Risk Based Joint Inspection Report

As per the said direction, the SOP and checklist benchmarking tool available at CDSCO website under public notice vide F.No. DCGI/Misc/2016(60) dated 26/05/2016 is used for the inspection purpose. The details are reported hereunder:**Name of the Manufacturing Unit**	
Address	
Mfg. Lic. No.	
Validity of License	
Constitution of the firm	
List of Directors/ Partners/ Proprietor	
License Issuing Authority	
Categories of drugs permitted to be manufactured	
Specify whether COPP has been issued to the firm	
Name and Designation of the Inspecting team members	
Site Specific Data	
No. of Products manufactured at site (during last year)	
No. of manufacturing blocks	
No. of Technical Personnel in Manufacturing	
No. of Technical Personnel in QA	
No. of Technical Personnel in QC	

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No. of Technical Personnel in Microbiology	
No. of Technical Personnel from another Department	
No. of Technical Personnel in R&D	
No. of technical personnel in Formulation development	
No. of Samples drawn by QC (during last year)	
No. of Samples declared OOS (during last year)	
No. of samples declared NSQ by Govt. Analyst (during last five year). Collect reasons for such failures and annexe with this checklist	

Observations should be descriptive without ambiguity and answer like "Yes" or "No" should be avoided

1	**Building and premises: -**		**Observations (guidance on what input to be given)**	**Rating**
1.1	Sch-M	Specify whether the whole facility is separated, dedicated and is not a part of any other non-drug facility.	The facility is seperated dosage form wise (Tablets / Capsules/ Steroid / non-Steroid/ SVP/LVP/ LCO/ External Powder etc.) , dedicated and not a part of any other non-drug facility. Refer point no. ----- Site Master File, Document No.--------.	
1.2	Sch-M	Specify whether the surroundings of the manufacturing area is clean and as per the SOP prescribed in this regard. (Mention the SOP nos.)	The manufacturing facility is located in 5 acre land out of which 1000 sft is built up area and remaining is open land with clean and green land scaping. The details specified in General building and surrounding maintenance as per SOPNo-----.	

1.3	Sch-M	Describe the pest, insects, birds and rodents control system followed in the premises. Specify pest control schedule- area wise, along with materials and methods used.	We have well defined Pest, insects and rodent control system. Insecticuters and rodent bait stations installed at all entry points where doors are exposed to outside of building. Pest Control activities are outsourced contract services and performed under supervision of responsible company employee once in a week. The area wise materials and methods used are detailed in Pest and Rodent Control system, SOP No……..	
1.4	Sch-M	What measures have been taken to make Interior surface (of walls, floors, and ceilings) smooth and free from cracks, and to permit easy cleaning Specify material of construction and finish for walls, ceiling, floor, coving etc. i.e. whether Epoxy or PU coated, kota / granite stone with epoxy sealed joints, solid / GI / gypsum / cal. Silicate board ceiling with epoxy, PU or any other pre-fabricated panel (GRP, powder coated SS or Aluminium etc.) paint.	To be updated from Site Master File	
1.5	Sch-M,	Specify the lux level maintained in various parts of the premise (Storage area, manufacturing area specially visual inspection, Laboratory areas etc.).	To be updated from Site Master File	
1.6	Sch-M,	Specify the air handling system used in various areas i.e. stores, production, packing, QC areas.	To be updated from Site Master File	
1.7	Sch-M,	Specify drainage system which prevents back flow and entry of insects and rodents into the premises. Specify number and location of drains installed.	To be updated from Site Master File	
2				

2.1	Sch-M,	Specify the position of rest and refreshment rooms and mention whether they are separated and not leading directly to the manufacturing and warehouse areas.	To be updated from Site Master File	
2.2	Sch-M,	Are there general change rooms in plant? specify number of washing station & toilets provided for number of users.	To be updated from Site Master File	
2.3	Sch-M,	Specify whether primary clean garments are provided for each personnel entering the factory premises.	To be updated from Site Master File	
2.4	Sch-M,	Is there in-house general laundry for garment washing / cleaning? If not, how garment washing is carried out and monitored.	To be updated from Site Master File	
2.5	Sch-M, Para	Whether change room facilities separated for both sexes.	Yes. Separate change room facilities are there for gents and women. Refer point no…. Site Master File Document No.-----.	
2.6	Sch-M, Para	Whether maintenance workshop is separated and away from production.	Yes. Separate maintenance workshop is there which is away from production.refer point no…. Site Master File Document No.-----.	
3				
3.1	WHO TRS	Is the men & material movement inside the factory premises, observed & checked through security system.	To be updated from Site Master File	
3.2	WHO TRS	Is CCTV available to control the Entry & Exit from Factory premises?	To be updated from Site Master File	
3.3	WHO TRS	Is there a system for identifying persons visiting the factory? How?	To be updated from Site Master File	
3.4	WHO TRS	What is the precautionary activity taken for the movement of carriers i.e., vehicles?	To be updated from Site Master File	
4				
4.1	Sch-M, Para	Verify whether a current drawing of the water system showing all equipment in the system from inlet to the points of use is available.		

4.1.1	Sch-M, Para	Specify the MOC of the water storage tank (Both PW & WFI) and its pipe line.	To be taken from Site Master File	
4.1.2	Sch-M, Para	Specify weather storage tank for WFI is steam jacketed.	To be taken from Site Master File	
4.2	Sch-M, Para	Specify whether water system validation/qualification has been carried out as per protocol and reports have been prepared and maintained.		
4.3	WHO TRS-970	Whether IQ protocol includes at least facility review, equipment specification vs. design, welding roughness testing on pipelines, absence of dead points / section in the pipelines, pipe and tank passivation, drawings, SOP for operations, cleaning, sanitation, maintenance and calibration of gadgets. Whether its report includes Conclusion / Summary, Data tables, Results, Conclusions, Protocol reference, Revision and approval signatures.	IQ protocol did not include at least facility review, equipment specification vs. design, welding roughness testing on pipelines, absence of dead points / section in the pipelines, pipe and tank passivation, drawings.	1
4.4	WHO TRS-970	Whether OQ protocol includes at least System production capacity (L/min), Flow type and water rate, Valve operation, Alarm system operation and Controls operation? Whether its report includes Conclusion / Summary, operations performed Data tables, Results, Conclusions, Protocol reference, Revision and approval signatures.	The record produced by the firm showed that OQ protocol did not include at least System production capacity (L/min), Flow type and water rate, Valve operation, Alarm system operation and Controls operation? Whether its report includes Conclusion / Summary, operations performed Data tables, Results, Conclusions, Protocol reference, Revision and approval signatures.	0
4.5	WHO TRS-970	Please specify whether Phase 1, Phase 2 and Phase 3 studies carried as part of PQ stages?	The record produced by the firm showed that Phase 1, Phase 2 and Phase 3 studies carried as part of PQ stages.	2
4.6	WHO TRS-970	Phase 1: Whether the operations parameters, cleaning and sanitation procedures & frequencies defined. Whether daily sampling records for every pre-treatment point and usage point for a period of 2 to 4 weeks maintained and SOP's prepared.	In the protocol the firm has incorporated parameters, cleaning, sanitation procedures & frequencies defined	2

4.7	WHO TRS-970	PHASE 2: Whether daily sampling records for every pre-treatment point and usage point for a period of 4 to 5 weeks after Phase 1 maintained and reviewed.	In 2nd Phase the firm has incorporated daily sampling records for every pre-treatment point and usage point for a period of 4 to 5 weeks after Phase 1 maintained and reviewed.	2
4.8	WHO TRS-970	PHASE 3: Whether weekly sampling records available of every usage point for a one-year period.	Yes, the weekly sampling records available of every usage point for a one-year period	2
4.9	Sch-M	Specify source of raw water and give details of treatment processes, sampling points, distribution and storage system for raw and purified water. Verify whether the Raw Water holding tank was sanitized as per specified SOP.	Source of water- Borewell Treatment process- Dosing of 2ppm Sodium hypo, multigrade filteration, activated carbon filtration, Softener, Pre-Ultra filtration, 2ppm sodium hypo dosing, 5 micron filtration, antiscalant dosing, 6 ppm sodium meta bisulphate dosing, 5 ppm sodium hydroxide dosing, double pass RO, EDI, post Ultra filtration. Refer Water treatment SOP/SOPs---------- Number of sampling points in water system: Raw Water- Purified water- WFI- Yes. Raw water holding tank is sanitized once in ---- days as per SOP No.----------	
4.10	Sch-M	Verify whether the softener column is regenerated as per the specified SOP.	Softener column is regenerated as per SOP no.----------	
4.11	Sch-M	Specify whether the quality of potable water used for the preparation of purified water meets the requirement of Schedule M in respect of microbiological limit.	The quality of potable water used for preparation of purified water meets the Schedule M requirements with respect to Microbiological limit. Refer Potable water Specification No.--------	

4.12	Sch-M	Specify whether the quality of Purified Water used for the preparation of WFI meets the requirement of IP/BP/USP.	The quality of purified water used for preparation of WFI meets requirements of IP/BP/USP. Refer Specification of purified water Specification no.-----	
4.13	Sch-M	What is the process for preparation of Water for Injection (WFI)?		
4.14	Sch-M	Specify the process of sanitization of SS storage tank of WFI.		
4.15	Sch-M	Specifywhether the quality of WFI meets the requirement of IP/BP/USP & Schedule M.		
4.16	Sch-M	Specify whether WFI is used for: 1) Bulk preparations of liquid injections 2) Final rinse of product containers for sterile preparations. 3) Final rinse of machine parts (for sterile preparations) 4) Preparation of disinfectant solutions for use in critical areas (for sterile preparations.)		
4.17	Sch-M	How bio burden in purified water & WFI are controlled / reduced (Mention the SOP no. followed in this regard).		
4.17.1	Sch-M	Specify whether WFI has been stored and circulated above 70 degree centigrade.		
4.18	WHO TRS-970	Verify whether the circulation rate of purified water & WFI is at least twice the storage capacity of the holding vessels per hour.		
4.19	WHO TRS-970	Verify the Dead leg of non-returned valve at the discharge point.		
4.20	WHO TRS-970	Specify how the circulation loop is sanitized. Verify the SOP.		
4.21	WHO TRS-970	Specify whether spray ball is used to wet the surface of head space in the storage vessel.		
4.22	WHO TRS-970	Specify whether pressure release valves are provided in the storage vessel.		
4.23	Sch-M	How water tanks are cleaned periodically and records maintained thereof.		

4.24	WHO TRS-970	Specify whether on line TOC test is available for WFI & PW.		
4.25	PIC/S Guidelines	Specify whether replacement of Air Vent filters on the purified/WFI water tank is carried out as per relevant SOP. Whether the provision to keep dry the vent filter is made.		
4.26	Sch-M	Specify the arrangement for preparation of pure steam & its use.		
4.27	Sch-M	Specify whether pure steam (condensate) used in production meets the microbiological specification of not more than 10 cfu/100ml and IP/BP/USP specifications of WFI.		
4.28	WHO TRS-970	Verify PQ of the PSG.		
4.29	Sch-M	Specify the system in place for the compressed gases / air used in the facility.		
4.30	ISO/PICS	Verify the qualification documents of compressed air system specially where it comes in contact with product or primary container.		
4.31	WHO TRS-970	Specify whether action and alert limits are followed based on qualification of water and compressed Air system.		
5				
5.1	Sch-M	Specify the system of disposal of sewage, and effluents (solid, liquid, and gas) from the manufacturing site. (Enclosed the copy of NOC obtained from State Pollution control board in this regard.)		
5.2	Sch-M	Mention the procedure for storage and disposal of rejected drugs and applicable SOP.		
5.3	Sch-M	Whether adequate records are maintained for the disposal of waste.		

5.4	Sch-M	Whether provision for disposal of bio-medical waste made as per the provisions of the Bio Medical Waste (Management and Handling) Rules 1996.		
6				
6.1	Sch-M	Whether all personnel prior to employment have undergone medical examination including eye examination and are all free from Tuberculosis, skin and other communicable or contagious diseases & thereafter at regular intervals.	All employees prior to employment undergo medical examination to ensure they are free from Tuberculosis, skin and other communicable or contageous diseases and thereafter once in a year. The employees who are assigned to perform visual inspection of product/ product containers undergo eye examination once in 6 months. Refer SOP on Employee Health Check up SOP No.----------.	
6.2	Sch-M	Whether investigational reports, e.g. of X rays etc. preserved. Whether records of such medical examination are maintained thereof	All medical investigational reports including x-ray and ECG for each emloyee are maintained employee wise in separate files and updated and maintained by HR official. Refer SOP on Refer Employee Health Check up SOP No.----------.	
6.3	Sch-M	Specify whether employees report their illness to the supervising authority before entering into the production area.	Yes. Employees are trained to report their illness if any to the supervising authorities before entering in to the production area Refer Employee Health Check up SOP No.----------.	
6.4	Sch-M	Specify whether person from infectious disease is barred to enter into production area.	Yes. Employees with infectious diseses are barred to entering in to the production area Refer Employee Health Check up SOP No.----------.	

