17.2.16 in format no. QA-021/F01. Revised SOP with training record is attached as **Attachment-27.**	Closed	The vendor assessment checklist shows sections where the vendor has to reveal information on any previous inspections from WHO, regulatory alerts, QMS procedures is accepted. The practice based on this checklist will be reviewed during	YES

S. No.	Observations	Category	Compliance	Remarks	Inspectors/ comments	Accepted yes /No
					the next routine inspection.	
3.0			Closed			
--	1. The cleaning validation approach was deficient in the following: a) The worst-case products had been identified using LD_{50} and not based on HBEL/ PDE values. b) There was no determination of PDE values of all the molecules and the washing detergents and regents from toxicological data and there for MACO was based on LD_{50}. 2. Whereas there was an SOP for continuous process verification that had been 05/2022. The change control for the addition of this procedure could not be produced during the inspection and furthermore there was no evidence of implementation of the same. 3. During the depyrogenation tunnel qualification it was noted that the failure safe interlock mechanism to stop the belt whenever there were excursions had not been changed. 4. There was no periodic health assessment report for the Oracle ERP system.	Major	1.We acknowledge the observation. We have defined the procedure in SOP to identify the worst case based visual, solubility, toxicity, dose criteria, and 10ppm criteria. No gap observed in the SOP. LD_{50} has been taken from the authenticated sources and based on LD50, NOEL, PDE and safe threshold value is being calculated. So, no impact observed on the existing validated cleaning validation. Though, to get the PDE value, we have identified the contract agencies and agreement is in process. PDE values shall be taken from the approved toxicologist. Further, we would like to inform and explain that we are not using any washing detergents and reagents in our cleaning procedures, hence not required to evaluate. 2. We acknowledge the observation. Presently we are evaluating the process through the APQR. For continuous process verification, validated excel shall be provided	**Qualification and validations** 28/02/23	Determination of worst case products and calculations of MACO based on LD_{50} shows acute toxicity effects whereas PDE/HBEL show chronic toxicity effects hence LD_{50} is not the best measure of maximum allowable carryover. The corrective action to engage an agency or PDE values is accepted. 2. The new SOP QA/085-00 on continuous process verification though without revision and effective dates but authorized on the 25th of January, 2023 is noted.	No

S. No.	Observations	Category	Compliance	Remarks	Inspectors/ comments	Accepted yes /No
			and dedicated person shall be deputed to record the process parameters w.r.t CPP and CQA before to release the batch. 30 batches CPP and CQA trending data shall be collected and then based on trending batch wise CPP and CQA shall be monitored. Separate SOP for Continuous Process Verification has been prepared and same is attached as **Attachment-28**. 3. Interlock mechanism & excursion of Depyrogenation tunnel during operation, we have proposed to perform the activity based on protocol. Need some time- **TCD-28/02/2023.** 4. We have reviewed our SOP for Computer System Validation (QA/076) where procedure for qualification and requalification of all computer systems is defined. SOP is attached as **Attachment-29.**		3. The CAPA provided for failure safe interlock mechanism to stop the belt during depyrogenation tunnel qualification is not satisfactory. Please provide more information on what any change control or risk cause identification documents that have been implemented. 5.The attached SOP was reviewed in May 2022. It doe not show any review on periodic health assessments.	
4.0			Open			
--	**1.** The incubation room was Grade D classified however there were no interlocking doors on entrance to the	Major	Interlocking doors on entrance to the incubation room from the unclassified corridor has been	**Quality Control**	The picture showing the airlock is noted.	

