GMP CHECKLIST

(Based on WHO Good Manufacturing Practices (GMP) for active pharmaceutical ingredients stated as per Annex 2- WHO Technical report Series(TRS), No. 957, 2010; Good Manufacturing Practice guide for Active Pharmaceutical Ingredients ICH Harmonised Triplicate Guideline stated as per ICH Q9; and GMP requirements as per Directives No. 2001/83/EC latest amended vide Directive 2011/62/EU)

1	***Location and surroundings:***	**Self appraisal to be filled by the manufacturer along with all details (yes or no type reply will not be acceptable)**	**Observations to be noted by the inspecting team at the time of inspection**	**Remarks**
1.1	How factory building is situated and controlled to avoid risk of contamination from external environment including open sewage, drain, public lavatory or any other factory which produces disagreeable or obnoxious, odors, fumes, excessive soot, dust, and smoke, chemical or biological emissions. *Pls specify industries / establishments adjoining manufacturing site.*			
2	**Building and premises: -**			
2.1	How the building has been designed constructed and maintained to suit the manufacturing operations so as to produce drugs under hygienic conditions. *Pls specify nature of construction used in the facility in respect of its maintenance and hygienic conditions.*			
2.2	Whether the building confirm to the conditions laid down in the Factories Act, 1948 *Pls attach valid factory certificate/ license issued by the competent authority.*			
2.3	Specify how the premises used for manufacturing operations and testing purpose prevents contaminations and cross contamination is: a) Compatible with other drug manufacturing operations that may be carried out in the same or adjacent area. Pls specify any special criteria for			

	the product manufacturered. e.g. temperature, humidity, air class requirements maintained for aseptic products, etc.			
2.4	b) Whether adequate working space is provided to allow orderly and logical placement of equipment, materials and movement of personnel so as to avoid risk of mix-up between different categories of drugs and to avoid possibility of the contamination by suitable mechanism. Pls specify space left around the machines. Pls attach equipment lay out, men and material movement, waste movement if applicable.			
2.5	c) Describe the pest, insects, birds and rodents control system followed in the premises. Attach copy of pest / rodent control schedule along with contract agreement if any.			
2.6	d) 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 Aluminum etc.) paint.*			
2.7	e) What measures have been taken so that the production and dispensing areas are well lighted and effectively ventilated, with air control facilities. Pls specify the lux level maintained in various parts of the premise.			
2.8	Pls specify the air handling system used in various areas like stores, production, packing, QC areas etc.			

2.9	f) Specify drainage system which prevents back flow and entry of insects and rodents into the premises. Drains should be of adequate size and should be provided with an air break or a suitable device to prevent back-siphonage *(pls specify number and location of drains installed)*			
2.10	Containment area: Any production activities (including weighing, milling or packaging) of highly toxic non-pharmaceutical materials such as herbicides and pesticides should not be conducted using the buildings and/or equipment being used for the production of APIs. Handling and storage of these highly toxic non-pharmaceutical materials should be separate from APIs.			
3	**Water system: -**			
3.1	Whether the unit has validated system for treatment of water drawn from own or any other source to render it potable in accordance with standards specified by BIS or local municipal norms. Pls specify source of raw water and give details of treatment processes, sampling points, distribution and storage system for raw and purified water.			
3.2	How bio burden in purified water controlled / reduced.			
3.3	How water tank are cleaned periodically and records maintained thereof. How water distribution system is sanitized to control microbial contaminations.			
4	**Disposal of waste: -**			
4.1	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).			

