S.No.	Particulars	Verified \ Not Verified	Reference Document	Remark
GRANULATION				
1.0 SOP's				
1.1	Is a complete index and a complete set of applicable SOP's available			
1.1.1	Are the index and the SOP's current version available?			
1.1.2	Is the set of SOP's correctly organized according to the index?			
1.1.3	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 any two employees working in the department. Are their training records up-to-date?			
2.2	Have the employees undergone training in the following areas during the last year? - GMP SOP's			
2.3	Question several employees about the operations they are performing. Are they knowledgeable about their job functions?			
2.4	Are all employees attired according to the appropriate garmenting SOP?			
2.5	Is the entry exit procedure followed?			

S.No.	Particulars	Verified \ Not Verified	Reference Document	Remark
3.0 FACILITIES				
3.1	Is the department maintained in a good state of repair?			
3.2	Is the department neat and orderly with sufficient space for equipment and operations?			
3.3	Are all the raw materials for one batch assembled on a pallet?			
3.4	Where more than one pallet is designated for one batch, is each pallet clearly labeled?			
3.5	Are all work areas clearly labeled with the name and the batch number of the product being processed?			
4.0 PREVENTION OF CROSS-CONTAMINATION				
4.1	Are doors closed at all times?			
4.2	Are door interlocking system working?			
4.3	Is negative pressure maintained in working areas at all times during work?			
4.3.1	Is there environmental monitoring record available?			
4.4	What is the quality of air in the department (filter designation)?			
4.5	Is personnel clothing clean, unstained, and dust free?			
5.0 EQUIPMENT AND FACILITY CLEANING				
5.1	Are pallets and drums brought into the area are clean and free from powder / dust / dirt?			
5.2	Is the equipment neat, clean, and rust free? (check the surface of			

S.No.	Particulars	Verified \ Not Verified	Reference Document	Remark
	equipment/projections if any)			
5.3	When not in use, are equipment covered so as to prevent accidental contamination?			
5.4	Are the equipment suitably designed for its purpose?			
5.5	Is the equipment constructed so that product contact surfaces are not reactive or absorptive, so that it will not contaminate or in any way affect the product being manufactured?			
5.6	Are there specific procedures for the cleaning of major equipment items?			
5.7	Visually inspect one piece of equipment that is not in use			
5.7.1	Is it labeled with respect to its cleanliness status?			
5.7.2	Is it clean?			
5.8	Do cleaning procedures include a requirement for the cleaning of small items (e.g., Scoops etc?)			
5.9	Is there an approved protocol for cleaning validation?			
5.9.1	Is there documented evidence that it is being followed?			
5.10	Is there a written procedure for washing the finger bags of fluid bed processor?			
6.0	**WORKING PROCEDURES**			
6.1	Examine the record of the daily check of balances in the department.			

S.No.	Particulars	Verified \ Not Verified	Reference Document	Remark
6.1.1	Is it complete and accurately filled out?			
6.1.2	Are all results within the acceptance criteria?			
6.1.3	If not, is there a record of the implementation of corrective action?			
6.2	Perform a visual examination of the weights with which the check is performed.			
6.2.1	Are they in a good state of repair?			
6.2.2	Do they bear a valid calibration sticker?			
6.3	Examine the batch record for a batch that is being processed. Product: Batch No.:			
6.3.1	Is the master formula signed as being an accurate copy of the original?			
6.3.2	Have any changes to the master formula been authorized by QA?			
6.3.3	Is the record completely and accurately filled out up to the appropriate stage of processing?			
6.3.4	Are all in-process results within the defined limits?			
6.4	Is there a written procedure for the cleaning of drums after use?			
6.5	Examine the in-process storage area for finished granules.			
6.5.1	Are the granules properly labeled?			
6.6	Do yield calculations after granulation conform to the relevant limits?			
6.6.1	If not, has a BMR been completed and an investigation conducted?			

