VENDOR AUDIT CHECKLIST

1.	**Name of the material/code**	:			
	Manufactured by (Name and address)	:			
	Supplied by (Name and Address)	:			
	Manufacturing Site (Address)	:			
	Contact Persons: Marketing department	Name:	Contact No.:	Email:	
	Quality Assurance department	Name:	Contact No.:	Email:	
2.	**General Information**	:			
	Area of manufacturing site	:			
	Products manufactured	:			
	Major customers	:			
3.	**Organization and Personnel**	:			
	Managing Director	: Name:			
	Plant Manager/In-charge	: Name:	Designation:		
	QA/QC Manager/In-charge	: Name:	Designation:		
4.	**Employee details**	:			
	QA:	QC:	Production:	Ware House:	Total:

VENDOR AUDIT CHECKLIST

S. No.	Check Point	To be checked	Yes/No/NA	Remarks
A.	**GENERAL**			
1.	Is organization chart available?	Organization chart.		
2.	Is the manufacturing facility is certified ISO 9001 / 14001?	ISO 9001 Certificate No. : ISO 14001 Certificate No.:		Expiry date: Expiry date:
3.	Is there any other products manufactured in the same plant?	List of products manufactured.		
4.	Since how long you are manufacturing this product?			
5.	What is the lead time for delivery of the product from date of purchase order?			
6.	Is the material supplied by the company of animal origin?	TSE/BSE certificate.		
7.	Are the materials being manufactured, along with cephalosporin/ penicillin?	Physical verification.		
8.	Are route of synthesis, flowchart and brief manufacturing process available for product of concern?			
9.	Id the MSDS available for the product of concern?			
B.	**WARE HOUSE**			
10.	Are standard operating procedures available and followed?	List of Ware house procedures.		
11.	Are adequate space provided for quarantine/ approved/ rejected areas?	Demarcation of the areas. Rejected area under lock and key.		
12.	Are de-dusting of materials carried out?	De-dusting area and record.		

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S. No.	Check Point	To be checked	Yes/No/NA	Remarks
13.	Are materials properly segregated to avoid mix-ups and errors?	Batch wise segregation of raw materials.		
14.	Is material labeled for identification?	Under test, approved/rejected, sampled labels on the containers.		
15.	Is inventory record of each material maintained?	Raw material inward register, Inventory / bin card.		
16.	Is sampling area / dispensing area cleaned after activity?	Sampling area cleaning record. Dispensing area		
17.	Is FIFO system is followed?	Inventory / bin card		
18.	Are finished product distribution records available?	Finished product inward register, dispatch register.		
19.	Is handling of return goods SOP available and followed.	Procedure on return goods. Return goods register.		
20.	Is calibration SOP and records available for weighing scales and standard weights?	Weighing balance calibration procedure. Calibration records (daily/monthly). External calibration certificate of weighing balance and standard weights (from Govt.).		
21.	Are there pest and rodent control in ware house	Rodent traps in ware house. (Records to be checked at HR department)		
C.	**PRODUCTION**			
22.	Are SOPs available and followed?	Production standard operating procedures.		
23.	Is housekeeping schedule is followed.	Housekeeping record.		
24.	Are preventive maintenance available If yes, followed as per schedule?	Preventive maintenance calendar, Schedule and records.		
25.	Is the product manufactures in batch process of continues process?			

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S. No.	Check Point	To be checked	Yes/No/NA	Remarks
26.	How the lot / batch numbering system described?	Lot / batch numbering system.		
27.	Are equipment dedicated to produce this product?	Equipment logbook.		
28.	If the equipment is non-dedicated, is validation is done. Cleaning procedures are established.	Product changeover cleaning record.		
29.	Is calibration SOP and records available for weighing scales?	Weighing balance calibration procedure. Calibration records (daily/monthly). External calibration certificate of weighing balance (from Govt.).		
30.	Is there an appropriate procedure for cross contamination and mix ups?	Physical verification.		
31.	Are status boards available for all equipment?	Physical verification at equipment.		
32.	Is equipment utilization log maintained	Physical verification.		
33.	Are batch manufacturing records available and followed? If yes, approved by whom?	Master batch record.		
34.	Are online documented the manufacturing process (If yes, check the batch records)	Online batch manufacturing records.		
35.	Are raw materials and intermediates in plant labelled properly?	Physical verification.		
36.	Is an in-process controlling system available?	Batch manufacturing record		
37.	Is the batch size fixed for material? What is the commercial batch quantity?	Batch manufacturing record		
38.	Is there a blending of batches? What is the commercial batch quantity?	Blending batch record.		

VENDOR AUDIT CHECKLIST

S. No.	Check Point	To be checked	Yes/No/NA	Remarks
39.	Is there an appropriate place available for packing of finished product?	Physical verification.		
40.	Is procedure for packaging and labelling of final product available?	Dispatch docket/records.		
41.	Is the drums labelled with product label containing product name, batch no., quantity, tare weight, gross weight, net weight, manufacturing date, retest / expiry date, manufacturing address, storage condition, any precautions / instructions for dangerous goods?	Product label.		
42.	Do you paste additional label for dangerous goods (if applicable) on each drum?	Packing instructions.		
43.	What is the packing, storage and retest condition of the product concerned?			
44.	Is there a procedure for non-confirming products (rejections)?	Product non-confirming procedure. Logbook and records.		
45.	Is training given any process changes and records available?	Training records of production persons.		
46.	Do you provide photographs of the labelled containers prior to dispatch of the product?			
D.	**QUALITY CONTROL:**			
47.	Are standard operating procedures established and followed?	List of QC SOPs.		
48.	Are in-process test procedures available and followed?	Specification and test procedure for in-process samples.		
49.	Is final product tested as per customer MOA?	Specification and test procedure for finished product.		