4.2	Whether provision for disposal of bio-medical waste made as per the provisions of the Bio Medical Waste (Management and Handling) Rules 1996.			
5	***Warehousing Area: -***			
5.1	Whether adequate areas have been allocated for warehousing of Raw Materials, intermediates, Packaging Material, products in quarantine, finish products, rejected or returned products. How these areas marked or segregated. Please specify the total area provided for warehousing.			
5.2	How the warehousing areas being maintained to have good storage conditions. Are they clean and dry and maintained within acceptable temperature limits?			
5.3	Specify the storage arrangement provided for materials which sensitive to temperature, humidity and light and how the parameters are monitored. Is cold room or deep freezers required for storage of goods? If yes, how the temperature is monitored.			
5.4	Whether proper racks, bins and platforms have been provided for the storage.			
5.5	Whether receiving and dispatch bays are maintained to protect in coming and out going materials.			
5.6	How incoming materials are treated and cleaned before entry into the plant. Please specify the cleaning system for the outer surface of the container.			
5.7	How quarantined materials are segregated from other materials. How access to quarantined area is restricted.			
5.8	Whether separate sampling area for active Raw Materials and Excipients is provided and maintained. If yes, 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. If not what provision has been made for sampling so as to prevent contamination, cross contamination and mix-ups at a time of sampling.			
5.9	Specify the arrangements provided to sample the primary packaging materials foils, bottles, etc which are used as such.			
5.10	Pls specify sampling plan used. Which type of sampling tools are used and how they are cleaned, dried and maintained.			
5.11	How containers are cleaned before and after sampling. Who carries out the sampling? (Pls specify whether the sampling is carried out as per the current SOP).			
5.12	What precautions are taken during sampling of photosensitive, hygroscopic materials?			
5.13	What provisions have been made for segregated storage of rejected, recalled or returned materials or products. How is the access to these areas restricted.			
5.14	How highly hazardous, poisonous and explosive materials, narcotics, and psychotropic drugs are handled and stored. How these areas are safe and secure. Is there certification from competent authority for handling of explosives etc. If any. Pls attach the certificate issued by the competent authority.			
5.15	How printed secondary packaging materials are stored in safe, separate and secure manner.			
5.16	Specify the arrangement provided for dispensing of starting materials. 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. Whether pressure differential is maintained between the dispensing and adjacent areas.			

5.17	Which type of dispensing tools are used and how they are cleaned, dried and maintained. How containers are cleaned before and after dispensing. Who carries out the dispensing? (Pls specify whether the dispensing is carried out as per the current SOP).			
5.18	How and where sampling of sterile materials carried out.			
5.19	What steps are taken against spillage, breakage and leakage of containers?			
5.20	What provisions have been made to prevent the entry of rodents, insects, birds. Which substance is used for pest control and how it is handled. (Pls specify whether the pest control is carried out as per the SOP).			
5.21	Whether record of master labels is maintained for comparision to issued labels?			
6	***Production Area: -***			
6.1	Please specify the design of the manufacturing area which allow uni-flow and logical sequence of operations so as to prevent product contamination/ mix ups. Is there any criss cross of flow of materials and men. Specify the position of IPQC lab in the manufacturing area . Please specify whether non storage areas used for storage of any material.			
6.2	Whether separate dedicated and self-contained facilities have been provided for the production of sensitive pharmaceutical product like Penicillin, Biological preparation with like micro-organism, Beta lactam, Sex Hormones and Cytotoxic substances. If yes pls explain how and attach copy of plan of premises of each category of drug.			

6.3	Please specify the provisions of storage of dirty, washed and cleaned equipment parts, tool room, in process storage areas etc. Which provide sequential / logical manner so as to prevent contamination and cross contamination?			
6.4	Please specify how service lines like pipe work, electrical fittings, ventilation openings etc. are identified by colors for nature of supply and direction of the flow. Whether service lines in production areas are through service pendants. If not, how they are placed so as to avoid accumulation of dust.			
7	***Ancillary areas: -***			
7.1	Please specify the position of rest and refreshment rooms and mention whether they are separate and not leading directly to the manufacturing and warehouse areas.			
7.2	Are there general change rooms in plant? Are toilets, change room separate from mfg. Area? Pls specify number of washing station & toilets provided for number of users. Whether change facilities separated for both sexes. How many sets of protective garments provided for each personnel entering production area. Is there in house general laundry for garment washing / cleaning? If not how garments washing are carried out and monitored			
7.3	Whether maintenance workshop is separate and away from production.			
7.4	Whether animals for production or testing are housed in the facility if so whether areas housing animals are isolated from other areas. Please specify the provision of air conditioned and ventilation system for the animal house. How quarantined, under test and tested animals housed and controlled. How animal carcass are disposed of. Pls attach copy of CPCSEA.			

8	**Quality Control Area: -**			
8.1	Whether QC area is independent of production area. Whether QC carries out its own: □ physico-chemical testing, □ biological testing, □ microbiological testing & sterility testing and □ Instrumental testing. Whether firm is outsourcing testing. If yes names of the testing laboratories contacted or approved. Pls give list of test currently outsourced. In case of contractual testing what are the responsibilities of contract giver and contract acceptor. (Copy of the contract should be enclosed) Are there safety installation such as shower, eye washer, fire extinguisher etc in the laboratory. Is there separate area for humidity chambers for stability studies. How many humidity chambers have been provided. Pls attach stability calendar.			
8.2	Please specify the arrangement provided for handling and storage of test samples, retained samples, reference standards / cultures, reagents. Whether retained samples are stored for a period of 1 year after expiry or 3 years after distribution whichever is earlier? Whether separate area for storage of reagents and glassware provided. Whether separate records room is provided.			
8.3	How hazardous or poisonous materials are stored and handled.			
8.4	How environmental conditions are met during the course of storage and testing of samples.			
8.5	Which grade of glassware are used in assay procedures.			
8.6	Whether separate AHU's are provided for biological, microbiological and radio iso-topes testing areas with HEPA filter arrangement.			