6.5	Sch-M	Specify if any unhygienic practice is observed within the manufacturing areas.	As all employees are trained on health and hygine related GMP, such practice would be very rare situation. But if any unhygenic practice is observed, it is handled through unplanned deviation, thouhrouly investigated and CAPA implemented to avoid in future.	
6.6	Sch-M	Whether all personnel are trained to ensure high level of personal hygiene. Mention the SOP no. followed in this regard.	Yes. All personnel are trained to ensure high level personal hygine . Refer SOP on Employee Health and Hygine practices, SOP No.----.	
6.7	Sch-M	Specify whether cross over bench is in place in the change room and if so whether it rules out the possibility of dust particle entering the clean side.	Cross over benches are in place in all change rooms and it rules out possibility of dust particle entering the clean side.	
6.8	Sch-M	Whether arrangements provided for cleaning of outside dust and dirt from foot.		
7				
7.1	Sch-M	Specify whether basic training on GMP is provided to all personnel attached to production and quality control activity at the time of induction.	Yes. All personnel are trained on basic GMP for all Technical Departmental employees at the time of induction as well as periodically once in a year . Refer SOP on Employee Training , SOP No.--	
7.2	Sch-M	Specify whether specific training related to the job duty are provided to all personnel at the time of induction.	Yes. Refer Induction training SOP No.--------	
7.3	WHO TRS-986	Specify whether continuous training is provided.	Yes. All necessary on job training & GMP training is provided to all employees. GMP training is carried out periodically once in a year.	
7.4	WHO TRS-986	Specify whether concept of QA and its importance is part of training session.		

7.5	WHO TRS-986	Are all the persons associated with various production activities properly trained as per guidelines provided in WHO working document. Verify the assessment records of the training of few selected people who are associated with critical operations and procedure		
8				
8.1	WHO TRS-986	Is access to the area restricted to authorized personnel only.		
8.2	Sch-M	Whether adequate areas have been allocated for warehousing of Raw Materials, intermediates, Packaging Material, products in quarantine, finish products, rejected or returned products. How are these areas marked or segregated. Please specify the total area provided for warehousing.		
8.3	Sch-M	How the warehousing areas being maintained to have good storage conditions. Are they clean and dry and maintained within specified temperature limits?		
8.4	WHO TRS-986	Is there any SOP defining maximum exposure time at room temperature for thermolabile materials i.e. prior to storage in a refrigerator.		
8.5	Sch-M	Specify the storage arrangement provided for materials which are sensitive to temperature, humidity and light and how the parameters are monitored. Is cold room or deep freezers required for storage of goods?		
8.6	WHO TRS-986	Verify the Thermal mapping of the cold rooms or deep freezers		
8.7	Sch-M	Whether receiving and dispatch bays are maintained to protect incoming and outgoing materials.		

8.8	Sch-M	How incoming materials are treated and cleaned before entry into the plant. Please specify the cleaning system for the outer surface of the container.		
8.9	Sch-M	How quarantined materials are segregated from other materials. How access to quarantined area is restricted.		
8.10	Sch-M	Specify the system followed for storing passed raw materials.		
8.11	Sch-M	Whether proper racks, bins and platforms have been provided for the storage.		
8.12	WHO TRS-986	What is the control on entry of material and men into the sampling area? Whether reverse LAF have been provided for sampling. Whether log book for sampling booth maintained.		
8.13	Sch-M	Specify the storage arrangement provided for primary packaging materials.		
8.14	Sch-M	Specify the arrangements provided to sample the primary packaging materials foils, bottles, etc. which are used as such.		
8.15	WHO TRS-986	Specify sampling plan used.		
8.16	WHO TRS-986	Which type of sampling tools are used and how they are cleaned, dried and maintained.		
8.17	WHO TRS-986	How containers are cleaned before and after sampling. (Specify whether the sampling is carried out as per the current SOP).		
8.18	Sch-M	What provisions have been made for segregated storage of rejected, recalled or returned materials or products. How is the access to these areas restricted?		
8.19	Sch-M	How printed secondary packaging materials are stored in safe, separate and in secure manner.		

8.20	Sch-M	How printed packaging materials, product leaflets etc. are stored separately to avoid chances of mix-up?		
8.21	Sch-M	How labels, cartons, boxes, circulars, inserts and leaflets are controlled. ?		
8.22	Sch-M	How records of receipt of all labelling and packaging materials are maintained.		
8.23	Sch-M	Whether unused packaging materials return to the store or destroyed.		
8.24	Sch-M	How returned/unused packaging material like foils is controlled so as to prevent contamination and cross- contamination.		
8.25	Sch-M	Specify the arrangement provided for dispensing of starting materials.		
8.26	WHO TRS-986	What is the control on entry of material and men into the dispensing area? Whether reverse LAF have been provided for dispensing with back ground clean air supply.		
8.27	WHO TRS-986	Whether pressure differential is maintained between the dispensing and adjacent areas.		
8.28	WHO TRS-986	Specify the pressure differential maintained.		
8.29	Sch-M	Examine the record of the daily check of balances in the dispensing area.		
8.30	WHO TRS-986	How containers are cleaned before and after dispensing. Who carries out the dispensing?		
8.31	WHO TRS-986	Specify whether appropriate air velocity is maintained in sampling & dispensing areas which rule out any influence in the balance readings placed inside the RLAFs Benches.		
8.32	Sch-M	Specify whether the dispensing is carried out as per the current SOP.		

8.33	Sch-M	Specify whether dispensed material for each batch of final product are kept together and conspicuously labelled.		
8.34	Sch-M	What steps are taken against spillage, breakage and leakage of containers?		
8.35	Sch-M	How highly hazardous, poisonous and explosive materials, narcotics, and psychotropic drugs are handled and stored. How these areas are safe and secure.		
9				
9.1	Sch-M	Please specify the procedures followed for receiving and processing of in-coming materials (Starting materials and packing material). Verify the SOP.		
9.2	Sch-M	Whether first in / first out or first expiry principal has been adopted.		
9.3	Sch-M	How they are labeled and stored as per their status – Under Test, Approved and Rejected		
9.4	Sch-M	Whether incoming materials are purchased from approved vendors.		
9.5	Sch-M	Whether list of approved vendors is available to the user.		
9.6	WHO TRS-986	Specify the norms of vendor qualification.		
9.7	Sch-M	How damaged containers are identified recorded and segregated		
9.8	Sch-M	Whether each batch of a consignment is considered for sampling, testing and release.		
9.9	WHO TRS-986	Whether all the containers of each batch of starting materials sampled for identification test.		

9.10	Sch-M	Whether labels of raw material in the storage area have information like; a) designated name of the product and the internal code reference, where applicable, and analytical reference number; b) manufacturer's name, address and batch number; c) the status of the contents (e.g. quarantine, under test, released, approved, rejected); and d) The manufacturing date, expiry date and re-test date.	e)	
9.11	Sch-M	Whether separate areas are provided for under test, approved and rejected materials.		
9.12	Sch-M	How the containers from which samples have been drawn labelled.		
9.13	Sch-M	Please specify the procedures by which it is ensured that the raw materials which has been released by the Quality Control Department and which are within their shelf life are going to be used in the product.		
10				
10.1	WHO TRS-986	Verify whether access to production area is restricted to authorized personnel only.		
10.2	WHO TRS-986	Whether the facility is provided with a well-sealed structure with no air leakage through ceilings, cracks or service penetrations.		
10.3	WHO TRS-986	Whether entry and exit doors, for materials and personnel, have an interlock mechanism or other appropriate system to prevent the opening of more than one door at a time.		
10.4	WHO TRS-986	Specify the procedures for entry of maintenance people into the production area.		
10.5	WHO TRS-986	Whether the change rooms have an arrangement with step-over/cross-over bench.		

10.6	Sch-M	Is there any cris-cross flow of materials and men?		
10.7	Sch-M	Whether the premises and equipment are appropriately designed and installed to facilitate cleaning and decontamination.		
10.8	WHO TRS-986	Specify the position of IPQC lab in the manufacturing area.		
10.9	Sch-M	Specify whether non storage areas are used for storage of any material.		
10.10	WHO TRS-986	Specify the provisions for storage of dirty, washed and cleaned equipment in process areas.		
10.1	Sch-M	Specify how service lines are identified for nature of supply and direction of the flow.		
10.12	WHO TRS-986	Whether service lines in production areas are through service pendants. If not, how they are placed so as to avoid accumulation of dust.		
11				
11.1	WHO TRS-986	Please specify whether following parameters are qualified: – (IQ, OQ, PQ) – Temperature – Relative humidity – supply air quantities for all diffusers – return air or exhaust air quantities – room air change rates – room pressures (pressure differentials) – room airflow patterns – unidirectional flow velocities – filter penetration tests (HEPA) – room particle counts – room clean-up rates – microbiological air and surface counts where appropriate – operation of de-dusting – warning/alarm systems		
11.2	WHO TRS-986	Verify the SOPs for AHUs operation and cleaning.		

11.3	WHO TRS-986	Specify whether the facilities and premises have following basic air-handling characteristics: a) The absence of direct venting of air to the outside. b) Whether the facility is maintained at a negative air pressure to the environment. c) The precaution taken to prevent the infiltration into the core areas. d) Whether appropriate air pressure alarm systems as well as alert and action limit is provided. e) The type of HEPA filters used in the HVAC system f) Whether the change rooms are supplied with the same quality of air as supplied to the working area. g) The measures taken to prevent air flow from the primary packing area to the secondary packing area.		
11.4	WHO TRS-986	Whether HVAC system description includes: 1) Schematic drawings detailing the filters and their specifications 2) Number of air changes per hour 3) pressure gradients		
11.5	WHO TRS-986	Specify the emergency power systems in case of power failure.		
11.6	WHO TRS-986	Specify whether recirculated air is used. If yes, specify the proportion of fresh air supplied.		
11.7	WHO TRS-986	Whether risk assessment study has been carried out in case of return air/ recirculated air system. Verify the records thereof.		
11.8	WHO TRS-986	Specify what precaution has been taken during filter change of AHUs.		

11.9	WHO TRS-986	Whether all exhaust systems from the facility, including dust extraction systems, vacuum system exhaust, fluid bed drier exhaust, coating pan exhaust, etc., are passed through safe change filter housings and wet scrubber before being exhausted to the atmosphere.		1
11.10	WHO TRS-986	Whether all exhaust points outside the building are located as far as possible from air entry points, exit points and at a high level, to minimize the possibility of re-entrainment of exhaust air.		2
11.1	WHO TRS-986	Whether the return air ducts are checked periodically for dust accumulation.		X
11.11	Sch-M	Whether the dust collectors are located in a room maintained at a negative pressure.		X
11.12	WHO TRS-986	Whether the filters cleaning facility is maintained at negative pressure.		1
11.13	WHO TRS-986	Whether records for safe disposal of all contaminated filters and dust are maintained.		1
11.15	WHO TRS-986	Specify whether total No. of AHUs used to cover the whole production Area is commensurate with the requirements.		X
11.16	WHO TRS-986	Specify the Terminal Air Filter of various core areas.		2
11.17	WHO TRS-986	Specify the no. of Air Change maintained in various core areas.		2
11.18	WHO TRS-986	Specify the pressure balancing to segregate different areas.		2
11.19	WHO TRS-986	Are the returns risers cleaned during Product Change Over?		2

11.20	WHO TRS-986	Verify if the AHU's / HVAC systems have been shut down. If yes, the reasons there of such as cleaning & maintenance & the procedures for re-initiation / re-start of the systems		2
12	**Cleaning Validation: -**			
12.1	Sch-M	Is a validation performed to confirm cleaning effectiveness?	Cleaning validation was done as per SOP no LP/QA-39 for cleaning validation.	2
12.2	WHO TRS-986	Does the protocol define the selection criteria for products or groups of products subject to cleaning validation?	The firm has maintained protocol which define the selection criteria for products or groups of products subject to cleaning validation.	2
12.3	WHO TRS-986	Is data produced supporting the conclusion that residues were removed to an acceptable level?	The report produced by the firm shown that residues were removed to an acceptable level.	2
12.4	WHO TRS-986	Specify whether the validation is implemented to verify cleaning of: 1) Surfaces in contact with the product 2) After a change in product 3) Between shift batches.	Type A cleaning for batch to batch change and type B for product change .	2
12.5	WHO TRS-986	Specify whether the Validation Strategy include contamination risks & equipment storage time.	Cleaning validation includes dirty hold time and cleaned hold time studies for equipments.	2
12.6	WHO TRS-986	Whether Quality Control responsible of the sampling for cleaning verification?	The record produced by the firm shown Quality Control were responsible of the sampling for cleaning verification	2
12.7	WHO TRS-986	Whether personnel engaged in cleaning, sampling etc. trained.	The record produced by the firm showed personnel engaged in cleaning, sampling etc. were trained	2
12.8	WHO TRS-986	Specify whether acceptance limits been set for cleaning verification and are based on following criteria: 1) Visually clean. 2) 10 ppm in another product. 3) 0.1% of the therapeutic dose?	The record produced by the firm showed that acceptance limits were based on following criteria: 4) Visually clean. 5) 10 ppm in another product. 6) 0.1% of the therapeutic dose?	2
12.9	WHO TRS-986	Specify whether detergent residues and degradation products are investigated during validation.	The record produced by the firm showed that conductivity and PH were done to detergent residues and degradation products.	2