S. No.	Observations	Category	Compliance	Remarks	Inspectors/ comments	Accepted yes /No
	incubation room from the unclassified corridor.		provided. Enclosed Photograph of the same as **Attachment-30.**			
--	2. There were no offsite alarm notifications though the onsite alarm notifications were received visually. This was despite the fact that the incubation room was not open 24 hours.	Major	Offsite alarm notifications has been provided for all the BOD Incubators. Enclosed Photograph of the same as **Attachment-31.**	Closed	The picture is noted however the alarm qualification or challenge documents should have been submitted for review	No
--	3. A refrigerator was used for storing culture. A non-continuous temperature monitoring was in place.	Major	Continuous temperature monitoring has been made in place for better control over temperature monitoring in the Refrigerator.	Closed	The PQ should have been submitted.	No
--	4. Sterility testing room could not be fully inspected. The passbox was being used for sterility inspection purpose and this allowed partial view of the process.	Major	Pass box view glass has been extended and complete view to sterility testing area has been assured. **Attachment-22.**	Closed	The pictures have been noted.	Yes
Minor						
1.0						
--	**Raw Materials Receiving** 1. There was no checklist for checking the supply chain route traceability during receiving of raw materials in the R.M. Receiving Store. 2. There was no procedure for checking the authorization status of the delivery vehicle during receiving of raw materials.	Minor	1 & 2. We acknowledge the observation. We have initiated the process to get the agreement from supplier with its vendors and transporters to ensure the supply route traceability. Agreements shall be taken from all suppliers. Further, it is defined in the SOP that all temperature sensitive or material which required controlled	**Pharmaceutical Quality System**	The corrective action to get agreements with suppliers and vendors so that data loggers are placed in delivery vehicles is accepted.	

S. No.	Observations	Category	Compliance	Remarks	Inspectors/ comments	Accepted yes /No
	3. There was no procedure in the receiving of raw materials SOP on handling of canisters for sterile samples that come without satellite samples. 4. There was no procedure in the receiving of raw materials SOP on confirming storage conditions of raw materials in transit from the supplier to Theon pharmaceuticals.		temperature, shall be received in refrigerated van with data logger. We have revised our SOP for verification of incoming vehicle bringing materials (No. WG/002) through change control no. CC/G/23/005 and incorporated procedure that temperature sensitive material or material which requires controlled temperature shall be received in refrigerated van with data logger (para 5.3.6, 5.3.7 & 5.3.8). W.R.T revision in procedure format for vehicle inspection report (No. WG-002/F02) has been also revised. Revised and effective SOP is attached as **Attachment-9.** 3. We would like to clarify that procedure to ensure satellite sample with consignment is already defined in the SOP for receiving and storage of raw materials (SOP No. WI/006) and it is also the checkpoint in receiving check list. In case satellite sample not received with material, then it shall be hold in Hold Area and shall be requested to vendor to provide the same. If sample will not receive then material shall be returned to vendor/supplier. SOP (No. WI/006) is attached as **Attachment-32.**		2. Inspecting the vehicle suing SOPWG/002-05 is accepted. The practice will be evaluated during the next routine inspection. 3. the procedure to withhold receiving of sterile samples without satellite samples is accepted. 5. The CAPA provided is satisfactory.	

S. No.	Observations	Category	Compliance	Remarks	Inspectors/ comments	Accepted yes /No
			4. SOP for verification of incoming vehicle bringing material (SOP No. WG/002) has been revised and incorporated procedure that material which required controlled temperature shall be received in refrigerated van and also provided provision in checklist to ensure the same. Revised SOP is attached as **Attachment-9.**			
2.0			Closed			
--	1. The approach to periodic risk review was not elaborate in the SOP and as such risk assessment was a once off process without continuous risk review of potential failure modes. 2. Risk assessment of the HVAC system was deficient in that potential failure modes such as duct leakage, components failures and absence of audio visual alarms of both the service flow and in the production floors were not available. 3. Risk assessment done for ceftriaxone injection had not considered key components of the product such the fact that it was a sterile product and what risk mitigation mechanisms had been put in place to ensure API sterility throughout its lifecycle.	Minor	1. Procedure for periodic risk review for critical and major risk assessments is already defined in SOP for quality risk management (No.QA/021) at para 5.6.1.8 in current SOP. 2. Re-risk assessment of HVAC system has been performed and attached as **Attachment-33.** 3. Re-risk assessment of concerned product has been performed and attached as **Attachment-34.** 4. We would like to inform that the nitrosamine risk assessment represented to auditor was of Product, not of API. For API, separate risk assessment from vendor with declaration is available	**Quality Risk Management** 31/03/23	1.Please attach SOP for quality risk management 2. The failure mode, effects and criticality analysis is accepted. 3. The failure mode, effects and criticality analysis is accepted. 4.The CAPA provided is satisfactory.	YES