8.7	Whether separate areas provided for sterility testing within microbiology lab. Whether support areas are under AHU. Whether double door autoclave provided for sterilization of materials.			
8.8	Whether entry to the sterility area is through three air lock systems. What is the air class of these testing areas and whether pressure difference is maintained in these areas?			
8.9	Which types of workbenches are provided in these areas for testing? When was the last filter integrity tests performed on HEPA filters			
8.10	How waste (cultures etc) disposed of. Whether in case of antibiotic potency testing, statistical proof of the determination of potency and validity of the test carried out.			
9	***Personnel: -***			
9.1	Whether the manufacturing and testing of drugs is conducted under approved technical staff Names of Technical Staff alongwith qualification & experience For Manufacturing: - For Analysis:			
9.2	Please specify whether head of Q.C. is independent of manufacturing unit			
9.3	Name, qualification and experience of the personnel responsible for Quality Assurance function.			
9.4	Whether responsibilities for production and QC laid down and followed.			
9.5	Whether adequate number of personnel employed in direct proportion to the work load.			
9.6	What is the firm‟s policy on training of personnel at various levels?			
9.7	How is Periodic assessment of the training checked?			
10	***Health, clothing and sanitation of workers: -***			

10.1	Whether personnel handling Beta lactam antibiotics are tested for penicillin sensitivity before employment.			
10.2	Whether personnel involved in handling of sex hormones, cytotoxic and other portent drugs are periodically examined for adverse effect. (Pls specify whether the current SOP is followed or not).			
10.3	Whether all personnel prior to employment have undergone medical examination including eye examination and all free from Tuberculosis, skin and other communicable or contagious diseases			
10.4	Whether there is a SOP for medical examination.			
10.5	Pls give name and qualification of contracted medical officer for medical examination.			
10.6	Whether investigational reports, films of X rays etc. preserved. Whether records of such medical examination are maintained thereof			
10.7	Whether all personnel are trained to ensure high level of personal hygiene. Pls attach training calendar of last two years.			
10.8	Whether proper uniforms and adequate facilities for personal cleanliness are provided. Pls specify nature and type of dress used by the personnel in various areas of operation. How many dress/footwear have been provided to each personnel. Please specify whether cross over bench is in place in the change room and if so whether it rule out the possibility of entering dust particle to the clean side. Whether arrangements provided for cleaning of outside dust and dirt from foot Please specify whether hands are disinfected before entering the production area Whether for sterile garments in			

	house clean laundry has been provided.			
11	***Manufacturing Operations and Controls: -***			
11.1	Whether the contents of all vessels and containers used in manufacture and storage is conspicuously labeled with the name of the products. Batch no, Batch Size, and stage of manufacture along with signature of technical staff.			
11.2	Whether the products not prepared under aseptic conditions are free from pathogens like Salmonella, Escherichia coli, Pyocyanea etc.			
11.3	If yes, pls give brief account of measures taken to assure freedom from pathogens.			
11.4	*Precautions against mix-up and cross-contamination: -*			
11.4.1	Whether proper AHU, pressure differential, segregation, status labeling have been provided to prevent mix-up and cross-contamination in manufacturing area			
11.4.2	Pls specify the areas of dust generation and mechanism involved in controlling the dust.			
11.4.3	Do all the areas have their own independent air locks separately for men and material entry.			
11.4.4	What criteria of pressure differential have been set for production v/s adjoining areas.			
11.4.5	Whether various operations are carried out in segregated areas.			
11.4.6	Whether processing of sensitive drugs like Beta lactum Antibiotics and Sex Hormones is done in segregated areas with independent AHU and proper pressure differentials alongwith demonstration of effective segregation of these areas with records.			
11.4.7	Please specify what measures has been taken to prevent contamination of products with Beta Lactum Antibiotics, Sex harmons and cyto toxic substances			

