Good Manufacturing Practices

CTPA GMP Audit 1992

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Guidance Notes

Introduction

CTPA Microbial Quality Management mentions the fact that audits should be carried out on a regular basis. This document sets out to provide a systematic approach to assist you in auditing any production facility.

Auditing is a critical improvement tool and can be used to determine whether:

- the quality assurance system is operating effectively;
- products are consistently manufactured to meet their specifications;
- procedures are followed;
- records are kept.

This document covers all major aspects of GMP and can be used as a means of improving internal standards and assessing external contractors and vendors. The audit is sub-divided into the following sections:

Warehouse and Distribution
Water
Bulk Manufacturing
Filling and Assembly
Technical Departments
Microbiology Facility
Laboratory Controls
Research and Development
Complaints and Recalls
Engineering and Maintenance Operations
Purchasing and Sub-Contract
Information Services
Personnel and Training
Housekeeping
Procedures

Each of these sections can be used separately or collectively as the need dictates.

The scoring system has been designed to highlight any areas of non-conformity and a summary scoring sheet is given at the back of the audit document.

The following guidance notes have been compiled in order to assist you with the audit.

Audit Guidance

1. This document is for guidance only and you can amend, add or delete questions to suit your particular requirements.

2. Agree in advance a time scale and agenda for the audit. This will allow the availability of relevant personnel within each area of the 'host' operation.

3. At a preliminary meeting, it is important to discuss the purpose of the audit and the company's quality policy.

4. A complete audit will take one or two days depending upon the size and complexity of the operation. However, separate sections of the audit may be used to assess individual departments of the operation.

5. Be aware of time restrictions but do not be rushed through the audit. Do not allow time wasting strategies of the host to affect its completion.

6. The audit will become more 'user friendly' with practice and experience. Initially, it is recommended that the sections common to each department i.e. Housekeeping, Procedures and Personnel and Training be duplicated as an 'aide memoir' for the auditor. These can be combined to give the overall score for these common sections. Any non-conforming area within the facility will automatically score 'no' for that question (i.e. the worse case is recorded).

7. Talk to people carrying out specific operations. Are they aware of their own responsibilities, as well as being aware of general GMP requirements? Do they know where to find relevant standard operating procedures (SOPs) etc? Are all answers received consistent?

8. Be aware of general attitudes throughout the plant and especially the awareness of GMP.

9. Observe work practices during the audit. Do they conform to the specific documented procedures. Ideally the person responsible for the department being audited should accompany the auditor.

10. Ensure you see all relevant documentation. A starting point would be to ask to see all documentation relating to a specific product or batch (which you have purchased or selected). Do not rely on information only given verbally.

11. For your company and products certain audit sections/questions may have high weighting. The price of non-conformance may be very high if certain requirements are not complied with. This will need to be highlighted in an accompanying report.

12. At the back of the document there is a an audit report that can be used to record the company, section (if applicable), date, person carrying out the audit and names of those who have received copies of the audit (see note 21).

13. Some sections of the audit document may not be relevant (e.g. contract filling operation) in which case it will be necessary to adjust the final percentage score accordingly.

14. At the conclusion of the audit, it is essential that time is allowed for a summary conference which will inform the host of the general conclusions and allow misunderstandings to be rectified prior to the issuing of the final written report.

15. Write a final report to accompany the audit document. This will be used to highlight areas where the standard is unacceptable or needs attention together with conclusions. It is important to differentiate between actual observations and conclusions drawn. If possible remedial action should be suggested. This should then be distributed to senior management within a maximum of two weeks. Agree with the host company that a response to the audit is made within a designated period of time, after which a follow up audit may be beneficial.

16. It is important to remember to compliment on good points in both the exit meeting and the audit report.

17. Arrange re-audits at suitable frequency.

18. Trends can be observed by comparing the relevant scores from previous audits. This should give a measure of improvement, and can be included in the latest report.