12.10	WHO TRS-986	Whether validation records include: Recovery study data, Analytical method, Acceptance Criteria, Swab recovery test, Signatures of the Quality Assurance Manager, Signature of the employee in charge of cleaning verification from Production and Quality Control.	The record produced by the firm showed that validation records include: Recovery study data, Analytical method, Acceptance Criteria, Swab recovery test, Signatures of the Quality Assurance Manager, Signature of the employee in charge of cleaning verification from Production and Quality Control.	2
13	**Manufacturing Operations and Controls: -**			
13.1	Sch-M	Whether the contents of all vessels and containers used in manufacture and storage is conspicuously labelled with the name of the products. Batch no, Batch Size, and stage of manufacture along with signature of technical staff.	Vessels and containers used in manufacture and storage is conspicuously labelled with the name of the products. Batch no, Batch Size, and stage of manufacture along with signature of technical staff.	2
13.2	Sch-M	Whether the products not prepared under aseptic conditions are free from pathogens like Salmonella, Escherichia coli, Pyocyanea etc.	The firm has not carried out pathogen specific test for finished product which concludes that products not prepared under aseptic conditions are free from pathogens like Salmonella, Escherichia coli, Pyocyaneaetc	0
13.3	Sch-M	If yes, pls give a brief account of measures taken to assure freedom from pathogens.	-	
13.4	WHO TRS-986	Verify whether handling of materials and products are carried out in accordance with the relevant SOP'S.	The firm has various SOPs for handling of materials.	2
13.5	WHO TRS-986	Specify Whether any deviation is approved in writing by a designated person and recorded.	As per records produced by the firm, deviation was approved in writing by a designated person and recorded.	2
13.6	WHO TRS-986	Is there an approved SOP for In process check?	The firm has SOP no LP/QA-065 for procedure for in process check.	2
13.7	WHO TRS-986	Is the personnel clothing clean, unstained & dust free, including shoes?	It was found that personnel clothing were cleaned, unstained & dust free, including shoes.	2
13.8	WHO TRS-986	Is there a cleaning SOP for slippers or shoes that is being used in the manufacturing area?	SOP no LP/SOP/PAD-020 procedure for footwear cleaning maintained.	2

13.9	WHO TRS-986	Whether process hold time studies has been carried out for various stages of production	SOP no PL/QA-061 Procedure for Hold time studies were maintained.	2
14	**Precautions against mix-up and cross-contaminations: -**			
14.1	Sch-M	Whether proper AHU, pressure differential, segregation, status labelling have been provided to prevent mix-up and cross-contamination in manufacturing area	In the RM store for general Tablets & Capsules block,the sampling and dispensing area has common AHU. It was found that common AHU provided in the Blister 1 of Beta Lactum Capsules Machine area and strip machine area.	0
14.2	Sch-M	Pls specify the areas of dust generation and mechanism involved in controlling the dust	Granulation, compression, capsule filling and dusting powder filling area generate dust and it was found that return riser were provided in said areas.	1
14.3	Sch-M	Do all the areas have their own independent air locks separately for men and material entry.	Air locks provided for men and material entry	2
14.4	Sch-M	What criterion of pressure differential has been set for production v/s adjoining areas.	Pressure differential has been found set for production v/s adjoining areas. However, during visit at granulation and compression areas of non beta-lactum pressure gauges were not found working and production was going on, no deviations were taken.	0
14.5	Sch-M	Whether processing of sensitive drugs like Beta lactam Antibiotics and Sex Hormones is done in segregated areas with independent AHU and proper pressure differentials along with demonstration of effective segregation of these areas with records.	It was found that processing of sensitive drugs like Beta lactam Antibiotics and Sex Hormones was done in segregated areas with independent AHU and proper pressure differentials along with demonstration of effective segregation of these areas with records.	2
14.6	Sch-M	Please specify what measures has been taken to prevent contamination of products with Beta Lactam Antibiotics, Sex hormones and cyto-toxic substances.	The firm has provided SOP no LP/QA- 26 for prevention of product mix up and cross contamination provided.	2

14.7	Sch-M	What measures has been taken to prevent mix-ups during various stages of production.	SOP no LP/QA- 26 for prevention of product mix up and cross contamination provided	2
14.8	Sch-M	Whether equipments use for production are labelled with their current status.	It was found that equipments use for production are labelled with their current status	2
14.9	Sch-M	Whether packaging lines are independent and adequately segregated.	It was found that packaging lines are independent and adequately segregated	2
14.10	Sch-M	How line clearance is performed. Whether records of line clearance are maintained according to appropriate checklist.	It was found that line clearance was performed. Records of line clearance were maintained according to the appropriate checklist.	2
14.11	Sch-M	Whether separate carton coding area has been provided or online carton coding is performed How carton coding procedure is controlled.	It was found that a separate carton coding area has been provided . QA has a procedure to control carton coding vide SOP no PL/SOP/PBI-027.	2
14.12	Sch-M	Please specify how temperature, humidity and air filtration are controlled in the areas where raw material and/or products are exposed and handled.	Temp and humidity was monitored twice a day for critical areas.	2
14.13	Sch-M	How access of authorized persons to manufacturing areas including packaging is controlled.	List of authorized persons found maintained.	2
14.14	Sch-M	Whether separate gowning provision is followed before entering the core areas.	It was found that separate gowning provision is followed before entering the core areas	2
14.15	Sch-M	Whether segregated secured areas for recall or rejected materials or for such material which are to be processed or recovered are provided.	It was found that secured areas for recall or rejected materials or for such material which are to be processed or recovered are provided.	2
14.16	Sch-M	Whether various operations are carried out in segregated areas.	It was found that various operations are carried out in segregated areas.	2
14.17	Sch-M	Are doors of all core areas closed at all times with interlock arrangements?	The firm has not provided door interlocking facility at General Non Beta-lactam and Beta-lactum section	0
14.18	Sch-M	Specify whether any SOP is followed to verify the effectiveness for prevention of cross contamination.	SOP no LP/QA- 26 for prevention of product mix up and cross contamination provided.	2

14.19	WHO TRS-986	Specify whether critical operations are carried out in closed system.	It was found that critical operations are carried out in closed system	2
14.20	WHO TRS-986	Specify the methods followed for product change-over.	SOP no LP/PC-002 provided for cleaning and product change over.	2
15	**Sanitation in the Manufacturing areas: -**			
15.1	Sch-M	Specify the cleaning procedure of the manufacturing areas and verify with the SOP in this regard.	The firm has provided SOP No-LP/QA-039 for cleaning validation.	2
15.2	Sch-M	Whether the cleaning procedure is validated.	As per records produced by the firm, cleaning procedure was validated.	2
15.3	Sch-M	Whether a routine sanitation program is in place.	As per records produced by the firm, a routine sanitation program is in place	2
15.4	Sch-M	Verify the SOP & the records in this regard.	No LPL/SOP/PAD-001& SOP No LPL/SOP/NPS-007 for routine sanitation and records of routine sanitization was produced.	2
15.5	Sch-M	Does the location facilitate cleaning of equipment as well as the cleaning of the areas in which they are installed?	It was found that the location facilitate cleaning of equipment as well as the cleaning of the areas in which they were installed.	2
15.6	Sch-M	Whether the production area is adequately lit.	It was found that production area was adequately lit	2
15.7	Sch-M	Mention lux levels observed in production, visual inspection and other areas.	Production area and other area s - LUX Levels not less than 300 and for visual inspection 3000 Lux	2
15.8	Sch-M	Specify in detail the procedure followed during product changeover.	SOP no LP/PC-002 provided for cleaning and product change over.	2
16	**Equipment: -**			
16.1	Sch-M	Whether the equipment are designed aiming to minimize risk of error and permit effective cleaning and maintenance in order to avoid cross contamination & buildup of dust.	It was found that equipment were designed aiming to minimize risk of error and permit effective cleaning and maintenance in order to avoid cross contamination & buildup of dust	2
16.2	Sch-M	Whether all equipment are provided with log book.	It was found that all equipment were provided with log book	2
16.3	Sch-M	Please specify the procedures to clean the equipment after each batch production.	SOP no LP/PC-002 provided for cleaning and product change over	2

16.4	Sch-M	Whether validity period for use after the cleaning of equipment is specified.	It was found that validity period for use after the cleaning of equipment was specified.	2
16.5	Sch-M	Whether separate area is provided for storage of machine parts etc.	It was found that separate area is provided for storage of machine parts etc	2
16.6	Sch-M	Whether balances and other measuring equipments with appropriate range are available in the Raw Material stores & production areas and they are calibrated in accordance with SOP maintained. Specify the calibration schedule of the balances.	Produced SOP for LP/QC/-065 for calibration, operation and cleaning of balance	2
16.7	Sch-M	Specify material of construction of contact parts of the production equipments.	SS 316L, SS 316 and SS 304	2
16.8	Sch-M	Which types of lubricants are used in the equipment. Specify the quality and control reference No. of these lubricants.	Firm informed that Food grade lubricants were used.	2
16.9	Sch-M	Specify the procedures to remove defective equipments from production areas.	The firm has not procedures/SOP to remove defective equipments from production areas	1
16.10	WHO TRS-986	Verify whether washing and cleaning of equipment are not a source of contamination.	Swap testing was carried out to	2
16.11	Sch-M	Whether all equipment is provided with an ID NO.	It was found that all equipment were provided with an ID NO	2
16.12	WHO TRS-986	Specify the procedures to clean the equipment after each batch production and verify with the SOP.	Type A/Type B cleaning was done as per SOP LP/PE-001	2
16.13	WHO TRS-986	Specify whether CIP or SIP is in place.	CIP and SIP was in place	2
16.14	WHO TRS-986	Specify whether the CIP / SIP system is qualified	Cleaning validation was carried out.	1
16.15	WHO TRS-986	Are there cleaning agent labelled with a catalogue no. indicating that they were received through the warehouse.	It was found that the cleaning agent labelled with a catalogue no. indicating that they were received through the warehouse.	2
16.16	WHO TRS-986	Are there records for preparation of cleaning agent?	The firm has produced records for preparation of cleaning agent	2
17	**Production Area for Sterile Preparation**			
17.1	**Building and Facilities: -**			

17.2	Sch-M	Specify the building is devoid of cracks especially in the Critical solutions preparation rooms, filling rooms, Sealing rooms.	No cracks in the Aseptic solutions preparation rooms, Filling rooms, Sealing rooms was observed. The firm was holding the valid product permission for Manufacturing of Dry Powder Injection (General Category) however no section was endorsed under plan layout and no area was provided for Manufacturing of Dry Powder Injection (General Category). As per BMR issuance register, it was found that they have manufactured 04 batches of Pantoprazole Dry Powder Injection from last 5 yearsand even the firm has not produced the product permission issued by SLA for manufacturing of Pantoprazole Dry Powder Injection.	X
17.3	Sch-M	Are the locations of services like water, steam, gases etc. Such that the servicing or repairs can be carried out without any threat to the integrity of the facility	It was found that the locations of services like water, steam, gases etc. Such that the servicing or repairs can be carried out without any threat to the integrity of the facility	2
17.4	Sch-M	Specify water lines pose any threat of leakage to the critical area	The water lines did not pose any threat of leakage to the critical area	2
17.5	Sch-M	Specify the manufacturing areas clearly separated into following Support Areas: 1) Washing of containers & closures 2) Storage of washed containers & closures 3) Sterilization of containers & closures 4) Preparation of bulk solution (critical/non critical) 5) Change room	Firm has provided the provision in the manufacturing area to maintain the required class of area in the manufacturing facility. i.e. manufacturing /mixing area class C, filtration, filling and sealing class A (Background class B).	2

17.6	Sch-M	Specify de-cartoning areas to remove outer cardboard wrappings of primary packaging materials segregated from the washing areas.	The firm has provided de-cartoning areas to remove outer cardboard wrappings of primary packaging materials segregated from the washing areas.	2
17.7	Sch-M	Specify whether particle shedding materials like wooden pallets, fibre board drums, cardboards etc. are taken into the preparation areas.	It was found that particle shedding materials like wooden pallets, fibre board drums, cardboards etc. were not taken into the preparation areas	2
17.8	Sch-M	Specify in the classified areas: 1) Walls are flat, smooth and devoid of recesses. 2) Surface joints like electric sockets, gas points flushed with walls. 3) Joints in the ceiling are properly sealed 4) Air grills and lights flushed with the ceiling. 5) Grade A & B areas devoid of sinks and drains. 6) Doors and windows made up of non-shedding materials. 7) Doors open towards higher pressure areas and close automatically due to air pressure.	The following was found that - Walls are flat, smooth and devoid of recesses. 1-Walls are flat, smooth and devoid of recesses 2-Surface joints like electric sockets, gas points flushed with walls. 3-Joints in the ceiling are properly sealed 4-Air grills and lights flushed with the ceiling. 5-Grade A & B areas devoid of sinks and drains. 6-Doors and windows made up of non-shedding materials. 7- Doors open towards higher pressure areas and close automatically due to air pressure.	2
17.16	WHO TRS-961 ANNEXE-06	Is there a glass panel between critical area & support area so that all operations in Grade A & B areas can be supervised from support areas?	It was found that a glass panel between critical area & support area so that all operations in Grade A & B areas can be supervised from support areas	2
17.17	WHO TRS-961 ANNEXE-06	Fire extinguishers are suitably fastened to the walls without gaps.	Fire extinguishers were suitably fastened to the walls without gaps.	2
17.18	Sch-M	Quality of the furniture used is smooth & washable and made of SS316.	Quality of the furniture used was smooth & washable and made of SS316	2
17.19	Sch-M	Change rooms entrance provided with air locks before entry to the sterile product manufacturing areas.	It was found thatv change rooms entrance provided with air locks before entry to the sterile product manufacturing areas.	2
17.20	Sch-M	How many change rooms are provided to enter into the critical areas?	Three change rooms were provided to enter into the critical areas	2