S. No.	Observations	Category	Compliance	Remarks	Inspectors/ comments	Accepted yes /No
	4. The nitrosamine risk assessment for the metformin had not included the step by step potential failure modes from the API manufacturing sequence to the API storage containers to the finished pharmaceuticals product. 5. Data integrity SOP had not been informed by risk assessment. **PQR** 6. The SOP for PQR stated that PQR would only be produced if 5batches or more were produced. It was not clear if previous year batches would be considered for trending of key material and products attributes.		as it is under scope of API manufacturer. For product related risk for nitrosamine has been evaluated in all aspects like risk due to excipients/APIs, water Air, utilities, MOC of equipment etc. Hence, no gap observed. Supporting documents are attached for reference as **Attachment-35.** 5. Risk assessment w.r.t Data integrity shall be performed department wise. TCD: 31/03/2023. 6. SOP for PQR has been revised through change control no. CC/Q/23/002 to incorporate the procedure that "Trending of data shall be done for 5 or more batches. If number of batches are less than five only data shall be compiled." Revised SOP is attached as **Attachment-36.**		5.The SOP will be evaluated in the next routine inspection. 6. The CAPA provided is satisfactory.	
3.0			Open			
--	**1.** The analyst worksheet was black and white for example the one for Metformin batch number MEF/22100057. These worksheets could easily be photocopied. **2.** The RM sample repository checklist was not available hence there was no procedure for checking the integrity of a sample during receiving.	Minor	We acknowledge the observation. Analyst work sheet are computer generated from validated LIMS software. All the printing machines cum photocopiers in quality control lab has been disabled for photo copy option and when it will take then water mark as copy will reflect on the print.	**Quality Control**	1. The CAPA provided is satisfactory. 2. The checklist include checking for appearance, condition	

S. No.	Observations	Category	Compliance	Remarks	Inspectors/ comments	Accepted yes /No
	3. The analyst allotment schemer was not displayed. This meant that the allocator did not have access to the schemer during allocation of duties. The number of samples allotted was not determined by the number of samples the analyst was already working on. 4. Whereas there were failure safe alarms for the cooling cabinets and incubation cabinets at the facility, it was noted that these had not been challenged during requalification. Furthermore it was noted that the alarms had no offsite notification capabilities. 5. It was noted that the COA for the qualification of WS by the external laboratory was not indicating the Reference lot number used.		2. We acknowledge the observation. To address the observation, SOP for sampling of raw materials (No. QC/L-01/003) has been revised through change control no.CC/G/23/004 and checklist has been incorporated to check the integrity of sample during receipt in QC Lab. Revised SOP is attached as **Attachment-37.** 3. We acknowledge the observation. SOP For Analyst certification in Quality control department (No. QC/L-01/27) has been revised through change control no. CC/G/23/004 and incorporated List of Qualified Analyst (QC/L-01-027/F05) for analyst allotment schemer. Further, SOP for Testing & release of raw material and finished goods (SOP NO. QC/L-01/005 &) has been revised through change control no. CC/G/23/004 and procedure elaborated that section head shall allocate the sample to the analyst with reference to their qualification after reviewed by the pending samples detail (Para 5.1.2). Both SOPs are attached as **Attachment-38.**		and sealing of container of sampled materials hence this is satisfactory. 3. The CAPA provided is satisfactory. 4. Failure safe mechanisms may need to be challenged during requalification. Since there is always someone 24 hours, there may be no need for offsite alarm notifications . 5. The COA showing the batch number of working	