11.4.8	What measures has been taken to prevent mix-ups during various stages of production.			
11.4.9	Whether equipments use for production are labeled with their current status.			
11.4.10	What is the policy for the use of Recovery material?			
11.4.11	Whether packaging lines are independent and adequately segregated.			
11.4.12	How line clearance is performed. Whether records of line clearance is maintained according to appropriate checklist			
11.4.13	Whether separate coding area has been provided or online coding is performed How coding procedure is controlled.			
11.4.14	Please specify how temperature, humidity and air filtration are controlled in the areas where raw material and/or products are exposed and handled.			
11.4.15	How access of authorized persons to manufacturing areas including packaging is controlled.			
11.4.16	Whether separate gowning provision is follows before entering into the procedure.			
11.4.17	Whether segregated secured areas for recall or rejected materials or for such material which are to be processed or recovered are provided. Please specify the room No. of such areas in the plant.			
11.5	***Sanitation in the Manufacturing areas:-***			
11.5.1	Specify the cleaning procedure of the manufacturing areas. Whether cleaning procedure is validated. Please specify validation protocol No. of the same.			
11.5.2	Whether the manufacturing areas are used as the general thoroughfare and storage of materials not under process.			

11.5.3	Whether a routine sanitation program is in place. Please specify detailed account of sanitation proramme specific to various areas, equipment.			
11.5.3	Dose the location facilitate cleaning of equipment as well as the cleaning of the areas in which they are installed.			
11.5.4	Whether production area is adequately lit. If yes. Please give lux levels provided in production, visual inspect			
12	***Raw Materials: -***			
12.1	Whether the hard copies of records of Raw Materials are maintained.			
12.2	Please specify the procedures followed receiving and processing of in-coming materials (Starting materials and packing material).			
12.3	Whether first in / first out or first expiry principal has been adopted.			
12.4	How they are labeled and stored as per their status – Under Test, Approved and Rejected			
12.5	Whether incoming materials are purchased from approved sources.			
12.6	What is the procedure for approving the source for incoming materials.			
12.7	Whether the raw materials are directly purchased from the manufacturers.			
12.8	Whether list of approved vendors is available to the user.			
12.9	How damaged containers are identified recorded and segregated.			
12.10	How damaged containers are identified recorded and segregated.			
12.11	Whether all the containers of each batch of starting materials is sampled for identification test.			
12.12	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.			
12.13	Whether separate areas are provided for under test, approved and rejected materials.			
12.14	How control on temperature and humidity conditions, wherever necessary, maintained in these storage areas.			
12.15	How the containers from which samples have been drawn labeled.			
12.16	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.			
12.17	How materials are stacked in the Stores i.e on Pallets, racks etc.			
13	***Equipment: -***			
13.1	Whether the equipments are designed aiming to minimize risk of error and permit effective cleaning in order to avoid cross contamination, build up of dust			
13.2	Whether all equipment are provided with log book.			
13.3	Please specify the procedures to clean the equipment after each batch production.			
13.4	Whether validity period for use after the cleaning of equipment is specified.			
13.5	Whether separate area is provided for storage of machine parts etc.			
13.6	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.			

13.7	Please specify material of construction of contact parts of the production equipments.			
13.8	Which types of lubricants are used in the equipment. Specify the quality and control reference No. of these lubricants.			
13.9	Specify the procedures to remove defective equipments from production areas.			
14	***Documentation and Records: -***			
14.1	How the documents are designed, prepared, reviewed and controlled to provide an audit trail. Whether documents are approved signed and dated by appropriate and authorized person. Whether documents are approved signed and dated by appropriate and authorized person. Whether documents specify title, nature and purpose. Whether documents are regularly reviewed and kept up to date. If yes. Please specify review period. Please attached the list of documents maintained by the firm			
14.2	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.			
14.3	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.			
14.4	Whether master formula and detailed operating procedures are maintained as hard copy.			
14.5	Who is responsible for maintenance of these records.			
15	***Labels and Other Printed Materials:***			
15.1	Whether the printing is in bright colour and legible on labels and other printed materials.			
15.2	How printed labels (art work) are approved. Is there any SOP for this if yes please give current SOP No.			