17.2	WHO TRS-961 ANNEXE-06	Specify an appropriate inter-locking system with visual and/or audible warning system installed to prevent the opening of more than one door at a time.	Provided appropriate inter-locking system with visual and/or audible warning system installed to prevent the opening of more than one door at a time.	2
17.2	Sch-M	Are the critical and support areas provided with intercom telephones or speak phones for communication purposes.	It was found that the critical and support areas provided with intercom telephones or speak phones for communication purposes.	2
17.2	Sch-M	Specify the critical areas and support areas provided with suitable air- locks or pass boxes with proper interlocking arrangements for material transfer.	Critical areas and support areas provided with suitable air- locks or pass boxes with proper interlocking arrangements for material transfer.	2
17.2	WHO TRS-961 ANNEXE-06	Specify whether dynamic pass box is used for material transfer between two different air class.	Provided dynamic pass box used for material transfer between two different air class	2
17.3	Sch-M	Specify the method of transfer of sterile rubber bungs & aluminum caps to the aseptic area.	Sanitisation by 70% IPA and provided pass box through UV treatment	2
17.3	Sch-M	Specify whether grade A/B area is devoid of sinks and drains.	It was found that the grade A/B area was devoid of sinks and drains.	2
18	**Air Handling System (Central Air Conditioning): -**			
18.1	Sch-M	Specify whether the Air Handling Units for sterile product manufacturing area are separated from those for other areas	It was found that the Air Handling Units for sterile product manufacturing area were separated from those for other areas	2
18.2	Sch-M	Give the Background Grade of air for following critical areas: 1) Aseptic filling area 2) Sterilized components unloading area for aseptic filling. 3) Batch manufacturing area for aseptic filling preparations. 4) Component washing and preparation area. 5) Change rooms to enter into Critical area.	Aseptic filling area- Background grade B Sterilized components unloading area for aseptic filling. Grade A/B Batch manufacturing area for aseptic filling preparations- Grade C Component washing and preparation area- Grade C/D Change rooms to enter into Critical area- Garde B/C	2
18.3	WHO TRS-961 ANNEXE-06	Specify the steps taken in air handling system to achieve the Grade A, B, C and D of air as per designated classified areas.	Provided AHUs to achieve the Grade A, B, C and D of air as per designated classified areas	2

18.4	Sch-M	Specify the recovery time of B & C zone from the time of personnel leaving the room after completion of operations and verify the records in this regard.	No such records provided.	1
18.5	Sch-M	Specify whether filling operations are challenged initially and there after periodically by simulation trials including sterile media fill.	As per records produced by the firm, filling operations were challenged initially and there after periodically by simulation trials including sterile media fill.	2
18.6	WHO TRS-961 ANNEXE-06	Specify the procedure followed for medial fill and the acceptance criteria.	SOP for LP/QA-063 for medial fill	2
18.7	WHO TRS-961 ANNEXE-06	Whether the medial fill trial is based on worst case situation taking into consideration all interventions, activities occurring during normal activity as well as worst case.	As per record produced by the firm, medial fill trial was based on worst case situation taking into consideration all interventions, activities occurring during normal activity as well as worst case	2
18.8	WHO TRS-961 ANNEXE-06	Whether simulation tests are repeated at defined intervals and after any significant modification to HVAC system, equipment or process.	As per records produced by firm at frequency of 6 months	2
18.9	Sch-M	Specify the number of air changes in Grade A/B and Grade C areas.	As per records produced by firm for Garde A/B NLT 70 and Grade C NLT 40 ACPH	2
18.10	Sch-M	Specify the air velocity maintained in Grade A Laminar Air Flow stations	As per records produced , Air velocity maintained in Grade A Laminar Air Flow stations was found 0.3 meter per second	2
18.1	Sch-M	Specify the differential pressure between areas of different environmental standards.	Between same classes NLT 1.0 mm water gauge and for different classes NLT 1.5 mm water gauge	2
18.1	Sch-M	Specify type of manometer installed for measurement and verification of Air Pressure Differential.	Provided manometer installed for measurement and verification of Air Pressure Differential.	2
18.13	WHO TRS-961 ANNEXE-06	Specify the air classification in final change room to enter A/B area.	Grade B	2
19	**Environmental Monitoring: -**			
19.1	Sch-M	Specify the temperature and humidity maintained in the critical areas.	Temp MLT 25 C and RH NMT 40%	2

19.2	WHO TRS-961 ANNEXE-06	Verify the area qualification records and specify whether the following were taken into consideration: 1) No. of Persons 2) ACPH (Air Changes per hours) 3) Particle count (Static & Dynamic) 4) Viable count (Static & Dynamic) 5) Temperature & Humidity 6) Air Sampling location and interpretation of results (Both viable and non-viable) 7) Whether the above method is in compliance with ISO 14644-1 8) Action and Alert limits for all the above parameters.	No number of persons were considered.	1
19.3	Sch-M	Mention the periodic monitoring frequencies of the followings: 1) Particulate Counts 2) HEPA filters integrity testing 3) Air Change rates 4) Air pressure differentials 5) Temperature and Humidity 6) Microbiological monitoring by settle plates and/ or swabs in Critical areas & Other areas	1-Particulate Counts- 6 months 2-HEPA filters integrity testing- 01 years 3-Air Change rates- 6 months 4-Air pressure differentials- Daily 5-Temperature and Humidity- Daily 6-Microbiological monitoring by settle plates and/ or swabs in Critical areas & Other areas- Daily (In injectable area only)	2
19.4	Sch-M	Does a written Environmental Monitoring Program exist?	SOP no LP/QA-035 for Environmental Monitoring Program	2
19.5	Sch-M	How long the settle plates are exposed in Grade A and other areas.	Minimum 4 hrs.	2
19.6	Sch-M	Verify the records of microbiological results also specify whether alert and actions limits are followed or not.	The firm has produced records of microbiological results also specify alert and actions limits were followed	2
19.7	Sch-M	What action is taken in case particulate and microbiological monitoring counts exceed the limits?	As per information produced by the firm no such deviation found	2

19.8	WHO TRS-961 ANNEXE-06	Specify what parameters are reassessed and approved before starting production and in case of major engineering modifications being carried out to the HVAC system of any area.	Area re-qualification to be carried out	2
20	**Garments:**			
20.1	Sch-M	Specify type of garments used in critical areas?	Lint free Sterile garments used in critical areas	2
20.2	Sch-M	Specify type of Zips used in garments	Zips not used in garments	2
20.3	Sch-M	Whether garments used in critical areas are sterile.	It was found that garments used in critical areas are sterile	2
20.4	Sch-M	Specify the process of sterilization of the garments & the practice followed to carry the sterilised garments to the final change room.	SOP no. LPL/SOP/QCM-022 for sterilization of the garments provided	2
20.5	Sch-M	Are garments, masks, gloves are changed at every work session?	It was found that garments, masks, gloves were changed at every work session	2
20.6	Sch-M	Are the gloves used made of latex or other suitable plastic material	Gloves are made of latex	2
20.7	Sch-M	Are powder free gloves used in clean rooms	Powder free gloves used in clean rooms	2
20.8	Sch-M	Are the gloves long enough to cover the wrists completely and allow the over-all cuff to be tucked in	Gloves long enough to cover the wrists completely and allow the over-all cuff to be tucked in	2
20.9	Sch-M	Are the foot-wear used made of plastic or rubber material	Foot-wear used made of rubber material	2
20.10	Sch-M	Are the foot-wear daily cleaned with a bactericide	Foot-wear daily cleaned with a bactericide	2
20.1	Sch-M	Does the safety goggles / numbered glasses worn inside the critical areas have side extensions	The safety goggles / numbered glasses worn inside the critical areas have side extensions.	2
20.1	Sch-M	Are safety goggles sanitized by a suitable method	It was found safety goggles sanitized by a suitable method-Autoclave	2
20.1	Sch-M	Specify the garment changing procedure documented	As per SOP No LPL/SOP/QCM-022	2
20.1	Sch-M	Specify whether operators are trained in garment changing procedure.	As per SOP No LPL/SOP/PBI-037	2

20.2	Sch-M	Specify a full-size mirror been provided in the final change room to ascertain that the operator has appropriately attired in the garments.	Provided full-size mirror been provided in the final change room to ascertain that the operator has appropriately attired in the garments	2
20.2	WHO TRS-961 ANNEXE-06	Specify how the garments used in clean areas are cleaned and sterilized.	SOP no. LPL/SOP/QCM-022 for sterilization of the garments provided	2
21	**Sanitation:**			
21.1	Sch-M	Specify the SOP followed for sanitation of sterile processing facilities and mention the SOP nos.	SOP No- LPL/SOP/NPS-007	2
21.2	Sch-M	Specify whether employees carrying out the sanitation of critical areas are specially trained for this purpose.	It was found that employees carrying out the sanitation of critical areas were specially trained for this purpose	2
21.3	Sch-M	Verify the training records.		
21.4	Sch-M	Specify the sanitizing agent/s used.	Verosil 20% for area sanitization	2
21.5	Sch-M	Specify the quality of water used for preparation of sanitising solution.	WFI used for preparation of sanitising solution	2
21.6	Sch-M	Specify the disinfectant used for hand sprays?	IPA 70% disinfectant used for hand sprays. However it was found that the firm has carried out validation/efficacy test of IPA 70 % solution used for sanitization purpose.	1
21.7	Sch-M	Specify whether disinfectant solutions are filtered through membrane into suitable sterile containers or sterilized before use?	Disinfectant solutions were filtered) through membrane into suitable sterile containers or sterilized before use.	2
21.8	Sch-M	Specify whether the diluted disinfectants bear ‘use before’ labels based on microbiological establishment of their germicidal properties & verify the records	It was found that diluted disinfectants bear ‘use before’ labels.	2
21.9	Sch-M	Specify whether fumigation is carried out in critical areas. If yes, specify fumigating agent and its conc. used.	Fumigation was carried out in critical areas Verosil 20% for area sanitisation.	2
21.10	Sch-M	Specify whether any SOP exist for the purpose of fumigation if so mentioned the SOP nos.	SOP No- LPL/SOP/NPS-016	2

21.1	Sch-M	Specify the cleaning procedure of critical areas.	SOP No- LPL/SOP/NPS-038 for cleaning procedure of critical areas	2
21.1	WHO TRS-961 ANNEXE-06	Specify whether particle monitoring in Grade A zones is undertaken for the full duration of critical processing including equipment assembly.	The firm has not produced records for particle monitoring in Grade A zones undertaken for the full duration of critical processing including equipment assembly	1
21.1	WHO TRS-961 ANNEXE-06	Specify whether particle monitoring in Grade B zones is undertaken for the full duration of critical processing.	The firm has not produced records of particle monitoring in Grade B zones undertaken for the full duration of critical processing.	1
21.1	Sch-M	Whether more than one sanitizing agent is used in rotation. If yes list the sanitizing agents their concentration and frequency.	As per SOP No LP/PD-003 more than one sanitizing agent was used in rotation .	2
22	**Equipment:**			
22.1	Sch-M	Specify whether the unit-sterilizers are double ended with suitable inter-locking between the doors.	It was found the unit- sterilizers were double ended with suitable inter-locking between the doors	2
22.2	Sch-M	Specify the initial effectiveness of sterilization process established by using microbial spore indicators.	As per SOP no LP/QM-006, for autoclave - GeobacillusStearothermophilus ATCC 7953 and for DHS Bacillus Atrophaeus microbial spore as indicators were used.	2
22.3	Sch-M	Specify whether thermal Mapping of heat sterilizers is carried out on regular basis. Check records.	As per records produced thermal Mapping of heat sterilizers was carried out on regular basis	2
22.4	Sch-M	Specify suitable vent filters and recording thermographs provided in autoclaves & dry sterilizers.	As per records produced, suitable vent filters and recording thermographs provided in autoclaves & dry sterilizers.	2
22.5	Sch-M	Specify HEPA filters for cooling air and recording thermographs provided in DHS/Tunnel.	0.3 micron HEPA filters used for cooling air and recording thermographs provided in DHS/Tunnel.	2
22.6	WHO TRS-961 ANNEXE-06	Specify whether provisions of CIP or SIP are available.	Firm has informed that they have provisions of CIP or SIP were available.	2
22.7	Sch-M	Specify whether pure steams are in use.	PSG was used for generation of pure steams	2

