S.No.	Particulars	Verified \ Not Verified	Reference Document	Remark
1.0	**SOP's**			
1.1	Are a complete index and a complete set of applicable SOPs available in the department?			
1.1.1	Are the annexure current?			
1.1.2	Select any three SOP's and check its contents for cGMP compliance and effectiveness, in order to identify the gaps if any.			
2.0	**PERSONNEL**			
2.1	Select three employees working in the department? Are their training records up-to-date?			
2.2	Have the employees undergone training as per - QC Procedures? - STP?			
2.3	Question several employees about the operations they are performing. Are they knowledgeable about their job functions?			
2.4	Record of analyst qualification available/updated?			
3.0	**FACILITIES**			
3.1	Is the laboratory maintained in a good state of repair?			
3.2	Is the laboratory neat and orderly arranged with sufficient space for equipment and operations?			
3.4	Are all reagents and solutions			

S.No.	Particulars	Verified \ Not Verified	Reference Document	Remark
	- Clearly labeled with their proper name? - Labeled with date of receipt and/or expiration date?			
3.5	Are prepared solutions labeled with the - Name of person who prepared them? - Date of preparation? - Expiration date?			
4.0	**INSTRUMENTATION AND CALIBRATION**			
4.1	Is there an approved preventive maintenance program for all equipment / instruments used in the laboratory?			
4.1.1	Is there evidence that it is followed?			
4.1.2	Is the program based on manufacturer's recommendations?			
4.1.3	If not, is there a documented rationale for the alteration of the schedule?			
4.1.4	Is there documented evidence that the person who performs the preventive maintenance is qualified to do so?			
4.2	Select three major instruments used in the laboratory.			
4.2.1	Are there written procedures for operating the instruments?			
4.2.2	Are there written procedures for calibrating the instruments?			
4.2.3	Is there a valid calibration sticker on each instrument?			

S.No.	Particulars	Verified \ Not Verified	Reference Document	Remark
4.2.4	Examine the calibration records for the instruments. - Are they up-to-date? - Are the results within limits?			
4.2.5	Is there an SOP for corrective action in the event that an instrument is found to be out of calibration?			
4.2.6	Where standards are used to calibrate an instrument, is there a written procedure for their preparation?			
5.0	**SAMPLE RECEIPT, STORAGE, AND DOCUMENTATION**			
5.1	Is a specific person responsible for the receipt of samples for testing?			
5.2	Is there a written SOP describing sample receipt and recording (Logging in)?			
5.3	Where are samples stored before and after testing?			
5.4	Are samples retained after completion of testing?			
5.5	What happens to samples after testing and reporting are complete?			
5.6	Is there a time limit on how long a sample may remain in the laboratory prior to testing?			
5.7	Are the reserve sample kept as per procedure?			
6.0	**TEST PROCEDURES**			
6.1	Are there approved test procedures available for all tests performed in the laboratory?			
6.2	Examine the work currently being performed on the HPLCs. Product Name :			

S.No.	Particulars	Verified \ Not Verified	Reference Document	Remark
	Batch No. :			
6.2.1	Is the test procedure at hand?			
6.2.2	Is it up-to-date?			
6.2.3	Is it being accurately followed?			
6.2.4	Is the analysis recorded in the protocol prior to beginning work, including the physical appearance of the sample?			
6.2.5	Has the analyst recorded all the relevant details of the product being tested, including the attachment of printouts or record of weighing?			
6.2.6	Is there documented evidence that system suitability was determined prior to use of the chromatography in the analysis?			
6.2.7	Is there a reference to the test method used in the analyst's Test Data Sheet (TDS) / protocol?			
6.2.8	Do retention samples form part of laboratory records.			
6.2.9	Is written cleaning procedure available for all equipment and Glassware?			
6.2.10	Are laboratory records having name of Product and Batch number?			
6.2.11	Are laboratory records indicating date of receipt of sample and expiry date?			
7.0	**RECORDING RESULTS**			
7.1	Examine an analyst's Test Data Sheet.			
7.1.1	Is it with numbered pages?			
7.1.2	Is it neatly filled in and legible?			