15.3	Which colour coding system is used to indicate the status of a product and equipment.			
15.4	How printed packaging materials, product leaflets etc. are stored separately to avoid chances of mix-up.			
15.5	How labels cartons boxes circulars inserts and leaflets are controlled.			
15.6	Whether the samples from the bulk are drawn tested, approved and released prior to packaging and labeling. How carryout the sampling			
15.7	How records of receipt of all labeling and packaging materials are maintained.			
15.8	Whether re-conciliation of used packaging materials is maintained. Whether unused packaging materials return to the store or destroyed.			
15.9	How returned/unused packaging material like foils is controlled so as to prevent contamination and cross-contamination.			
15.10	How the labels of reference standard and culture maintained.			
16	***Quality Assurance: -***			
16.1	Specify the comprehensive quality assurance system maintained by the firm *Inter-alia* to cover deviation, reporting, investigation and change control. How the products are designed and developed in accordance with GMP.			
16.2	Please specify the arrangements provided to ensure that correct starting and packaging materials are used for manufacture.			
16.3	Please specify the mechanism by which all control like IP QC Calibration, Validation etc. are ensured.			
16.4	Please specify the mechanisms to ensure that the finished product has been correctly processed and checked in accordance with the established procedures.			
16.5	Please specify the mechanisms to ensure that Pharmaceuticals products are released for sale by authorization person.			

17	***Self Inspection and Quality Audit: -***			
17.1	Whether the firm has constituted a self inspection team supplemented with a quality audit procedure to evaluate that GMP is being followed. If no. How internal audits are carried out.			
17.2	What is the system of monitoring, evaluation of self inspection.			
17.3	How conclusion and recommended correcting actions are followed and adopted.			
17.4	What is the frequency of self-inspection.			
17.5	Is there any proforma for carrying out the self-inspection. Please indicate the date of last self-inspection.			
18	***Quality Control System: -***			
18.1	Please specify the details of quality control system of the unit.			
18.2	How the reference standards are stored, evaluated and maintained. Please provide list of reference standard and reference impurities procured from the authentic sources.			
18.3	Please specify the procedures of preparation of working standard from the reference standards.			
18.4	Whether SOPs for sampling, inspecting, testing of Raw Materials, Finish products, Packing Materials and for monitoring environmental conditions are available.			
18.5	Whether approved specifications for different materials, products, reagents, solvents including test of identity content, purity and quality available.			
18.6	How reference samples from each batch of the products are maintained.			
18.7	Who releases batch of the products for sale			
18.8	Whether there is check list for release of a batch. Please specify current SOP No. for batch release.			
18.9	Please specify the sampling procedures from various stages of production.			
18.10	How it is ensured that the sample collected are representative of the whole batch.			

18.11	Please specify the procedures for carrying out the stability studies.			
18.12	Under what condition stability studies of the products are tested. How many stability chambers have been provided.			
18.13	How self life is assigned to a product. Please give current stability protocol No.			
18.14	Whether records of stability studies are maintained.			
18.15	Please attach stability calendar of last year.			
18.16	How complaints are investigated.			
18.17	How instruments are calibrated and at which interval.			
18.18	How testing procedure validated before they are adopted for routine testing.			
18.19	Specify the validation procedure is responsible for validation of procedures.			
18.20	How validation procedures are documented (Please indicate various protocols/ recoding system applied during validation).			
18.21	Whether specifications for raw materials intermediates final products and packaging materials are available.			
18.22	Whether periodic revision of these specifications are carried out. Please specify No. of STPs being maintained by the firm.			
18.23	Which pharmacopoeias in original are available in the plant.			
19	***Specifications: -***			
19.1	Whether specification of raw material include. (a) the designated name and internal code reference; (b) reference, if any, to a pharmacopoeial monograph; (c) qualitative and quantitative requirements with acceptance limits; (d) name and address of manufacturer or supplier and original manufacturer of the material; (e) specimen of printed material; (f) directions for sampling and testing or reference to procedures;			

	(g) storage conditions; and (h) Maximum period of storage before re-testing. Whether specification of finished product include (a) the designated name of the product and the code reference; (b) the formula or a reference to the formula and the pharmacopoeial reference; (c) directions for sampling and testing or a reference to procedures; (d) a description of the dosage form and package details; (e) the qualitative and quantitative requirements, with the acceptance limits for release; (f) the storage conditions and precautions, where applicable, and (g) the shelf-life.			
19.2	Whether the container and closures meet the pharmacopial specifications. Whether second hand or used containers and closures used.			
20	**Master Formula Records: -**			
20.1	How master formula records are prepared, authorized and controlled.			
20.2	Whether head of production, quality control and quality assurance unit endorse this documents. Whether master formula is batch size specific.			
20.3	Whether all products have master formula containing. (a) the name of the product together with product reference code relating to its specifications; (b) the patent or proprietary name of the product along with the generic name, a description of the dosage form, strength, composition of the product and batch size; (c) name, quantity, and reference number of all the starting materials to be used. Mention shall be made of any substance that may „disappear" in the course of processing. (d) a statement of the expected final yield with the acceptable limits, and of relevant intermediate yields, where applicable. (e) a statement of the processing			