22.8	Sch-M	Specify filter integrity test carried out before and after the filtration process.	As per SOP No- LPL/SOP/NPS-022	2
22.9	Sch-M	Specify the material of construction of the equipment & glass containers.	As per records produced by the firm, Material of construction of the equipment as SS 316 & glass class 1 containers.	2
22.10	Sch-M	Specify the tubing used in critical areas	Type A tubing used in critical areas	2
22.1	Sch-M	Specify the qualifications of critical equipment.	Validation of autoclave shown. Graphs of bowie dick test not produced.	1
22.1	WHO TRS-961 ANNEXE-06	Verify the qualification, protocol and reports for the critical equipment.	Performance re-qualification report , protocol LP/PQ/ACV/P-001-01 for Autoclave ID No QCD/ALV/002 was verified	2
22.1	Sch-M	Specify SOPs available for each equipment for its operation and cleaning.	The firm has produced various SOPs for equipment operation and cleaning.	2
22.1	Sch-M	Specify whether the measuring devices attached to equipment calibrated at suitable intervals.	It was found that the measuring devices attached to equipment calibrated at suitable intervals.	2
22.2	Sch-M	Specify whether a written calibration program is available	SOP No LP/QA-027	2
22.2	Sch-M	Specify whether calibration status documented and displayed on the equipment and the gauges	It was found that calibration status documented and displayed on the equipment and the gauges	2
23	**Manufacturing Process**			
23.1	Sch-M	Specify whether the bulk raw materials and bulk solutions monitored for bio-burden periodically (solutions not to contain more than 100 cfu/ml).	As per records produced by the firm, bulk raw materials and bulk solutions monitored for bio-burden periodically (solutions not to contain more than 100 cfu/ml)	2
23.2	Sch-M	Specify the minimum possible time between the preparation of the solution and its sterilization or filtration through microorganism retaining filters followed.	12 hrs.	2
23.3	Sch-M	Specify the porosity of the filters when any external gases are coming into contact with the sterile product.	0.22 micron filter	2
23.4	Sch-M	Specify whether gas cylinders are kept out side of the critical areas.	It was found that gas cylinders were kept out-side of the critical areas	2

23.5	Sch-M	Specify the procedure of sterilization of washed containers.	By Autoclave	2
23.6	Sch-M	Specify whether the sterilized containers not used within an established time, rinsed with WFI and re-sterilized.	It was found that the sterilized containers not used within an established time, rinsed with WFI and re-sterilized.	2
23.7	Sch-M	Is each lot of the finished product filled in one continuation operation?	It was found that each lot of the finished product filled in one continuation operation	2
23.8	Sch-M	Specify whether all critical process is validated. Verify the records.	During review of product validation, discrepancies were found for the below product with respect of batch size. 1.For product Trimzole DS Tablets, process validation was carried out with B. Size- 20.40 Lakhs Tabs and the B. Size for actual manufacturing was 7.0 Lakhs tabs as per batch manufacturing record. 2.For product Paracetamol 500 Tablets, process validation was carried out with B. Size- 25.5 Lakhs Tablets and the B. Size for actual manufacturing was 12.24 Lakhs Tablets as per batch manufacturing record. 3.For product MicolabTablets , process validation was carried out with B. Size- 6.12 Lakhs Tablets and the B. Size for actual manufacturing was 4.0 Lakhs Tablets as per batch manufacturing record. 4. For product Abide Plus Tablets , process validation was carried out with B. Size- 1.2 Lakhs Tablets and the B. Size for actual manufacturing was 2.5 Lakhs Tablets as per batch manufacturing record	0

23.9	WHO TRS-961 ANNEXE-06	Verify the process validation protocol and reports for the critical operation.	The firm has not produced process validation protocol and reports of products- 1. Testosterone Propionate Injection USP 25 mg 2. Testosterone Enanthate Injection USP 250 mg 3.Hydroxyprogesterone Caproate Injection IP 100 mg 4. Iron Sucrose Injection USP 5. Grisolab Tablets (Griseofulvin 250mg Tabs).	X
23.10	WHO TRS-961 ANNEXE-06	Specify whether critical operations are carried out in closed system.	It was found that critical operations are carried out in closed system	2
24	**Aseptic processing and sterilization by filtration:**			
24.1	Sch-M	Specify whether the filling area is of Grade Aenvironment with Grade B background.	It was found that the filling area of Hormonal section was of Grade Aenvironment with Grade B background. It was found there was no separate entry and exit provided for the filtration room and manufacturing room of the Hormonal section. For batch manufacturing area (Grade C) person has to go through filling room (Grade A/B).	X
24.2	Sch-M	Specify the room classification of solutions preparation area which is sterilized by filtration.	Grade A Under LAF background B	2
24.3	Sch-M	Specify the filter used for sterilization of solution by filtration.	Sterile 0.45 and 0.22 micron PES filters used for sterilization of solution by filtration.	2
24.4	WHO TRS-961 ANNEXE-06	Specify the maximum possible time used for filtration process.	Maximum 6 hrs if there was a large batch size.	2
24.5	Sch-M	Specify whether integrity of the sterilizing filters is verified before and after use. If so, by which method.	It was found that integrity of the sterilizing filters was verified before and after use	2
24.6	WHO TRS-961 ANNEXE-06	Specify whether the personal working in the aseptic area is qualified for clean room procedure or not. If so, verify the training records.	As per the training records, the personal working in the aseptic area was qualified for clean room procedure	2

25	**Product Containers & Closures:-**			
25.1	Sch-M	Specify whether the containers and closures used comply with pharmacopoeia or other specific requirements.	The records produced by the firm, containers and closures used comply with pharmacopoeia	2
25.2	Sch-M	Specify whether Specifications, Test methods, cleaning procedures, Sterilizing procedures etc. are available of the containers/ closures and other component parts of drug packages.	By Autoclave	2
25.3	Sch-M	Specify whether the container & closures are compatible with the product without affecting its quality and purity. Verify the records.	It was found that the container & closures were compatible with the product without affecting its quality and purity.	2
25.4	Sch-M	Specify whether containers and the closures are finally washed with WFI before sterilization.	It was found that containers and the closures were finally washed with WFI before sterilization.	2
25.5	Sch-M	Specify whether a written procedure exist for washing of glass ampoules/vials.	As per SOP no. LPL/SOP/PBI-006	2
25.6	Sch-M	Specify whether the material quality of the stoppers and closures ensures that it does not affect the quality of the product and avoids the risk of toxicity.	It was found that the material quality of the stoppers and closures ensures that it did not affect the quality of the product and avoids the risk of toxicity.	2
26	**Sterilization**			
26.1	Sch-M	Whether the sterilizing processes have been validated (Dry heat, Moist heat, filtration, ETO, ionizations whichever applicable.	It was found that sterilizing processes have been validated (Dry heat, Moist heat, filtration)	2
26.2	Sch-M	Whether the validity of the process verified at regular intervals (at least annually)	Annually	2
26.3	Sch-M	Whether the terminal sterilizer's capacity is sufficient to sterilize one batch completely at one time. If not specify controls and measures taken in lot sterilizations.	NA	NA
26.4	Sch-M	Whether biological indicators used in monitoring of sterilization.	As per SOP no LP/QM-006, for autoclave - GeobacillusStearothermophilus ATCC 7953 and for DHS Bacillus Atrophaeus microbial spore as indicators were used	2

26.5	WHO TRS-961 ANNEXE-06	Verify that the probe is placed at the coolest point on the basis of validation studies	As per records produced by the firm, probe was placed at the coolest point on the basis of validation studies	2
26.6	WHO TRS-961 ANNEXE-06	Verify the qualification, protocol and reports for the sterilizers	The firm has produced qualification, protocol and reports for the sterilizers.	2
26.7	Sch-M	Whether the biological indicators stored and used as per manufacturer's instructions. Whether quality of BI's checked by positive controls.	Biological indicators stored and used as per manufacturer's instructions	2
26.8	Sch-M	Whether a clear means of differentiating 'sterilized' from 'unsterilized' products is in place. Specify.	It was found clear means of differentiating 'sterilized' from 'unsterilized' products was in place	2
26.9	Sch-M	Whether the label on the basket / tray or other carrier of product / component clearly states: ● Name of the material ● Its batch number ● Its sterilization status ● Indicator (in case it has passed through sterilization process)	It was found that label on the basket / tray or other carrier of product / component clearly states: ● Name of the material ● Its batch number ● Its sterilization status ● Indicator (in case it has passed through sterilization process)	2
26.10	Sch-M	Whether sterilization records including thermographs and sterilization monitoring slips attached with the Batch Production Record.	It was found that sterilization records including thermographs and sterilization monitoring slips attached with the Batch Production Record	2
27	**Sterilization (By Dry Heat)**			
27.1	Sch-M	Whether the sterilization cycle recording device of suitable size and precision provided in DHS/ Tunnel.	There was in-build facility for sterilization cycle recording.	2
27.2	Sch-M	Whether the position of temperature probes used for controlling and / or recording determined during validation and (where applicable) been checked against a second independent temperature probe located in the same position.	As per record produced by the firm, the position of temperature probes used for controlling and / or recording determined during validation and (where applicable) have been checked against a second independent temperature probe located in the same position.	2
27.3	Sch-M	Whether the chart forms a part of the batch record.	It was found that chart forms a part of the batch record	2

27.4	Sch-M	Whether sterilization cycle validated only by biological indicator and chemical indicators or physical validation is also carried out.	Sterilization cycle validated only by biological indicator and chemical indicators.	2
27.5	Sch-M	Whether the time allowed reaching the required temperature before commencing the measurement of sterilizing time, separately determined for each type of load.	As per records produced, the time allowed reaching the required temperature before commencing the measurement of sterilizing time, separately determined for each type of load	2
27.6	Sch-M	Are adequate precautions taken to protect the load during cooling after it has gone through the high temperature phase of a heat sterilization cycle	Adequate precautions were taken to protect the load during cooling after it has gone through the high temperature phase of a heat sterilization cycle	2
27.7	Sch-M	In case the cooling is affected with any fluid or gas in contact with the product, is it sterilized.	NA	NA
27.8	Sch-M	Whether the equipment air inlet and outlets been provided with bacteria retaining filters.	It was equipment air inlet and outlets been provided with bacteria retaining filters	2
27.9	Sch-M	In the process of sterilization by dry heat, does the equipment have: 1) Air circulation facility within the chambers 2) Positive pressure to prevent entry of non-sterile air	It was found that in the process of sterilization by dry heat, does the equipment have: 1- Air circulation facility within the chambers 2- Positive pressure to prevent entry of non-sterile air	2
27.10	WHO TRS-961 ANNEXE-06	Verify the sterilizer loading pattern & whether is complied with the validated loading pattern.	Sterilizer loading pattern was complied with the validated loading pattern.	2
27.1	Sch-M	Whether the process of dry heat sterilization intended to remove the pyrogens. If so, has the validation been done with challenge tests using endo-toxins.	It was found that challenge tests using endo-toxine were not carried out during validation of DHS.	1
28.	**Sterilization (By Moist Heat)**			
28.1	Sch-M	Whether recording of both temperature and pressure carried out to monitor the process.	It was found that recording of both temperature and pressure carried out to monitor the process.	2
28.2	Sch-M	Whether the control instrumentation independent of the monitoring instrumentation and recording charts.	The control instrumentation was independent of the monitoring instrumentation and recording charts	2

28.3	Sch-M	Whether the equipment has automated control and monitoring system, if so, have these been validated to ensure that critical process requirements are met.	The equipment has automated control and monitoring system and found validated	2
28.4	Sch-M	Whether the system and cycle faults are recorded inbuilt and also observed by the operator and record maintained.	The system and cycle faults were recorded inbuilt and also observed by the operator and record maintained.	2
28.5	Sch-M	Whether the readings of the thermograph during sterilization cycling are routinely checked by the operator against the reading shown by the dial thermometer fitted with autoclave.	The readings of the thermograph during sterilization cycling were routinely checked by the operator against the reading shown by the dial thermometer fitted with autoclave	2
28.6	Sch-M	Whether the sterilizer fitted with a drain at the bottom of the chamber If so, does the record of temperature at this position is recorded throughout the sterilizing period	The record of temperature at this position was recorded throughout the sterilizing period.	2
28.7	Sch-M	Are frequent leak tests conducted on the chamber of the autoclave on each day of operation.	Frequent leak tests conducted on the chamber of the autoclave on each day of operation	2
28.8	Sch-M	Whether all items to be sterilized (other than sealed containers) are wrapped for sterilization.	All items to be sterilized (other than sealed containers) were wrapped for sterilization.	2
28.9	Sch-M	Whether the wrapping material allows removal of air and penetration of steam ensuring contact with the sterilizing agent at the required temperature for required time	The wrapping material allows removal of air and penetration of steam ensuring contact with the sterilizing agent at the required temperature for required time.	2
28.10	Sch-M	Whether the wrapping prevent contamination after sterilization	The wrapping prevent contamination after sterilization	2
28.1	Sch-M	Whether the steam used for sterilization is of suitable quality and doesn't contain additives at a level which could cause contamination of the product or equipment.	The steam used for sterilization was of suitable quality and doesn't contain additives at a level which could cause contamination of the product or equipment.	2
29.	**Others:**			
29.1	Sch-M	Specify whether products released only after complete filling and testing.	SOP no LP/QA/060-procedure for release of batch for dispatch	2