S.No.	Particulars	Verified \ Not Verified	Reference Document	Remark
6.6.2	Is yield calculation performed after each distinct phase of production?			
6.7	Is there a record of checking the integrity of sieve screens after use for signs of damage?			
7.0	**LUBRICANTS**			
7.1	Is equipment designed in such a way that lubricants or coolants cannot come into contact with components or drug product?			
7.2	Is there an approved list of food-grade lubricants for use where they may contact product?			
7.2.1	Is there a written procedure for the receipt and approval of such lubricants?			
7.3	Examine the lubricants available in the department. Are they clearly labeled and stored in a sanitary manner?			
7.3.1	Is there an SOP defining the maximum period of time that granules may be stored prior to tableting? (Hold time study)			
7.3.2	Is it adhered to?			
8.0	**EQUIPMENT CALIBRATION**			
8.1	Is there an approved annual program for the Calibration of all production equipment?			
8.2	Select one equipment and examine the Calibration records.			
8.2.1	Are the equipment items identified with a distinguishing code			

S.No.	Particulars	Verified \ Not Verified	Reference Document	Remark
	number?			
8.2.2	Is all critical instrumentation on the equipment items identified with a valid calibration tag?			
8.2.3	Physically verify that all instruments found on the equipment items are included in the Calibration file.			
8.3	Are all stirrers in the department calibrated?			
8.4	Are the Calibrations reports checked by appropriate personnel?			
8.4.1	Are the reports completely and accurately filled out?			
8.5	Where compressed air is supplied to machinery, is it oil free and filtered?			
8.5.1	Is there an SOP for filter replacement?			
8.6	What filtration is provided to incoming air in fluid bed processor?			
8.6.1	Is there an SOP for the cleaning and replacement of these filters?			
8.6.2	What measures are taken to prevent cross-contamination of product from these filters when inlet air is not functioning?			
9.0	**LAST AUDIT COMPLIANCE:**			
9.1	Check & Verify the compliance of the observations noted in last audit.			
COMPRESSION				
11.0	**SOPs**			
11.1	Are a complete index and a complete set of applicable SOPs			

S.No.	Particulars	Verified \ Not Verified	Reference Document	Remark
	available in the department?			
11.1.1	Are the index and the SOPs current?			
11.1.2	Is the set of SOPs correctly organized according to the index?			
11.1.3	Select any five SOP's and check its contents for cGMP compliance and effectiveness, in order to identify the gaps if any.			
12.0	**PERSONNEL**			
12.1	Select two employees working in the department. Are their training records up-to-date?			
12.2	Have the employees undergone training in the following areas during the last year? - GMP SOPs			
12.3	Question several employees about the operations they are performing. Are they knowledgeable about their job functions?			
12.4	Are all employees attired according to the appropriate garmenting SOP?			
12.4.1	When necessary, do operators wear masks and gloves?			
13.0	**FACILITIES**			
13.1	Is the department maintained in a good state of repair?			
13.2	Is the department neat and orderly with sufficient space for equipment and operations?			
13.3	Are all work areas clearly labeled with the name and the batch			

S.No.	Particulars	Verified \ Not Verified	Reference Document	Remark
	number of the product being processed?			
14. 0	**PREVENTION OF CROSS-CONTAMINATION**			
14.1	Are doors closed at all times?			
14.2	Are door interlocking system working			
14.3	Is negative pressure maintained in working areas at all times during work?			
14.3.1	Is there a record of the pressure?			
14.4	What is the quality of air in the department (filter designation)?			
14.5	Is personnel clothing clean, unstained, and dust free?			
15.0	**EQUIPMENT AND FACILITY CLEANING**			
15.1	Are pallets and drums brought into the area are clean and free from powder / dust / dirt?			
15.2	Is the equipment neat, clean, and rust free? (check the surface of equipment/projections if any)			
15.3	When not in use, are equipment covered so as to prevent accidental contamination?			
15.4	Are the equipment suitably designed for its purpose?			
15.5	Are there specific procedures for the cleaning of tableting machines?			
15.6	Select a tableting machine.			
15.7	Visually inspect one machine that is not in use.			