	location and the principal equipment to be used. (f) the methods, or reference to the methods, to be used for preparing the critical equipments including cleaning, assembling, calibrating, sterilizing; (g) detailed stepwise processing instructions and the time taken for each step; (h) the instructions for in-process control with their limits; (i) the requirements for storage conditions of the products, including the container, labeling and special storage conditions where applicable; (j) any special precautions to be observed; (k) packing details and specimen labels.			
21	**Packaging Records: -**			
21.1	Whether authorized packaging instructions for each products, pack size and type are maintained and complied with. Whether following are included in the packaging instructions. (a) Name of the product; (b) the pack size expressed in terms of the weight or volume of the product in the final container; (d) complete list of all the packaging materials required for a standard batch size, including quantities, sizes and types with the code or reference number relating to the specifications of each packaging material.; (e) reproduction of the relevant printed packaging materials and specimens indicating where batch number and expiry date of the product have been applied; (f) special precautions to be observed, including a careful examination of the area and equipment in order to ascertain the line clearance before the operations begin. (g) description of the packaging operation, including any significant subsidiary operations and equipment to be used;			

	(h) details of in-process controls with instructions for sampling and acceptance; and (i) Re-conciliation after completion of the packing and labeling operation. (j) Whether line clearance records are part of batch packing records.			
22	***Batch Processing Records*** **(BPR)**			
22.1	Whether BPR are based on current master formula record.			
22.2	How BPR are designed to avoid transcription errors. Whether the Batch Processing Records for each product on the basis of currently approved master formula is being maintained. Whether following information are recorded in BPR (a) the name of the product, (b) the number of the batch being manufactured, (c) dates and time of commencement, significant intermediate stages and completion of production. (d) initials of the operator of different significant steps of production and where appropriate, of the person who checked each of these operations, (e) the batch number and/or analytical control number as well as the quantities of each starting material actually weighed, (f) any relevant processing operation or event and major equipment used, (g) a record of the in-process controls and the initials of the person(s) carrying them out,and the results obtained, (h) the amount of product obtained after different and critical stages of manufacture (yield), (i) comments or explanations for significant deviations from the expected yield limits shall be given, (j) notes on special problems including details, with signed authorization, for any deviation from the Master Formula, (k) Addition of any recovered or			

	reprocessed material with reference to recovery or reprocessing stages. Specify the procedures for all the entries made in BPR‟s. (l) Procedure for reprocessing and policy of the firm for adding of recovery.			
23	**Standard Operating Procedure and Records: -**			
	Whether SOPs and records are being maintained and complied for the following. SOP for receipt of in coming material (a) SOP for Internal labelling, quarantine, storage, packaging material and other materials (b) SOP for each instrument and Equipment (c) SOP for sampling (d) SOP for batch numbering (e) SOP for testing (f) SOP for equipment assembly and validation (g) SOP for Analytical apparatus and calibration (h) SOP for maintenance, cleaning and sanitation (i) SOP for training and hygiene for the personal (j) SOP for retaining reference Samples (k) SOP for handling, re-processing and recoveries (l) SOP for distribution of the product (m) SOP for warehousing of products. Whether applicable SOPs are available in each area where they are required. Whether recording formats are referred in SOP. Is there SOP for writing an SOP.			
24	**Reference Samples**			
24.1	Specify the procedures for collection of reference samples of active ingredients and finished formulations and how they are stored and maintained.			
25	**Reprocessing and Recoveries**			
25.1	Is appropriate Validation of recoveries and reprocessing done is			