29.2	Sch-M	Specify whether result of the tests relating to sterility, bacterial endo-toxins are maintained in the analytical records	it was found that result of the tests relating to sterility, bacterial endo-toxins were maintained in the analytical records	2
29.3	WHO TRS-961 ANNEXE-06	Whether process hold time studies has been carried out for various stages of production	As per SOP No- LP/QA- Procedure for Hold Time Studies.	2
30.	**Documentation and Records**			
30.1	Sch-M	Whether all daily documents are filled correctly and timely.	Yes, found filled at the time of injection	2
30.2	Sch-M	How the documents are designed, prepared, reviewed and controlled to provide an audit trail.	The firm has no policy for audit trail while issuing the documents.	0
30.3	Sch-M	Whether documents are approved signed and dated by appropriate and authorized person.	The documents found signed by the persons	2
30.4	Sch-M	Whether documents specify title, nature and purpose.	Yes documents specified with title, nature and purpose	2
30.5	Sch-M	Whether documents are regularly reviewed and kept up to date.	Yes found reviewed	2
30.6	Sch-M	Whether the records are made at the time of each operation in such a way that all significant activities concerning to the production are traceable.	Yes found prepared during inspection	2
30.7	Sch-M	Whether data is recorded by electronic data processing system or by other means. If by electronic data processing system then how access is controlled to enter, modify etc. the data.	The firm is not having any SOP and procedure in place for preserving the data electronically.	0
30.8	Sch-M	Whether master formula and detailed operating procedures for each product are available?	At the time of inspection MFR of Medoxyprogestrone is not found prepared.	0
30.9	Sch-M	Specify the duration of retaining the documents after the expiry of the respective product and who is responsible for its maintenance.	As per SOP LP/QA-025	2
	Do the manufacturing records pertaining to			

	manufacture of Sterile & Non- Sterile products indicate the following details: Serial number of Batch Manufacturing ,Record ,Name of the product, Reference to Master Formula Record, Batch/ Lot number, Batch/ Lot size, Date of commencement and completion of manufacture, Date of manufacture and assigned date of expiry, Date of each step in manufacturing, Names of all ingredients with reference number given by the quality control department ,Quantity of all ingredients, Time and duration of blending, mixing etc. where ever applicable, PH of solutions whenever applicable, Filter integrity testing records, Temperature and humidity records whenever applicable, Records of plate-counts whenever applicable, Results of bacterial endo-toxin and toxicity, Records of weight or volume of drug filled in containers, Bio burden records before sterilisation, Leak test records, Inspection records, Sterilization records including load details, date, duration, temperature, pressure etc. Container washing & testing records, Total number of containers filled, Total number of containers rejected at each stage, Theoretical yield, permissible yield, actual yield and variation thereof, Clarification for variation in yield ,beyond permissible yield, Reference number of relevant analytical reports, Details of re-processing, if any, Names of all operators carrying out different activities, Environmental monitoring records, Specimens of different packaging material, Records of destruction of rejected containers and packaging material, and Signature of the competent technical staff responsible for manufacture and testing.		The BMR of Iron sucrose Injection Batch No. EHFSI-001, M/D 03/2023, E/D 02/2025 was verified and found incorporated all parameters mentioned .	1
31	**Labels and Other Printed Materials: -**			
31.1	Sch-M	Whether the printing is in bright colour and legible on labels and other printed materials?	Yes found legible	2
31.2	Sch-M	How printed labels (art work) are approved. Verify the SOP.	The firm is having SOP no. QA-041	2
31.3	WHO TRS-986	Specify whether cut labels or rolled labels are used.	Firm has not produced records of cut labels or rolled labels used.	1

31.4	Sch-M	Whether the labels comply with requirements of Rule 96 & 97 & other relevant provisions	The firm is having SOP for Art work approval vide no. LP/QA-041, however details of Rule 96 and 97 were not mentioned in details in said SOP. It was found that the firm was manufacturing Products i.e. 1-Gentamicin, ChlorpheniramineMeleate and Zinc Suplhate Eye Drops and 2. Ciprofloxacin, ChlorpheniramineMeleate and Zinc Suplhate Eye Drops however it was found that using benzalkonium chloride (**BKC**) as preservative in both products. However, on review of the label and product carton, no preservative was mentioned however Schedule FF of D&C Rules and IP mentioned that for Ophthalmic preparation, preservative should be mentioned on product label.	X
32	**Master Formula Records: -**			
32.1	Sch-M	How master formula records for each product are prepared, authorized and controlled.	The firm is having SOP LP/QA-031 for preparation and control of MFR.	2
32.2	Sch-M	Whether master formula is batch size specific.	The Master formula is not batch specific	0
32.3	Sch-M	Whether master formula record covers all the points as prescribed in Schedule 'M'.	The format includes all parametres described inline with	2
32.4	WHO TRS-986	Whether master formula record covered all the points as prescribed in WHO-TRS 986 & PIC/S guidelines	Master formula record does not covered all the points as prescribed in WHO-TRS 986 & PIC/S guidelines	0
33	**Batch Processing / Manufacturing Records: -**			
33.1	Sch-M	Whether the BPR/BMR for each product is prepared on the basis of currently approved master formula.	Yes found as per approved format	2
33.2	Sch-M	Whether BPR / BMR covered all the points as prescribed in Schedule 'M'	Yes found covered	2
33.3	WHO TRS-986	Whether BPR / BMR covered all the points as prescribed in WHO-TRS 986 & PIC/S	The firm is not considering the same.	1

33.4	Sch-M	Whether all the documents generated during Batch production are attached with the BPR /BMR	Yes found attached for some batches	2
34	**Batch Packaging Records: -**			
34.1	Sch-M	Whether authorized packaging instructions for each product of various pack size and type are maintained and complied with.	Yes as per shown the BM & PR of product Iron Sucrose Injection Batch no. EHFSI-001	2
34.2	Sch-M	Specify whether all material, equipment, rooms and packaging lines are labelled with an indication of product being processed with batch no.	Yes boards were displayed	2
34.3	Sch-M	Whether packaging lines are independent and adequately segregated.	The packing lines were found segregated	2
34.4	Sch-M	How line clearance is performed. Whether records of line clearance is maintained according to appropriate checklist.	The line clearance SOP QA-065 is in place	2
34.5	Sch-M	Do the packaging materials arrive on a covered trolley?	Cage trolly were found provided	2
34.6	Sch-M	Are packaging materials verified against a master set to ensure that they are the most recent edition and the correct materials for the batch?	Yes found verified by QA	2
34.7	Sch-M	Are the quantities of packaging materials verified against the amounts stated as dispensed from the warehouse?	Yes verified by QA	2
34.8	WHO TRS-986	Specify the monitoring code (bar code, pinholes etc.) for final packing materials.	Not for all products	1
34.9	Sch-M	Is the batch yield calculated immediately upon completion of packaging operation & prior to the introduction of a new batch into the area?	Yes the yield is calculated after that	2
34.10	Sch-M	Is the yield calculation independently verified by second individual and whether any significant deviation from accepted yield is recorded and investigated?	The yield was found calculated by the production officer and verified by QA. Till date no deviation is reported as per Deviation log.	2
34.11	Sch-M	Is any excess printed packaging material destroyed on completion of the batch?	Destroyed after completion	2

34.12	Sch-M	Is there a provision in the department for the separation of printed packaging material for destruction & rejected product?	There was no provision in the department for the separation of printed packaging material for destruction & rejected product	0
34.13	Sch-M	Whether Batch packaging record covered all the points as prescribed in Schedule 'M'	Yes found incorporated	2
34.14	WHO TRS-986	Whether Batch packaging record covered all the points as prescribed in WHO-TRS 986 & PIC/S	Batch packaging record does not covered all the points as prescribed in WHO-TRS 986 & PIC/S.	1
34.15	Sch-M	Whether all the documents generated during packaging are attached with the Batch packaging record.	Found attached with some BPRs	2
34.16	Sch-M	Whether BPR are based on current master formula record.	Yes MFR reference no. is mentioned	2
35	**Standard Operating Procedure and Records: -**			
35.1	Sch-M	Verify the List of SOPs and mention total number of SOPs followed by the firm.	The firm is having 547 SOPs in place	2
35.2	Sch-M	Has all the SOPs been displayed.	Displayed at various places	2
35.3	Sch-M	The formats, logs & SOPs arecurrent	Yes the formats , logs and SOPS were found current	2
35.4	Sch-M	Is any obsolete copy seen in the Area?	No copy of obsolete SOP is seen	2
36	**Reprocessing and Recoveries: -**			
36.1	Sch-M	Verify the SOP for reprocessing.	The firm is having SOP for re-processing No. LP/PT-029	2
36.2	WHO TRS-986	Whether reprocessed batch is subjected to stability evaluation.	Procedure was in place that reprocessed batch is subjected to stability evaluation .	1
36.3	Sch-M	Whether the recoveries are added into the subsequent batches. If yes specify the procedures.	No such policy	1
37	**Finished Product: -**			
37.1	Sch-M	Specify whether finished products are held in quarantine until their final release.	Yes the firm is releasing the FG only after the completion of all testing.	2
37.2	Sch-M	Specify the storage arrangement of finished products after final release by QA	The firm has provided FG store with appropriate area.	2
38	**Quality Control Area: -**			
38.1	Sch-M	Specify whether QC area is independent of production area.	Yes the QC Lab is situated in the second floor of General Block.	2

38.2	Sch-M	Specify the working space provided for QC:	The firm has provided chemical, instrumental, wet lab and microbiology laboratory.	2
38.3	Sch-M	Specify the procedure followed for approval/rejection of raw materials, packaging materials, intermediate products and finished products. Verify the SOP and record.	As per pharmasuit electronically controlled	2
38.4	Sch-L1	Specify the arrangement provided to protect sensitive electronic balances from vibrations, electrical interference, humidity etc.	Anti-Vibration table not provided for weighing balances .	1
38.5	Sch-L1	Specify the safety measures taken to avoid any accidental hazards in the QC department.	Eye shower, goggles , Fire extinguisher were provided.	2
38.6	Sch-M	Specify whether separate washing and drying area is provided for glassware	Separate area provided for washing and drying.	2
38.7	Sch-L1	Specify which grade of glassware is used in assay procedures and whether they are certified/calibrated. Verify the certificates and calibration records.	Grade A glassware are used	2
38.8	Sch-M	Specify whether any particular test is outsourced. If so mention the name of laboratory and verify the contract made in this regard.	The firm is having outsourced testing facility agreement:- A) M/s. Auriga Research Pvt. Ltd, DC Complex, Opposite Gianz Hotel, Vill. Bagbania, Nalagarh, Solan B) M/s Shree Krishna Analytical Services Pvt Ltd , Mayapuri Industrial Area New Delhi C) M/s Oxygen Analytical Laboratories Village Malpur , Tehsil BaddiDisttSolan HP	1
39	**Microbiology Lab**			

39.1	Sch-M	Whether separate AHU's are provided for microbiological testing areas.	The firm has provided only one AHU in microbiology laboratory which caters two rooms includes sterility and MLT testing, however no AHU is provided in the air locks before entering into the lab	x
39.2	Sch-M	Whether support areas are under the same AHU which is used for sterile area.	No AHU in airlock.	0
39.3	Sch-M	Briefly describe layout of the microbiology lab (attach copy of the layout if available)	The firm has separate entry for man and dynamic pass box is provided for transfer of material.	1
39.4	Sch-M	Whether entry to the sterile area is through three air lock systems with separate exit	Entry to the sterile area was through three air lock systems with separate exit however no AHU provided for airlocks.	0
39.5	WHO TRS-986	Specify whether access in sterile area is controlled, and if so the system followed in this regard	The access in sterile area was not controlled	0
39.6	Sch-M	Verify the list of equipment used in the microbiological lab and also specify whether these are placed logically and function accurately	The capacity of incubators is not matching with current requirements of incubation.	1
39.7	Sch-M	Specify whether operators are trained in gowning procedures. Verify the training records.	Training is provided	2
39.8	Sch-L1	Specify the gowning procedure to enter the sterile area. Verify the entry and exit records.	Sterile garments were provided by the firm	1
39.9	Sch-L1	Specify the air class of sterile areas and whether pressure difference is maintained. Verify the records.	Air class of sterility area grade A/B and pressure difference was maintained	2
39.10	WHO TRS-986	Specify whether an environmental monitoring programme is followed with alert and action limit.	Action and alert limit is prepared by the firm	2
39.1	Sch-M	Specify whether a documented cleaning and disinfection programme is in place.	cleaning and disinfection programme is in place	2
39.1	WHO TRS-986	Specify whether a procedure for dealing with spillages in sterile area is in place.	Yes SOP is in place	2
39.1	WHO TRS-986	Whether separate areas provided for sterility testing, assay of antibiotics & vitamins and MLT in sterile area.	Two separate rooms were provided	2
39.1	Sch-M	Specify the type of workstations (LAF) provided in the sterile area.	Vertical LAF is provided	2

39.2	Sch-M	Whether double door autoclave is provided for transferring of materials from unclassified area to sterile area.	Double door autoclave was not provided.	1
39.2	WHO TRS-986	Verify the area qualification document for sterile area.	The firm is having protocol for the same, however no video of air pattern is preserved by the firm	1
39.2	WHO TRS-986	Verify the procedure for selection of sampling location and interpretation of results for environmental monitoring of sterile area along with the SOP and documents. (Specify whether the method is in compliance with ISO 14644-1).	SOP was prepared however physical demarcation was not provided for sample location.	1
39.2	Sch-L1	Specify whether qualification of all equipment and instruments used in this department is covered under VMP.	All equipments were found covered	2
39.2	Sch-L1	Verify the qualification document of major equipment like autoclave/incubator, hot air oven, refrigerator, LAF etc.	Re-qualification of incubator was found satisfactory carried out.	2
39.20	Sch-L1	Specify the Calibration procedure of temperature measurement devices used in autoclave and incubator. Verify whether it is traceable to standard temperature.	Yes traceability certificate is in place	2
39.2	Sch-M	Verify the procedure for the handling and disposal of chemical and microbial waste.	The SOP is in place	2
39.2	WHO TRS-986	Specify the procedure followed to verify the validity of the test in case of antibiotic potency testing.	Yes it is carried out	2
39.2	WHO TRS-986	Specify whether there is separate autoclave for decontamination.	Yes available	2
39.2	WHO TRS-986	Specify whether the Vendors for dehydrated media is approved and qualified.	The firm has not approved Vendors for dehydrated media.	1
39.3	WHO TRS-986 / IP	Specify whether GPT is carried out for dehydrated media.	The firm has shown the record of GPT of dehydrated media	2
39.3	Sch-L1	Specify whether performance of culture media (recovery or survival maintenance) is carried out and the results meet acceptance criteria.	The firm has shown the record for performance of culture media.	2