S.No.	Particulars	Verified \ Not Verified	Reference Document	Remark
7.1.3	Are any cross-outs initialed and dated?			
7.1.4	Is there a record of the instrument used for testing together with any raw data?			
7.1.5	Are all calculations recorded?			
7.1.6	Are all charts, graphs, and printouts labeled with the - Product name and batch number? - Date of the test?			
7.1.7	Are numbers rounded in accordance with an approved SOP?			
7.1.8	Do the dates on graphs/charts match with the dates of analysis?			
7.1.9	Is there a statement in the TDS as to whether or not the sample passes the test?			
7.1.10	Is the analyst's signature recorded in the TDS?			
7.1.11	Are references of Instruments/Equipment's and volumetric solution used given in the TDS?			
8.0	**REFERENCE STANDARDS / WORKING STANDARDS**			
8.1	Examine a reference standard.			
8.1.1	Is it stored appropriately?			
8.1.2	Is document available for receipts of same?			
8.1.3	Is the standard tested internally to confirm its quality?			
8.2	Is there a written SOP for the preparation of working standards?			

S.No.	Particulars	Verified \ Not Verified	Reference Document	Remark
8.2.1	How often are working standards prepared?			
8.2.2	What expiration date is given to working standards?			
8.2.3	Has the expiration date been validated?			
8.2.4	Are working standards certified against compendia standards?			
8.3	Is there a record of the preparation of volumetric solutions?			
8.3.1	Are volumetric solutions freshly prepared?			
8.3.2	If stored, what expiration date are they given?			
8.3.3	Examine a test where a volumetric solution was used. Was the titer correctly recorded in the notebook?			
9.0	**OUT OF SPECIFICATION**			
9.1	Any OOS observed?			
9.1.1	OOS proper investigate in laboratory or not?			
9.1.2	Is there an SOP for OOS handling?			
9.1.3	After verification of completion of OOS investigation-Final approval done or not?			
10.0	**EVALUATION/ SUPERVISION OF RESULTS**			
10.1	Is there an SOP for review of test data and calculations?			
10.2	Are raw data reviewed prior to release from the laboratory by a person other than the analyst who performed the test?			
10.2.1	Are TDS routinely reviewed by a supervisor?			
10.2.2	Do reviewers sign the TDS to indicate that it has been reviewed?			

S.No.	Particulars	Verified \ Not Verified	Reference Document	Remark
11.0	**STABILITY STUDY**			
12.0	**METHODS VALIDATION**			
12.1	Have all in-house methods been validated?			
12.2	Is there a written SOP relating to the validation of analytical methods?			
12.3	Does methods validation provide data to demonstrate - Linearity? - System precision? - Method precision? - Method specificity? - Robustness? - Method ruggedness? - Accuracy? - Solution stability?			
13.0	**LAST AUDIT COMPLIANCE:**			
13.1	Check & Verify the compliance of the observations noted in last audit.			
14.0	**OTHER OBSERVATIONS:**			

S.No.	Particulars	Verified \ Not Verified	Reference Document	Remark

S.No.	Particulars	Verified \ Not Verified	Reference Document	Remark

Sr. No	Particulars	Verified \ Not Verified	Reference Document	Remark
1.0	**SOPs**			
1.1	Are a complete index and a complete set of applicable Standard Operating Procedure (SOP) / Microbiological Method (MM) available in the department?			
1.1.1	Are the index and the SOPs / MM current?			
1.1.2	Is the set of SOPs / MM correctly organized according to the index?			
1.1.3	Select any five SOP's and check its contents for cGMP compliance and effectiveness, in order to identify the gaps if any.			
2.0	**PERSONNEL**			
2.1	Select any one employee working in the department. Are his training records up-to-date?			
2.2	Have the employee undergone training in the following areas during the last year? - GMP - SOPs / MS's - Microbiological techniques			
2.3	Question several employees about the operations they are performing. Are they knowledgeable about their job functions?			
2.4	Have the employees undergone qualification according to the relevant SOP?			
2.5	Are detailed, written job descriptions available for all employees?			
2.6	Are all employee attired according to the appropriate garmenting SOP?			