S.No.	Particulars	Verified \ Not Verified	Reference Document	Remark
15.7.1	Is it labeled with respect to its cleanliness status?			
15.7.2	Is it clean?			
15.8	Do cleaning procedures include a requirement for the cleaning of accessories? (e.g., scoop, balances, etc.)?			
15.9	Is there an approved protocol for the cleaning validation of tableting machines?			
16.0	**WORKING PROCEDURES**			
16.1	Examine the record of the daily check of balances in the department			
16.1.1	Is it complete and accurately filled out?			
16.1.2	Are all results within the specifications?			
16.1.3	If not, is there a record of the implementation of corrective action?			
16.2	Perform a visual examination of the weights with which the check is performed.			
16.2.1	Are they in a good state of repair?			
16.2.2	Do they have a valid calibration report?			
16.3	Examine the batch record for a batch that is being processed. Product: Batch No.:			
16.3.1	Is the master formula signed as being an accurate copy of the			

S.No.	Particulars	Verified \ Not Verified	Reference Document	Remark
	original?			
16.3.2	Have any changes to the master formula been authorized by QA?			
16.4	Is the dust collecting system functioning during work?			
16.4.1	Question the employee. Does he or she know what the correct procedure is if the dust collecting system stops functioning?			
16.5	Do yield calculations after tabletting conform to the relevant SOP?			
16.6	Examine the drums used for collecting tablets.			
16.6.1	Are they correctly labeled?			
16.6.2	Is the weight recorded on real time (i.e., after the drum is Completely filled)?			
16.7	Is there an SOP for the receipt of punches and dies in the department?			
16.7.1	Are punches lubricated in the department and, if so, with an approved lubricant?			
17.0	**IN-PROCESS CONTROL**			
17.1	Is there an approved SOP for in-process control?			
17.2	Does the SOP state at what frequency tests must be performed by Production personnel?			
17.2.1	Examine a batch record. is the test frequency adhered to?			
17.2.2	Do all test results conform to specifications?			
17.2.3	Are there TRF copy available for release of each stage with the			

S.No.	Particulars	Verified \ Not Verified	Reference Document	Remark
	- Product name? - Batch number? - Date of release?			
17.3	Examine a batch manufacturing record.			
17.3.1	Do the recorded specifications conform with the approved Product specifications?			
17.3.2	Do the recorded data match the attached printouts?			
17.3.3	Are results recorded in the correct units as stated on the form?			
17.4	Is all testing equipment labeled with a valid calibration sticker?			
17.5	Are tablets stored in bulk containers before coating and / or packaging?			
17.5.1	If yes, has a time limitation been set regarding the maximum amount of time bulk storage is permitted?			
17.5.2	Is the time limitation adhered to?			
18. 0	**LUBRICANTS**			
18.1	Is there an approved list of food-grade lubricants for use where they may contact product?			
18.2	Examine the lubricants available in the department. Are they clearly labeled and stored in a sanitary manner?			
19.0	**EQUIPMENT QUALIFICATION / CALIBRATION**			
19.1	Is there an approved annual program for the calibration of all			

S.No.	Particulars	Verified \ Not Verified	Reference Document	Remark
	tableting equipment?			
	COATING			
21.0	**SOPs**			
21.1	Are a complete index and a complete set of applicable SOPs available in the department?			
21.1.1	Are the index and the SOPs current?			
21.1.2	Is the set of SOPs correctly organized according to the Index?			
21.1.3	Select any five SOP's and check its contents for cGMP compliance and effectiveness, in order to identify the gaps if any.			
22.0	**PERSONNEL**			
22.1	Select any employees working in the department. Are their training records up-to-date?			
22.2	Have the employees undergone training in the following areas during the last year? - GMP SOPs			
22.3	Question several employees about the operations they are performing. Are they knowledgeable about their job functions?			
22.4	Are all employees attired according to the appropriate garmenting SOP?			
23.0	**FACILITIES**			