39.3	Sch-L1	Specify the source of procurement of reference culture and its maintenance.	The firm has purchased the same from IMTEC Chandigarh	2
39.3	Sch-L1	Specify the Air Grades for following areas: —Sterility testing room —Microbiological Assay room —MLT room —Airlocks (entry and exit both)	As the firm has provided only one AHU in the microbiology lab, it is not possible to maintain different Grades with one AHU.	1
39.3	Sch-M	Verify the following records: —Log book for the entry/exit in the sterile area —media preparation record —records for water testing (micro) —records for MLT	The entry exit record is produced by the firm	2
39.30	IP	Verify how the concentration of the inoculums is determined.	The firm is not having any SOP in this context.	1
39.3	Sch-M	Whether firm has provided microbiology lab for MLT test for non sterile dosage form. If no how this test is complied.	The firm has provided an MLT test facility.	2
40	**Quality Control System: -**			
40.1	Sch-L1	Specify the source of procurement of various reference standards	IPC Ghaziabad and Chromachemie Bangalore	2

40.2	Sch-L1	How the reference standards are stored, evaluated and maintained.	The QC has SOP no SOP LP/QC-004 for storage and evaluation of reference standards. It was found that the QC has no provision for maintaining uses reconciliation records of primary standard and primary standard was not stored in properly as primary standard were kept within leak test apparatus rather than dedicator. Working Standard were stored in amber vials with rubber stopper which was sealed with Teflon tape rather than aluminum seal- for example- Working standard of CefiximeTrihydate, WS No- WS-CEF/50, Fluconazole BP, WS no – WS-FLU/218 were stored in amber vials with rubber stopper, sealed with Teflon tape rather than aluminum seal and vials was easily get moisture.	0
40.3	WHO TRS-986	Specify whether authorized access system is followed for reference standards.	No such system is provided.	1
40.4	Sch-L1	Verify the SOP and records for preparation of working standard from the reference standard.	As per SOP LP/QC-004.	1
40.5	Sch-L1	Verify the SOP and records for destruction of unused working standard	Firm has provided log book for consumption of working standard.	1
40.6	Sch-M	Verify the sampling SOPs and records for: – starting materials – primary packaging materials – secondary packaging materials – in process materials – finished products – water analysis – wash water analysis – swab analysis – wash water analysis of cleaned garments	SOP ‘ s were checked for starting materials – primary packaging materials – secondary packaging materials – in process materials – finished products – water analysis – wash water analysis – swab analysis – wash water analysis of cleaned garments	2

40.7	Sch-M	Specify whether approved specifications are available for all: – starting materials – primary packaging materials – secondary packaging materials – in process materials – finished products – water analysis – wash water analysis – swab analysis – wash water analysis of cleaned garments	STP ‘s regarding the same are available with the firm	2
40.8	Sch-L1	Verify whether all approved specifications are based on validation.	Firm has approved the specifications on the basis of AMV in case of in house products and method verification for pharmacoeial products however Firm has not performed Analytical Method Validation for Related Substances in case of Montelukast&LevocetrizineHCl tablets.	0
40.9	WHO TRS-986	Is there any SOP for handling of OOS product (out of specification)?	SOP for OOS ie LP/QA-036	2

40.10	WHO TRS-986	Specify the procedure for review of test data & calculations.	SOP for review of test data LP/QA-018. It was found that Raw Material-Aspartame Power, B no A2212072P25 was sampled on 25-03-2023 with a total 8 samples and sent to QC for testing . It was found that identification was carried out by FTRI ID No- QCD/FTIR-001 on 27-03-2023, however instead of 08 samples, 10 samples were run at said Instrument for Raw Material- Aspartame Power, B no A2212072P25. One sample run on 25-03-2023 and another 09 run was carried out on 27-03-2023, however the QC team has not produced the IR Chromatographs for all 10 runs, only 08 IR Chromatographs of said material.	0
40.1	Sch-L1	Specify whether a designated person is responsible for receipt of samples for testing.	The firm has not designed a person responsible for receipt of samples for testing.	1
40.1	Sch-L1	Specify the procedure followed for receiving and recording (logging in). Verify the SOP and records	Procedure for receipt , issuance and storage SOP LP/QC-005	2
40.1	Sch-L1	Specify the procedure for storage and distribution of received samples to different analyst.		

40.1	Sch-L1	Is there a maximum time limit for retention of sample in the laboratory prior to testing?	The firm has not provided maximum time limit for retention of sample in the laboratory prior to testing. As per Log book for Bulk/Finished product Analysis no LP/QC-029/FT-005, QC has received samples of Norlab-5 tabs, B. no- TNORT-001 on 10-01-2023. However, till date the sample was not tested and released the report.	1
40.2	Sch-L1	Specify the procedure followed for preparation, consumption & destruction of volumetric solution. Verify the SOP and records.	SOP for preparation, standardization ie LP/QC-012 However firm failed to produce consumption and destruction record of volumetric solution.	1
40.2	Sch-L1	Specify whether there is a log book for the preparations of the reagent including name of the analyst, name of the reagent, Calculations, Date of preparation & expiration.	It was found that there was a log book for the preparations of the reagent including name of the analyst, name of the reagent, Calculations, Date of preparation & expiration	2
40.2	Sch-L1	Specify the procedure followed for using GR, LR and AR grade of chemicals / solvents used for calibration & sample testing.	SOP no LP/QC-015	2
40.2	Sch-L1	Specify whether respective STP is followed by the analyst for analysis.	STP checked randomly and found in place	1
40.2	Sch-L1	Specify the procedure of reporting the result of analysis by the analyst to QC Head.	Done manually along with raw data sheet	1
40.20	Sch-L1	Specify the procedure followed for storage of samples after testing.	SOP no LP/QC-066	2
40.2	Sch-L1	Specify the procedure for retention of samples after testing is completed.		
40.2	Sch-L1	Specify the procedure followed for issuance of COA.	SOP no LP/QA-029	2
40.2	Sch-L1	Specify procedures for safe removal of waste from the laboratory.	SOP no LP/SOP/QCM-009	2
41	**Analytical Method Validation (AMV):-**			

41.1	IP	Specify whether following Characteristics are considered during validation of analytical methods: – Specificity – Linearity – Range – Accuracy – Precision – Detection – Limit – Quantification – Limit – Robustness. – Solution Stability/Filter Study	Firm has not performed Analytical Method Validation for Related Substances for product-Montelukast&LevocetrizineHCl tablets.	0
42	**HPLC Calibration**			
42.1	IP	Verify the records of calibration of following parameters: – Calibration of pump. – Calibration of Gradient proportionate valve (GPV). – Calibration of Auto injector. – Calibration of Detector. – Temperature calibration for Column oven and – Sample Trays compartment. – Auto Sampler Carry over. – Manual injector calibration – System suitability	The firm has provided one HPLC ID No QCDL/HPLC-001 (Manual Instrument) and it was found that during its calibration on 15/07/2023, calibration of Gradient proportionate valve (GPV) and Temperature calibration for Column oven not carried out.	1
43	**Dissolution Apparatus Calibration**			
43.1	IP	Verify the records of calibration of following parameters: – Checking of RPM – Checking of Temperature – Checking of distance between inside bottom of the vessel & paddle – Checking of distance between inside bottom of the vessel & Basket – Checking Wobbling of paddle – Checking of Wobbling of Basket – Checking of Timer: Calibrate against standard stop watch – Performance verification test **[Verify whether dissolution is calibrated against standard prednisolone tablets]**	It was found that last calibration was done on 30-10-2022 with said parameters.	2

44	**UV-VIS**			
44.1	IP	Verify the records of calibration of following parameters: – Control of wavelengths (Wavelength accuracy) – Control of absorbance (Photometric accuracy) – Limit Of Stray Light – Resolution Power – Resolution (second order derivative spectrum) – CELLS Verification – I0 flatness – Calibration of Visible Wavelength – Calibration of absorbance reproducibility for visible wavelength – Photometric linearity at 430nm	The firm has not carried out the following parameters 1- CELLS Verification 2- I0 flatness during calibration of UV-VIS spectrophotometer dated 06-02-2023.	1
46	**FTIR**			
46.1	IP	Verify the records of calibration of following parameters: – Verification of the wave number scale – Control of resolution performance	It was found that last calibration was done on 19-12-2022 with said parameters.	2
47	**TOC Analyzer:**			
47.1	USP	Verify the records of calibration of following parameters: – System suitability: – Calibration (Four-point calibration)	The firm has not installed TOC analyzer	1
48	**Stability Studies**			
48.1	Sch-M	Specify whether stability study is carried out in the QC and if so, is there separate area for Stability Chamber for stability studies. How many Stability Chambers have been provided? Specify whether shelf life of the product is fixed on the basis of stability studies.	There are 2 stability chambers provided one is for conducting the real and another is for conducting accelerated stability study. Yes, the Self life is assigned on the basis of stability study conducted by the firm.	2
48.2	WHO TRS-986	Verify the qualification documents of all the stability chambers.	Yes. Firm has performed the qualification of the stability chambers.	2
48.3	WHO TRS-986	Specify whether a written programme for ongoing stability determination is in place.	Stability planner for ongoing stability determination maintained	2

48.4	WHO TRS-986	Specify whether a complete description of stability study is available.	A complete description of stability study was available.	2
48.5	WHO TRS-986	Verify the stability calendar along with stability protocol and documents. Attach the copy of stability calendar	Stability calendar and protocol were in place.	1
48.6	WHO TRS-986	Specify whether the stability protocol indicates complete set of testing parameters and methods.	The stability protocol indicates complete set of testing parameters and methods	2
48.7	WHO TRS-986	Specify whether summary of all generated data from the study are retained.	Randomly the summary sheet of stability study of Diclofenac sodium tablets BP bearing batch no. DORT-001 verified.	2
48.8	WHO TRS-986	Specify the testing schedule for each product	For real time/long term study the frequency of testing schedule defined in protocol is after 3,6,9,12,24,36 & 48 Months and for accelerated study the frequency of testing schedule is 3 & 6 months.	1
48.9	WHO TRS-986	Specify whether stability study is performed after any significant changes in process equipment, packaging materials etc.	Firm has mentioned in their SOP no. LP/QA-047 that in case of any change in process equipment, packaging the stability study will be performed.	1
48.10	WHO TRS-986	Specify the validation method for stability chambers	Temperature and humidity mapping.	2
48.1	WHO TRS-986	Specify the Temperature and humidity for real times studies carried out for fixing shelf life of drug in the country.	Temperature 30 ±2 ºC and relative humidity 75 ± 5% as defined in the protocol.	2
49	**Quality Assurance: -**			
49.1	Sch-M	Mention the documents prepared and maintained by QA department	QA has 78 SOP .	2
49.2	Sch-M	Specify the responsibility of the QA Head.	Firm has SOP for Job responsibilities LP/QA-028	2
49.3	Sch-M	Specify the procedure followed by QA department to ensure the implementation of all SOPs in the plant.	Training schedule is provided by QA.	1
49.4	Sch-M	Verify the total list of SOPs maintained by QA and how QA ensure that no obsolete SOP is in circulation.	QA has 78 SOP . Firm has an issuance and retrieval procedure for ensuring that no obsolete SOP is in circulation.	1

49.5	WHO TRS-986	Specify whether any procedure is followed for preparation of SOPs and its circulation to all concerned. How master, controlled and uncontrolled copy of SOPs are processed.	Firm is having SOP for preparation,approval,authorization,control revision, retrieval and destruction of SOP ie LP/QA-001.	0
49.6	WHO TRS-986	Mention the change control procedures & examine three recent change control forms.	Firm has SOP for change control LP/QA-003 ie LPL/CCP-23-001 ; LP/CCP-23-002;LP/CCP-23-003 however change control no LP/CCP-23-003 not closed till date. Quality Manual System: A) During the review of change control log the firm has raised 04 change controls since 01st Jan 2023. The firm is having SOP No. LP/QA-003 for change control during review it is found that the firm has not fixed the timeline for the closure of change control. Also as per SOP point number 5.4, the indent will be raised by concerned department to QA. However as per Change control number LPL/CCP-23-003 (01.03.2023) for renovation of capsule section, no indent is found raised by the concerned department (production), no impact analysis was performed however it was categorized as minor.	0
49.7	WHO TRS-986	Specify the procedures followed to ensure CAPA process. Verify the SOP and three recent records in this regard.	Firm has SOP for CAPA LP/QA-012 and CAPA recorded as per change control	1
49.8	WHO TRS-986	How deviation are controlled. Verify SOP and three recent deviations. Specify whether all deviations are reported and records maintained.	SOP for deviation ie LP/QA-004 and no deviation has been taken on record.	1