3.0	**FACILITIES**			
3.1	Is the laboratory maintained in a good state of repair?			
3.2	Is the laboratory neat and orderly with sufficient space for equipment and operations?			
3.3	Is there evidence of good housekeeping?			
3.4	Are all reagents and solutions - Clearly labeled with their proper name? - Labeled with date of receipt and/or expiration date?			
3.5	Are prepared solutions labeled with - Name of person who prepared them? - Date of preparation? - Expiration date?			
3.6	Is the clean room maintained in a good state of repair?			
3.7	Is there an SOP for the cleaning and disinfection of the clean room?			
3.7.1	Is the SOP equivalent to that used in production?			
3.8	Are there records of the preparation of disinfectants?			
3.8.1	Are disinfectants labeled with expiration dates?			
3.9	Are cleaning records available and correctly filled out?			
4.0	**EQUIPMENT AND INSTRUMENTATION**			
4.1	Is there an approved preventive maintenance program for all equipment used in the laboratory?			
4.1.1	Is there evidence that it is followed?			
4.2	Is there an approved calibration schedule for all instrumentation in the laboratory?			

4.2.1	Is there evidence that it is followed?			
4.3	Select one equipment used in the laboratory.			
4.3.1	Are there written procedures for operating the equipment?			
4.3.2	Is there a valid calibration sticker on each instrument?			
4.4	Are temperature recorders attached to all incubators and refrigerators?			
4.4.1	Are there an approved SOP / MM that requires the routine checking and signing of temperature charts?			
4.4.2	Are there an SOP / MM defining cleaning and sanitization procedures for the incubators and refrigerators?			
4.4.3	Is there documented evidence that it is being followed?			
4.5	Examine the most recent validation file for the autoclave.			
4.5.1	Was the validation performed as per schedule?			
4.5.2	Do the results meet the relevant acceptance criteria?			
4.5.3	Validation of F0 value of autoclave.			
5.0	**SAMPLE RECEIPT, STORAGE, AND DOCUMENTATION**			
5.1	Is a specific person responsible for the receipt of samples for testing?			
5.2	Is there a written SOP describing sample receipt and recording (Logging in)?			
5.3	Where are samples stored before and after testing?			
5.4	Are samples retained after completion of testing?			
5.5	Examine the contents of a refrigerator and an incubator.			
5.5.1	Is the equipment clean?			
5.5.2	Are all test samples recorded in the laboratory logbook?			
5.5.3	Are all items clearly labeled?			

6.0	**TEST PROCEDURES**			
6.1	Are there approved test procedures available for all tests performed in the laboratory?			
6.2	Is there a written procedure for ensuring that all pharmacopoeial procedures are updated when a supplemental monograph is issued?			
6.3	Examine the work currently being performed. Product Name : Batch No.: Test Procedure:			
6.3.1	Is the test procedure at hand?			
6.3.2	Is it up-to-date?			
6.3.3	Is it being accurately followed?			
6.3.4	Has the test method been validated for precision and reliability?			
6.3.5	Are records available for the preparation of media used for performing the test?			
6.3.6	Is the medium labeled with an expiration date?			
6.3.7	Is labeling done in accordance with an approved SOP?			
6.3.8	Is the analysis recorded in the analyst's Test Data Sheet			
6.3.9	(TDS) prior to beginning work?			
6.3.10	Has the analyst recorded all the relevant details of the product being tested, including the attachment of printouts or records of weighing?			
6.3.11	Is there a reference to the test method used in the analyst's TDS?			
6.3.12	Are review sheets of Instrument Operating Procedure (IOP) / Equipment Operating Procedure (EOP) updated.			
6.4	Is there a written Microbial monitoring programme for non-sterile Products?			
6.5	Does a procedure exist for media preparation?			