	being performed?			
26	**Distribution records**			
26.1	Whether pre dispatch inspections are carried out before release.			
26.2	Whether periodic audits of distribution center are carried out to access warehousing practices			
26.3	Whether distribution records are part of the batch record. If not how batch wise distribution record up to retail levels are maintained.			
26.4	Whether instruction for warehousing and stocking of products like LVPs, Heat sensitive etc are available in store.			
26.5	Whether Good Distribution Practices followed			
27	**Validation and Process Validation: -**			
27.1	Specify the validation policy of the company. Whether validation master plan has been prepared.			
27.2	Whether validation studies of processing, testing and cleaning procedures are conducted as per pre defined protocol.			
27.3	How records and conclusion of such validation studies are prepared and maintained.			
27.4	Whether master formula is based on approved process validation.			
27.5	Specify how significant changes to the manufacturing process equipments material etc are controlled.			
27.6	Whether DQ,IQ,OQ & PQ are in place for all major equipment and facility.			
27.7	Whether validation records of all utilities and major equipments are available.			
28	***Product Recalls: -***			
28.1	Specify the product recall system followed by the firm. How promptly recall operation at the level of each distribution channel up-to the retail level can be carried out. Whether there is a SOP for recall of products clearly defining responsibility, procedure, reporting,			

	re-conciliation etc.			
29	***Complaints and Adverse Reactions:***			
29.1	Specify the review system for complaints concerning the quality of products.			
29.2	How records of complaint maintained.			
29.3	Whether reports of serious complaints with comments and documents immediately sent to Licensing Authority			
29.4	Is there any criteria for action to be taken on the basis of nature of complaint.			
30	***Site Master file: -***			
30.1	Whether all the relevant information have been included in the site master file.			
30.2	Whether quality policy has been included in the site master file. Please attach the current version			
30.3	Is there a master plan (Master validation plan) covering:			
30.4	Resources and those responsible for its implementation.			
30.5	Identification of the systems and processes to be validated			
30.6	Documentation and standard operating procedures (SOPs), Work Instructions and Standards (applicable national and international standards)			
30.7	Validation list: facilities, processes (e.g. aseptic filling), products			
30.8	Key approval criteria			
30.9	Protocol format			
30.10	Each validation activity, including re-validation and reasonable unforeseen events (power failures, system crash and recovery, filter integrity failurer. Please attach validation calendar.			
30.11	Pls specify whether the critical processes validated Prospectively, retrospectively or concurrently.			
30.12	Whether validation of following performed and documented: Analytical methods, Production and assay equipment, Sterile production processes, Non-sterile production processes, Cleaning procedures, Critical support systems (purified			

	water, water for injections, air, vapor, etc.), Facilities			
30.13	Please list reasons considered important for validation or re-validation.			
30.14	In case electronic data processing systems are used, are these validated? Please specify whether periodical challenge tests performed on the system to verify reliability.			
30.15	Are the validation studies performed according to pre-defined protocols? Is a written report summarized, results and conclusions prepared and maintained? Is the validity of the critical processes and procedures established based on a validation study?			
30.16	Are criteria established to assess the changes originating a revalidation? Are trend analyses performed to assess the need to re-validate in order to assure the processes and procedures continue to obtain the desired results?			
31	**WATER SYSTEM PURIFIED WATER WATER FOR INJECTIONS**			
31.1	Please specify whether waster system qualification (IQ, OQ and PQ) has been carried out as per protocol and repots have been prepared and maintained.			
31.2	Whether IQ protocol 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, SOP for operations, cleaning, sanitation, maintenance and calibration of gadgets. Whether its report includes Conclusion / Summary, description of the performed assay, Data tables, Results, Conclusions, Protocol reference, Revision and approval signatures.			
31.3	Whether OQ protocol include at least System production capacity (L/min), Flow type and water rate, Valve operation, Alarm system			

	operation and Controls operation?			
31.4	Whether its report includes Conclusion / Summary, description of the performed assay, Data tables, Results, Conclusions, Protocol reference, Revision and approval signatures.			
31.5	Please specify the water whether Phase 1, Phase 2 and Phase 3 studies carried out in at PQ stages?			
31.5.1	Phase 1 : Whether the operations parameters, cleaning and sanitation procedures & frequencies defined. Whether daily sampling records for every pretreatment point and usage point for a period of 2 to 4 weeks maintained and SOP‘s prepared.			
31.5.2	PHASE 2 : Whether daily sampling records for every pretreatment point and usage point for a period of 4 to 5 weeks after Phase 1 maintained and reviewed.			
31.5.3	PHASE 3 : Whether weekly sampling records available of every usage point for a one-year period. In the case of water for injections systems, are the daily sampling records of at least one usage point available, with all the usage points sampled weekly? Whether results of these records summarized to show suitability. Are there personnel training records?			
32	**EQUIPMENT**			
32.1	Are the equipment installation Qualification (IQ) protocols contains followings: Introduction, Installation description, Responsibilities, Performed tests/assays, Qualification acceptance criteria and Data recording and reporting?			
32.2	Whether report contains Summary, Description of performed tests/assays, Obtained data tables, Results, Conclusions, Installation diagrams, Revision and approval signatures.			
32.3	Whether the equipment operation qualification (OQ) protocols contains following: Introduction, Equipment description, Description of the equipment operation steps			