49.9	Sch-M	Is the production batch record and release test results reviewed for accuracy and completeness before a batch/lot of finished product is released?	SOP for release LP/QA-029 and QA is responsible for release.	2
49.10	Sch-M	Verify the checklist and SOP in this regard.		
49.1	Sch-M	Whether QA is involved in control of starting materials, intermediate products, bulk products, process controls, calibrations, validation and release of finish goods.	Firm has SOP for Job responsibility of QA LP/QA-028	2
50	**Annual Product Quality Review (APQR): -**			
50.1	WHO TRS-986	Specify Whether Annual Product Quality review is carried out for each product	The firm is having APQR SOP no LP/QA-024 but not prepared for all produts	1
50.2	WHO TRS-987	Specify whether following criteria are considered for review: – Starting materials and packaging materials – Critical in-process controls and finished product results; – All significant deviations or non-conformance – All changes made to the processes or analytical methods; – Results of the stability monitoring programme and any adverse trends – All quality-related returns, complaints and recalls and the investigations performed at the time – Adequacy of any other previous corrective actions on product process or equipment – The qualification status of relevant equipment and utilities e.g. HVAC, water, or compressed gases	In APQR all parameters were found incorporated	1
50.3	WHO TRS-988	Verify whether Cp and CpK values are calculated and what is the acceptance criteria fixed.	In the mentioned APQR the calculation of Cp and CpK is mentioned however readings were not found	1
51	**Product Recalls: -**			

51.1	Sch-M	Specify the product recall system.	The firm has SOP for product recall however it is ineffective as no material of NSQ product is returned backed.	1
51.2	Sch-M	Verify the procedure followed to handle the recalled products	No product received back	1
51.3	Sch-M	Are distribution records available for a prompt recall of products from the market?	The distribution record is available	2
51.4	Sch-M	Verify the SOP for recall of products clearly defining responsibility, procedure reporting, reconciliation etc.	The firm is having SOP for recall	1
52	**Complaints and Adverse Reactions: -**			
52.1	Sch-M	Are complaints, whether received in oral or written form, documented in writing, and retained in a designated file?	As per market complaint/ NQS logbook, it was found that the firm has received 04 market complaints/NSQs from last 5 years including Drug Alert for Product Doxycline and Ambroxol Capsules, B No- DBQC-004 as product does not conforms to claim as per Patent & proprietary in respect to Assay of Doxycycline Hydrochloride calculated as Doxycycline, Ambroxol Hydrochloride. As per SOP no LP/QA-016, Procedure for market recall, it was mentioned that in case of critical health or safety risk, a full recall shall be initiated. This will involve contact with wholesalers/ distributors, pharmacist and medical Practitioners and possible the consumers. The firm has initiated the recall of said Product from market and only distributor was contacted for recall. The firm has not followed the said SOP. It was found that till date the said market complaint was not closed.	0
52.2	WHO TRS-988	Are complaints reviewed on a timely basis by the Quality Assurance unit?	Complaints reviewed on a timely basis by the Quality Assurance unit	2

52.3	WHO TRS-988	Is CAPA process followed in response to each complaint documented?	Yes as per available SOP	2
52.4	WHO TRS-988	Specify whether system of route cause analysis is followed by the firm on the complaint of adverse drug reaction.	No such information is available	2
52.5	Sch-M	Specify the review system for complaints concerning the quality of products.	The firm is performing review of complaint	2
52.6	Sch-M	How records of complaint and adverse reactions maintained.	No such complain is received	2
52.7	Draft Rules	Whether the firm has provided Pharmacovigilance department for analysing complaints of adverse drugs reactions resulting from the use of a drug.	Draft rules under consideration	2
52.8	Sch-M	Are there any criteria for action to be taken on the basis of nature of complaint / adverse reaction?	SOP mentioned the recall procedure in as per nature of complaints	1
53	**Site Master File: -**			
53.1	Sch-M	Whether all the relevant information has been included in the site master file.	The SMF was not factual as the firm holds valid product permission for Tablet section (Beta Lactum) which was not mentioned on SMF. The firm is holding product permission for Hormone section and Dusting powder which is also not mentioned in SMF. It violates section 29.1 of Sechdule M of Drugs and Cosmetics Act 1940	0
53.2	Sch-M	Whether quality policy has been included in the site master file.	Quality policy was mentioned in SMF	2
53.3	Sch-M	Verify whether all information as per schedule M	The other contents of SMF were inline with Schdule M	2
53.4	WHO TRS-988	Verify whether all information as per WHO TRS 986 and PIC/S document.	The firm has not incorporated all information in SMF as per WHO TRS and PIC/S document .	1
54	**Validation:**			
54.1	WHO TRS-988	Specify the validation policy of the company	Firm has policy for validation.	2
54.2	WHO TRS-988	Whether a Validation Master Plan has been prepared.	Firm has VMP i.e. LP/VMP/QA-002	2
54.3	Sch-M	Verify resources and those responsible for its implementation.	QA is responsible for implementation.	2

54.4	WHO TRS-988	Identify the systems and processes to be validated as per VMP	VMP covers requalification of processes , revalidation of equipments, area qualification process validation and cleaning validation,analytical method validation and water system validation.	2
54.5	WHO TRS-988	Verify whether documentation, standard operating procedures (SOPs), Work Instructions and Standards (applicable for national and international) are incorporated in VMP	Firm has prepared separate SOP but have incorporated work instructions,documentation in VMP	2
54.6	WHO TRS-988	Validation list for facilities/equipment, processes / procedure and products.	Yes, List provided with VMP.	2
54.7	WHO TRS-988	Specify whether key approval criteria are mentioned in the VMP & how record and conclusion of such validation studies are prepared and maintained.	Objectives are mentioned in the VMP and Validation reports are prepared as per protocol .	1
54.8	WHO TRS-988	Verify Protocol format for each validation activity, including re-validation and reasonable unforeseen events (power failures, system crash and recovery, filter integrity failure.	The firm is having SOP for filter integrity and recovery, however no policy for system crash is in place.	1
54.9	WHO TRS-988	Whether validation calendar is specified in VMP.	Validation calender attached with VMP.	2
54.10	Sch-M	Specify whether the critical processes validated Prospectively, retrospectively or concurrently.	Firm is performing process validation concurrently.	1
54.1	WHO TRS-988	In case electronic data processing systems are used, are these validated?	No such procedure	0
54.1	WHO TRS-988	Please specify whether periodical challenge tests performed on the system to verify reliability.	Firm is performing a media fill challenge test for injections and a visual inspector challenge test for qualification of visual inspector.	1
54.1	Sch-M	Are the validation studies performed according to pre-defined protocols?	Firm has performed as per protocol	1
54.1	Sch-M	Is a written report summarized, results and conclusions prepared and maintained?		

54.2	WHO TRS-988	Is the validity of the critical processes and procedures established based on a validation study?	As per protocol	1
54.2	WHO TRS-988	Are criteria established to assess the changes originating a revalidation?	As per validation plan	1
54.2	WHO TRS-988	Are trend analyses performed to assess the need to revalidate in order to assure the processes and procedures continue to obtain the desired results?	Trend analysis performed for water testing, annual product review. It was found that the system (Computer) used for preparing trend analysis of WFI were not enabled with login/ID password. It was found that trend analysis of WFI Sample ID no -07, 08, 09 and 10 prepared and saved at the said system were not matching with the result produced by the QC.	0
55	**Internal Quality / GMP Audit Programme:**			
55.1	Sch-M	Does a formal auditing function exist in the Quality Assurance department?	SOP no. LP/QA-019 was in place.	2
55.2	Sch-M	Does a written SOP specify who shall conduct audits and qualifications (education, training, and experience) for those who conduct audits?	SOP no. LP/QA-019 in place for conducting the self-inspection and list of auditors also maintained. All the HOD are included.	2
55.3	Sch-M	Does a written SOP specify the scope and frequency of audits and how such audits are to be documented?	Yes, as per SOP the frequency of audit specified is 6 months for all departments.	2
55.4	WHO TRS-988	Specify whether record is maintained for CAPA on the basis of self-quality audit / inspection and whether same is reviewed by the management	Yes firm has maintained the record for CAPA taken on the basis of self-quality audit.	2
56	**Pharmaceutical Development:**			
56.1	ICH/Q-8-PICS	Whether there is Research and Development facility available.	No such facility available	2
56.2	ICH/Q-8-PICS	Whether formulation development facility up to development of exhibit batches available.	No FND facility available	2
56.3	ICH/Q-8-PICS	Whether firm hires consultants for technology transfer. If so, details thereof.	No consultant is hired	2

56.4	ICH/Q-8-PICS	Whether firm has adopted latest tools (quality by design) to develop new products.	No such new product is developed by the firm	2
57	**Quality Risk Assessment System: -**			
57.1	ICH/Q-9-PICS	Whether the firm has adopted QRM principle to mitigate risk involved in pharmaceutical development, manufacturing and distribution. If yes specify which guidelines are followed in this regard.	Firm has SOP for quality risk management ie LP/QA-042 , Document number LPL/QA-042/FT-002 Effective date 13/01/2023 ,and guideline mentioned is ICH Q9.	2
57.2	ICH/Q-9-PICS	Whether firm has policy document on QRM. Specify document number and its effective date.		
57.3	ICH/Q-9-PICS	Which known principles have been adopted to analyse risks e.g. FMEA, HAZOP, HACCP, FTA etc.	FMEA principle was adopted.	2
57.4	ICH/Q-9-PICS	Whether risk priority number (RPN) is calculated based on severity, probability and detectability. If so, what is the criteria of acceptance.	Firm is calculating RPN number using severity, occurrence and detection and criteria is less than 3 for acceptance.	2
57.5	ICH/Q-9-PICS	How many products, process etc. have been analysed for risk. Give brief.	Tablet process - compression,packing and visual liquid injection, Dry injection beta category are covered for risk	2
58	**Data Integrity**			

58.1	Sch-M	Whether the records are completed at the time of the operation and are legible maintained with raw data if applicable.	At the time of visit to the microbiology lab, it is observed that the firm has started sterility testing for below mentioned products- 1- Amilab 500 mg Inj, Batch No- ANSI-009, 2- Diclolab Injection, Batch No- DSSI-054, 3- Ceflox Eye/Ear Drops, Batch No- ACSE-005 4. TroxoneInj,Batch No- ACFSI-005. Date of analysis mentioned as 12.04.2023, however no sample of these products were found charged in the incubator, which revealed that the firm was involved in the generation of fake data for sterility testing. Other charged/incubatedsamples were also examined by the team and found that no growth even in the positive samples were observed.	x
58.2	Sch-L1	Whether the firm has software-based manufacturing and testing equipment	Firm was using pharmasuit for warehouse and product release	2
58.3	Sch-L1	Whether the individuals are provided log in IDs for access. All login and logout information should be available.	It was found that OPUS software used for FTIR instrument and there were three level of users – Administrator, Lab Manager and Default. It was found that common password was maintained for all three users and analysis (Default) was using right of administrator and Lab Manager as well.	0
58.4	Sch-L1	Whether rights to work, amend, modify, delete are specified in written document.	Firm has SOP for GDP -LP/QA-018	1

58.5	Sch-L1	Whether right to access and modify are with two different individuals. If yes, how QA is involved in modification of data.	Firm produced SOP for data Integrity LP/QA-073.	1
58.6	Sch-L1	Whether audit trails related to project creation (study creation), project (study) modification, deletion etc. are available.	It was found that, in QC, total 04 HPLC (01 Agilent, 02 Shimadzu and 01 Waters) has been provided. One HPLC (Waters) was manual and not having audit trail facility and date and time can be changed. It was found that HPLC data was saved in E drive and firm has practice of manual integration and there was no provision for back up of HPLC data. As per Audit trail of HPLC ID No-HPLC-003, it was found that analyst has changed expected retention time from 3.91 minutes to 5.34 minutes on 11-04-2023 at 12.24 AM for product LABDIC RELIEF TABLETS, B NO-LRDST-158, the reason for change of retention time was mentioned as wedfcwe. The analyst has not justified the full form of wedfcwe and requirement of such change . It was found that the same changes was not reviewed by reviewer/lab manager/QA.	0
58.7	Sch-L1	Whether the data is backed up at regular intervals. If yes what is the written back up policy. The data backup must be server based.	It was found that HPLC data was saved in E drive and firm has practice of manual integration and there was no provision for back up of HPLC data.	1
58.8	Sch-L1	How Excel sheets are validated if calculation are done in Excel sheet.	The firm has not validated the excel sheet and PC in QC system.	1
58.9	Sch-L1	Whether the firm has QA SOP for review of data integrity or audit trail. If yes, how the modification and deletions are reviewed.	Firm has not practice for review of modification and deletion of data as part of integrity/audit trial.	0
59	**Pharmaceutical Quality Management System (PQS):**			

59.1	WHO TRS-986	Specify the management responsibility defined as per the quality manual	Firm has defined the responsibility of management as per quality manual LP/QM/QA/001 Effective date 31.01.2023.	2
59.2	WHO TRS-986	Specify the Procedures followed for continual improvement of process performance and product quality	Firm has SOP for Annual Product Quality Review LP/QA-024.	1
59.3	WHO TRS-986	Specify the performance indicators presently followed by the firm to monitor the effectiveness of PQS like product quality monitoring, CAPA, change management and management review	Firm has SOP for CAPA LP/QA-012 ,SOP for deviation LP/QA-004 and SOP for Annual Product Quality Review LP/QA-024.	1
59.4	WHO TRS-987	whether purchases are also included under PQS	The firm has included purchase in PQS vide SOP no.SOP LP/QA-077.	2
59.5	WHO TRS-986	Specify whether life cycle approach is followed	There is no life cycle approach followed.	1.
59.6	WHO TRS-986	Give synopsis of last to management review meeting held by the firm	Firm has conducted the last meeting of management on 13.03.2023 related to raw material store,production and quality assurance.	2