S. No.	Observations	Category	Compliance	Remarks	Inspectors/ comments	Accepted yes /No
			4. The cooling cabinet provided in the QC lab is to keep the WS and RS at condition 2 to 8 deg. C. The cabinet is PLC controlled and equipped with integrated alarm provision. There is off line temperature monitoring throughout the day for 24X7 at the interval of twice in day. There is always a responsible person in each shift for monitoring purpose. Further, we have also Stand by cooling cabinet in case of any breakdown or excursion. 5. It is already part of current practice to mention the Lot/batch no. of reference standard on WRS COA, which also been shown and justified during the laboratory walkthrough. For reference, few COAS of WRS are **Attached-39.**		standard is satisfactory.	
4.0			Closed			
--	1. The conductivity sensor was not temperature compensated. 2. There was no temperature monitoring of the vent filter during thermal sanitization of the PW in the storage tank. 3. The functionally of the spray ball was only ensured during requalification	Minor	We acknowledge the observation. 1. We have reviewed the qualification documents and found certificate of conductivity sensor which confirms that the sensor is temperature compensated. The certificate is attached as **Attachment-40.** 2. As per the observation, we have replaced the existing housing of vent	**Water System**	1. The CAPA provided is satisfactory. 2. The CAPA provided is satisfactory. 3. The CAPA provided is satisfactory.	YES

S. No.	Observations	Category	Compliance	Remarks	Inspectors/ comments	Accepted yes /No
	but this was not done as part of preventive maintenance.		filter. New housing have the provision of temperature monitoring. Accordingly SOP for sanitization of purified water storage tank for mother loop (No. ER/273) has been revised for monitoring of vent filter housing temperature during sanitization process (Para 5.1.6) through change control no. CC/I/23/002. Provision for recording of temperature provided in Format No. ER-273/F01. Revised SOP is attached as **Attachment-41.** 3. We acknowledge the observation. To ensure the proper working of spray ball, checkpoint has been elaborated in preventive maintenance checklist of Purified water system (checklist no. PM/036) through change control no. CC/I/23/002. Revised checklist is attached as **Attachment-42.**			
5.0			Closed			
--	1. All deviations were closed within 30 days regardless of the level of deviation. 2. The SOP (SOP number QA/015-00) was silent on the way to handling recurring deviation. There was no	Minor	We acknowledge the observation. SOP for handling of deviation (QA/015) has been revised through change control number CC/Q/23/002 and time interval for critical, major and for minor has been defined. Also procedure for	**Deviations**	The CAPA provided is satisfactory.	YES

S. No.	Observations	Category	Compliance	Remarks	Inspectors/ comments	Accepted yes /No
	action required after identifying the recurring deviations.		handling of repetitive deviations has been defined at Para 5.5 Revised SOP is attached as **Attachment-43.**			
6.0			Closed			
--	1. The training planner was not matched against the actual training programmed.	Minor	We have reviewed the respective training documents of concerned employee. During review it was found that when the concerned employee Ms. Dipali had joined, she had completed all training as per on Job TNI. After completion of on job trainings she had also completed all trainings as per planner. So, no gap observed. Might be the observation was not addressed properly at the time of audit.	**Training**	The explanation is noted.	YES
7.0			Closed			
--	1. There was no procedure for handling repeat non-compliance observations in the SOP for carrying out self-inspections.	Minor	We acknowledge the observation. The SOP for Internal audits (No. QA/008) has been revised through change control no. CC/Q/23/002. Procedure for handling of repeated observation has been incorporated in the SOP at para 5.28. Revised SOP is attached as **Attachment-44.**	**Self-Inspection**	The CAPA provided is satisfactory.	YES
8.0			Closed			
--	1. There was no mock recall done that could be extrapolated to the Zimbabwean setting.	Minor	We acknowledge your suggestion. The frequency for Mock recall is every 2 year. Presently we have mock recall from Nigeria market of	**Recalls**	The explanation is satisfactory.	YES

S. No.	Observations	Category	Compliance	Remarks	Inspectors/ comments	Accepted yes /No
			year 2022 and same is attached as **Attachment-45** for reference. Presently, we have no any active batch in Zimbabwe market as last batch was manufactured in 2018 and expired in 07/2020, so, presently mock recall is not feasible. Whenever it will be available, we will consider for the mock recall study.			
	2.			Closed		

Conclusion

The premises was found operating at an acceptable level of cGMP. The premises shall be inspected in the next three(3) years from the last date of inspection.

Reviewed by:

Reviewed by: Rhoda Mudare Date:6th March 2023

Second Reviewer: Sly Mutyavaviri Date: 6th March 2023