7.0	**RECORDING RESULTS**			
7.1	Examine an analyst's Test Data Sheet (TDS).			
7.1.1	Is the log book issued or not?			
7.1.2	Is it a stapled book with numbered pages?			
7.1.3	Is it neatly filled in and legible?			
7.1.4	Are any cross-outs initialed and dated?			
7.1.5	Are all calculations recorded?			
7.1.6	Are numbers rounded in accordance with an approved SOP?			
7.1.7	Is there a statement in the TDS as to whether or not the			
7.1.8	Sample passes the test?			
7.1.9	Is the analyst's signature recorded in the TDS?			
8.0	**STOCK CULTURES**			
8.1	Is there an SOP for the receipt and handling of American Typed Culture Collection (ATCC) / National Collection of Typed Culture (NCTC) cultures?			
8.2	Are cultures received with a certificate of analysis?			
8.3	How often are ATCC / NCTC cultures transferred?			
8.3.1	Identification of master cultures.			
9.0	**OUT OF SPECIFICATION**			
9.1	Any OOS observed? If yes			
9.1.1	OOS properly investigated in laboratory or not?			
9.1.2	Re-testing done on same sample or new sample?			
9.1.3	After verification of completion of OOS investigation-			
9.1.4	Final approval done or not?			

10.0	**EVALUATION/SUPERVISION OF RESULTS**			
10.1	Is there an SOP for review of test data and calculations?			
10.2	Are raw data reviewed prior to release from the laboratory by a person other than the analyst who performed the test?			
10.2.1	Are TDS routinely reviewed by a supervisor?			
10.2.2	Do reviewers sign the TDS to indicate that it has been reviewed?			
11.0	**ENVIRONMENTAL AND PERIODIC MONITORING (CLEAN ROOM)**			
11.1	Is there an SOP for monitoring differential air pressures?			
11.2	Are there written records of air pressures checked and signed?			
11.3	Is there an SOP for environmental monitoring in the clean room?			
11.3.1	Do results conform to the limit stated in the SOP?			
11.3.2	When out-of-limit results were obtained, was corrective action implemented in accordance with the SOP?			
11.4	Examine records of PAO/DOP and air velocity monitoring for the past six months.			
11.4.1	Are there records of checking laminar airflow velocities?			
11.4.2	Are there records of checking PAO/DOP?			
11.5	Check the trend charts of environment control (settle plate exposure and air sampling) in production areas.			
12.0	**METHOD VALIDATION**			
12.1	Have all in-house method been validated?			
12.2	Is there a written SOP relating to the validation of microbiological method?			
12.3	Does validation of method provide data to demonstrate			

	- Method of Sensitivity - Recovery of organism - Effect of any inactivating anti microbial agent			
13.0	**WATER SYSTEM**			
13.1	Check the updated schematic diagram of sampling points of potable/purified water.			
13.2	Check the trend charts of seasonal variation for potable water.			
13.3	Check the trend charts of purified water IP.			
13.4	Are there updated schematic diagrams of location plan of settle plate exposure and air sampling in microbiology lab & production areas?			
14.0	**OTHER DOCUMENT**			
14.1	Validation of cleaning / use of disinfectants in production areas.			
14.2	Validation of Microbiology testing area.			
14.3	Are the media stocks prepared in accordance to First In First Out (FIFO) rule?			
14.4	Identification of master cultures.			
14.5	Identification of environment control isolates & isolates of microbial limit test water analysis.			
14.6	Calibration of UV hour meter and intensity check of UV lights on LAF bench and Pass box.			
14.7	Records of calibration of air sampling available and are found satisfactory.			
15.0	**LAST AUDIT COMPLIANCE :**			
15.1	Check & Verify the compliance of the observations noted in last audit.			

16.0	Other Observations