S.No.	Particulars	Verified \ Not Verified	Reference Document	Remark
23.1	Is the department maintained in a good state of repair?			
23.2	Is the department neat and orderly with sufficient space for equipment and operations?			
23.3	Are all work areas clearly labeled with the name and the batch number of the product being processed?			
24.0	**PREVENTION OF CROSS-CONTAMINATION**			
24.1	Area doors closed at all times?			
24.2	Is personnel clothing clean, unstained, and dust free?			
24.3	Is negative pressure maintained in working areas at all times during work?			
24.4	Are there approved SOPs for the maintenance of AHU filters?			
24.5	Is dirty equipment covered prior to transfer to the washing room?			
25.0	**EQUIPMENT AND FACILITY CLEANING**			
25.1	Are drums brought into the area clean and free from powder / dust?			
25.2	Is the equipment neat, clean, and rust free?			
25.3	Is the equipment suitably designed for its purpose?			
25.4	Are there specific procedures for the cleaning of tablet coating machines?			
25.5	Visually inspect one machine that is not in use.			
25.5.1	Is it labeled with respect to its cleanliness status?			

S.No.	Particulars	Verified \ Not Verified	Reference Document	Remark
25.5.2	Is it clean?			
25.6	Do cleaning procedures include a requirement for the cleaning of accessories?			
25.7	Check the cleanliness of the machine and ensure that it is visually cleaned or not?			
26.0	**WORKING PROCEDURES**			
26.1	Examine the record of the daily check of balances in the department.			
26.1.1	Is it complete and accurately filled out?			
26.1.2	Are all results within the specifications?			
26.1.3	If not, is there a record of the implementation of corrective Action?			
26.2	Perform a visual examination of the weights with which the check is performed?			
26.2.1	Are they in a good state of repair?			
26.2.2	Are they clean?			
26.2.3	Do they bear a valid calibration sticker?			
26.3	Examine the batch record for a batch that is being processed. Product: Batch No.:			
26.3.1	Is the master formula signed as being an accurate copy of the original?			

S.No.	Particulars	Verified \ Not Verified	Reference Document	Remark
26.3.2	Have any changes to the master formula been authorized by QA?			
26.4	Is there an SOP that specifies the maximum amount of time a coating solution may be kept after preparation prior to the completion of coating?			
26.5	Do yield calculations after coating conform with the relevant SOP?			
27.0	**IN-PROCESS CONTROL**			
27.1	Is there an approved SOP for in-process control?			
27.2	Examine a batch record.			
27.2.1	Do all test results conform to specifications?			
27.2.2	Is the SOP specific with regard to corrective action in the event that results do not conform to specifications?			
28.0	**EQUIPMENT QUALIFICATION / CALIBRATION**			
28.1	Is there an approved annual program for the calibration of all coating equipment?			
28.2	Select one machine			
28.2.1	Is the machine identified with a distinguishing code number?			
28.2.2	Is all critical instrumentation identified with a valid calibration sticker?			
PACKING				
30.0	**SOP'**			
30.1	Are a complete index and a complete set of applicable SOPs			

S.No.	Particulars	Verified \ Not Verified	Reference Document	Remark
	available in the department?			
30.1.1	Are the index and the SOPs current?			
30.1.2	Is the set of SOPs correctly organized according to the index?			
30.1.3	Select any three SOP's and check its contents for cGMP compliance and effectiveness, in order to identify the gaps if any.			
31.0	**PERSONNEL**			
31.1	Select any two employees working in the department. Are their training records up-to-date?			
31.2	Have the employees undergone training in the following areas during the last year? - GMP SOPs			
31.3	Question few employees about the operations they are performing. Are they knowledgeable about their job functions?			
31.4	Are all employees attired according to the appropriate garmenting SOP?			
31.4.1	When necessary, do operators wear masks and gloves?			
32.0	**FACILITIES**			
32.1	Is the department maintained in a good state of repair?			
32.2	Is the department neat and orderly with sufficient space for equipment and operations?			
32.3	Examine the area at the end of a day's work. Is it left neat and tidy?			