	(SOP‘s), Responsibilities, Qualification acceptance criteria, Data recording and reporting. Whether report contains Summary, Description of performed tests/assays, Obtained data tables, Results, Conclusions, Revision and approval signatures.			
32.4	Whether equipment performance qualification (PQ) protocols contains followings: Introduction, Responsibilities, Performed assays, Qualification acceptance criteria, Data recording and reporting.			
32.5	Whether report contains Summary, Description of performed tests/assays, Obtained data tables, Results, Conclusions, Revision and approval signatures.			
32.6	Whether Preventive Maintenance Schedule of the equipments is followed and records available?			
33	**Analytical Method Validation**			
33.1	Please specify whether following Characteristics are considered during validation of analytical methods: — specificity — linearity — range — accuracy — precision — detection limit — quantitation limit — Robustness.			
33.2	Whether Paharmocopial methods are also validated. If yes, how.			
33.3	Whether system suitable testing is included in testing protocols e.g. HPLC, GC etc.			
33.4	Whether the procedure covers all aspects of impurity profiling required			
33.5	Whether procedure covers all aspects of Organic Volatile Impurities detection and quantification			
34	**CLEANING**			
34.1	Is a validation performed to confirm cleaning effectiveness?			
34.2	Does the protocol define the selection criteria for products or			

	groups of products subject to cleaning validation?			
34.3	Is data produced supporting the conclusion that residues were removed to an acceptable level?			
34.4	Please specify whether the validation is implemented to verify cleaning of: Surfaces in contact with the product, After a change in product, Between shift batches.			
34.5	Please specify whether the Validation Strategy include contamination risks, equipment storage time, the need to store equipment dry and sterilize and free of pyrogens if necessary?			
34.6	Whether the cleaning Validation Protocol include: a. Interval between the end of production and the beginning of the cleaning SOP‘s. b. Cleaning SOP‘s to be used. c. Any monitoring equipment to be used. d. Number of consecutive cleaning cycles performed? e. Clearly defined sampling points.			
34.7	Whether Quality Control responsible of the sampling for cleaning verification?			
34.8	Whether personnel engaged in cleaning, sampling etc. trained.			
34.9	Please specify whether acceptance limits been set for cleaning verification and are based on following criteria: a. Visually clean. b. 10 ppm in another product c. 0.1% of the therapeutic dose?			
34.10	Please specify whether detergent residues investigated and degradation products verified during validation.			
34.11	Whether validation records include Recovery study data, Analytical methods including Detection Limits and Quantification Limits, Acceptance Criteria, Signatures of the Quality Assurance Manager, employee in charge of cleaning and the verification from Production and Quality Control.			

35	**Air Handling System**			
35.1	Please specify whether following parameters have been qualified: — 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 — containment system 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 where applicable.			
35.2	Whether strategic tests like Particle count, air pressure differential, air flow volume, air flow velocity etc. included in Air Handling System qualification.			
36	**Media fill test**			
36.1	Whether medial fill tests carried out twice in a year during normal working conditions.			
36.2	Pls give date of last such test.			
36.3	How many units are filled and tested.			
36.4	What is the criterion for qualification of this test?			
36.5	In case of failure of media fill test, what precautions or actions are taken.			
37	**Product Information**			
37.1	Name of product			
37.2	Whether validated master formula is available?			
37.3	Whether specific SOP for product processing is available?			
37.4	Comments on the above SOP			
37.5	Process Validation performed for the product covers all aspects and the approach is Risk Based			
37.6	No. of Batches Produced			
37.7	Stability studies (i) Accelerated			

	(ii) Real Time (iii) Whether the expiry date assigned on the basis of stability study?			
37.8	Whether trend analysis was carried out and interpretation thereof?			
37.9	Whether Annual product review (APR) is carried out? Whether the following parameters considered in the Annual product review? 1 critical in-process control and critical API test results 2 all batches that failed to meet established specification(s) 3 all critical deviations or non-conformances and related investigations 4 any changes carried out to the processes or analytical methods 5 results of the stability monitoring programme 6 quality-related returns, complaints and recalls and adequacy of corrective actions			
37.10	Is there any complaint received for the product and If any, whether the investigation report along with ATR is maintained?			