VENDOR AUDIT CHECKLIST

S. No.	Check Point	To be checked	Yes/No/NA	Remarks
50.	Is there an Out-of-Specification procedure available and implemented?	OOS procedure. OOS logbook and records.		
51.	Are control samples available for all dispatched products?	Control sample register. Physical verification.		
52.	Are all specifications and test methods reviewed and approved?	Specification and test procedure for in-process, intermediates and finished products.		
53.	Is laboratory testing records available?	Analytical reports. Calculation protocols.		
54.	Are analytical test reports signed by analyst and checked by the supervisor?	Analytical reports. Calculation protocols.		
55.	Is working standard available for final product?	Working standard COA. Working standard evaluation.		
56.	Are qualification reports and calibration schedules available for instruments?	IQ/OQ for all QC instruments. Calibration schedule and records for all QC Instruments.		
57.	Is training given to chemists? (If yes, check there any training record)	Training plan. Training record to QC chemists.		
58.	Are stability / holding time study program conducted for final product?	Protocol for stability / holding time study. Reports and raw data for the studies.		
59.	Is there expiry / retest period established for the product of concern? Mention the retest / expiry period.	Protocol for stability / holding time study. Reports and raw data for the studies.		
60.	Are calibration with standard weights SOP and records available for weighing balances	Weighing balance calibration procedure. Calibration records (daily/monthly). External calibration certificate of weighing balance and standard weights (from Govt.).		
61.	Are instruments logs available and followed?	Instrument logbooks.		
62.	Are quality trend charts for final product available?			

VENDOR AUDIT CHECKLIST

S. No.	Check Point	To be checked	Yes/No/NA	Remarks
E.	**QUALITY ASSURANCE**			
63.	Are there procedures for document preparation, control, review, approval and distribution?	Document control procedure. Distribution record.		
64.	Are there procedures for change control, do they cover changes to site, process, method, specification changes?	Change control procedure. Change control logbook. Change control records.		
65.	Is there a provision for informing customer in case of a major change occurs?	Change control procedure.		
66.	Are there procedures for deviation handling	Deviation control procedure. Deviation control logbook. Deviation control records.		
67.	Are there procedures for complaint handling	Complaint handling procedure. Complaint logbook and records.		
68.	Are there procedures for internal audit? Are there records to show the compliance to the procedures?	Internal audit procedure. Frequency of Internal audit. Schedule and records.		
69.	Are the deviations, audit findings, complaints investigated? Are the corrective and preventive actions taken?	Corrective and preventive action logbook. Corrective and preventive action reports.		
70.	How the vendors are approved? Is there any procedure for approval of vendors?	Vendor approval procedure. Records.		
71.	Is training SOP and records available.	Training procedure. Training schedule and records.		
72.	Is there an Annual Product Review available?	Annual product review report.		
F.	**CHEMICAL SUBSTANCE MANAGEMENT (RoHS):**			

VENDOR AUDIT CHECKLIST

S. No.	Check Point	To be checked	Yes/No/NA	Remarks
73.	Do you ever handle the 6 substances prohibited by RoHS in its manufacturing site? (Here, manufacturing site means not only production line but also all value added sites, eg finished goods store, packaging, and the like) If Yes, has the supplier already abolished the use of the prohibited 6 substances completely? (Such abolishment shall include the case in which prohibited substances content is within the limit value specified by Murata) (a) Lead (Pb) and its compound (b) Mercury Hg) and its compound (c) Cadmium (Cd) and its compound (d) Hexavalent chromium (Cr[VI]) and its compound (e) Poly-brominated biphenyl's (PBB) (f) Poly-brominated biphenyl ethers (PBDE)			[NOTE 1] RoHS stands for Restriction Of the use of certain Hazardous Substance in electrical and electronic equipment [NOTE 2] Prohibited 6 substances by RoHS [NOTE 3] Upper limit value (threshould value) for (c) in NOTE2 is 100ppm and the rest of others are 1,000ppm. The limit value is determined by weight of the prohibited substance in homogeneous part of material in question. Note that these limit values are only for unintentionally added impurity. If intentionally added in order to enhance performance of finished product, the upper limit value shall not be applied, i.e., no 6 substances shall be contained in its finished product.
74.	Do you perform acceptance tests on Chemical Substance Management (RoHS)?			
75.	Do your supplier / manufacturer has chemical substance management program?			
76.	If your supplier / manufacturer give training their employees on Chemical Substance Management (RoHS)?			

VENDOR AUDIT CHECKLIST

1. COMENTS :

2. RECOMMENDATIONS:

3. CONCLUSION:

4. MEMBERS PRESENT:

S. No.	Department	Name	Designation	Sign & Date

5. AUDITED BY:

S. No.	Department	Name	Designation	Sign & Date