S.No.	Particulars	Verified \ Not Verified	Reference Document	Remark
32.4	Are all work areas clearly labeled with the name and the batch number of the product being processed?			
32.5	Is there adequate physical separation between different packaging lines to prevent mix-ups and / or cross-contamination?			
32.6	Are all parts of the line where product or primary packaging components are exposed covered to prevent accidental contamination of the product?			
33.0	**CLEANING PROCEDURES**			
33.1	Is there a written procedure for the cleaning of the packaging machine?			
33.1.1	Is there documented evidence that the cleaning procedure is being followed?			
33.2	Is there a written procedure for the cleaning of packaging equipment - Between batches of the same product? - Between batches of different products?			
33.2.1	Does the procedure specify which parts of the machine must be disassembled for cleaning?			
34.0	**LINE CLEARANCE PROCEDURES**			
34.1	Watch personnel performing line clearance. Is each stage of the process performed by one individual and then independently			

S.No.	Particulars	Verified \ Not Verified	Reference Document	Remark
	verified by a second individual?			
34.2	Examine the area prior to the introduction of packaging materials. Is it clean and free from any material from the previous batch?			
34.3	Do the printed packaging materials arrive under lock and key?			
34.4	Are packaging materials verified against BPR?			
34.5	Are the quantities of packaging materials verified against the amounts stated as dispensed from the packaging store?			
35.	**WORKING PROCEDURES**			
35.1	Is there a procedure for the daily checking of balances used in the department?			
35.1.1	Are there records to indicate that the procedure is being Followed?			
35.2	Is all instrumentation in the department labeled with a valid calibration sticker?			
35.3	Are all product covers for product protection closed at all times during the packaging operation?			
35.4	Are samples of all printed packaging materials used in the batch attached to the batch record?			
35.5	Is there a written procedure for the reconciliation of printed packaging materials?			
35.5.1	Watch the reconciliation being made. Are remaining packaging Materials accurately counted?			

S.No.	Particulars	Verified \ Not Verified	Reference Document	Remark
35.5.2	Are rejected packaging materials collected throughout the Batch in a manner that permits accurate counting for reconciliation?			
35.6	Is there a written procedure for the issuance of additional packaging materials if the amount dispensed is not sufficient?			
35.6.1	Does the procedure require documentation of the above in the batch record, including samples of the additional materials?			
35.6.2	Is the procedure followed?			
35.7	Is there a written procedure for cleaning and inspection the packaging area at the end of the batch?			
35.7.1	Is the inspection documented in the batch record?			
35.8	Is the batch yield calculated immediately upon completion of the packaging operation and prior to the introduction of a new batch into the area?			
35.9	Is any excess overprinted packaging materials destroyed on completion of the batch?			
35.9.1	Is there a written procedure for the destruction of printed packaging materials on completion of the batch?			
35.9.2	Is it followed?			
36.0	**IN-PROCESS CONTROL**			
36.1	Examine the records for the batch being processed. Are there written records of in-process control checks?			

S.No.	Particulars	Verified \ Not Verified	Reference Document	Remark
36.1.1	Is the frequency of checks in accordance with the relevant SOP?			
36.2	Is there a written procedure for the examination of packaged product during finishing operations to ensure correct labeling?			
37.0	**LAST AUDIT COMPLIANCE:**			
37.1	Check & Verify the compliance of the observations noted in last audit.			