19. For multiple answer questions e.g. no. 207, if the primary question is answered in the negative, all subsequent questions will be negative.

20. The auditor may find a calculator, camera and a means of recording information useful.

21. The results of audits and audit reports need to be kept strictly confidential. The numbering of each report with a record of who has received it is recommended.

22. The costs of completing an audit are modest – probably the time and expenses of one or two people. However, the benefits which may accrue from the improvements in GMP throughout an operation will be substantial and outweigh the cost incurred. An audit itself will not rectify deficiencies in GMP, but it will provide guidance on where significant improvements should be made.

Section 1: Warehouse and Distribution

		YES	NO	PERSON RESPONSIBLE
1	Do all the storage areas provide the correct and specified environmental conditions for the storage of:			
a	Raw materials?			
b	Componentry?			
c	Bulk product?			
d	Finished goods?			
2	Is there a segregated area for the storage of flammable/hazardous materials?			
3	Are the procedures for the receipt, identification, storage and handling of the incoming products followed?			
4	Upon receipt, and before acceptance, are all containers examined visually for identification as to contents, damage, broken seals, contamination, and or compliance with the proper documentation?			
a	Are the drums clean or cleaned on receipt?			
b	Are all incoming deliveries weighed on receipt?			
5	Is there a specified quarantine area for the receipt of all incoming deliveries prior to approval?			
6	Is there a written procedure for tanker deliveries which includes the receipt, documentation and sanitisation of the delivery equipment?			

		YES	NO	PERSON RESPONSIBLE
7	Are bulk deliveries isolated until approved?			
8	Are all outside delivery ports clearly labelled?			
9	Are inventory records maintained?			
10	Does the inventory include the:			
a	Allocated batch number?			
b	Suppliers lot number?			
c	Quantity?			
11	Is material stored to allow for ready identification of contents, batch and status?			
12	Are products stored away from walls?			
13	Are products stored off the floor?			
14	Are pallets properly stacked and racked?			
15	Are all cartons and containers closed and intact?			
16	Are the aisles clear?			
17	Are non conforming raw materials and components identified and handled according to written procedures?			
18	Is there an inventory control and locator system in place that supports an effective stock rotation system?			
19	Are all materials issued under the correct stock rotation system?			

		YES	NO	PERSON RESPONSIBLE
20	Are they issued in a clean and sanitary manner?			
21	Are returns from the production area received in an intact, clean and sanitary manner with the correct documentation and located to comply with the correct stock rotation system?			
22	Is there a positive release system in operation, supported by written procedures?			
23	Is the positive release system operated by the designated person?			
24	Is there an inventory control and locator system in place that supports an effective stock control system for finished goods?			
25	Is there a system in effect to assure that over-age product is not distributed unless re-examined and approved by quality control?			
26	Is there a written system in effect to readily determine the distribution of each lot of product in the event of a recall?			
27	Does the procedure specify that all orders and shipping records include:			
a	Product name (and strength, if available)?			
b	Batch number/code?			
c	Lot or batch size?			
d	Name and address of consignee?			
e	Quantity shipped?			
f	Date shipped?			

		YES	NO	PERSON RESPONSIBLE
28	Are shipping records maintained in a secured file and retained for the required length of time?			
29	Is the correct stock rotation system followed in the pick and pack area?			
30	Is the accuracy of picked orders verified by appropriate stock audits?			
31	Is there a documented procedure for the removal of spillages in a sanitary and timely manner, and is it followed?			
32	Are written procedures available, which describe, in sufficient detail, the handling of returned goods and are they followed?			

NUMBER OF QUESTIONS SCORED 'NO'	_____
NUMBER OF QUESTIONS SCORED 'YES'	_____
TOTAL NUMBER OF QUESTIONS	_____
% THAT SCORED 'YES'	_____%
AUDITOR:	_____
SIGNATURE:	_____
DATE OF AUDIT:	_____

Section 2: Water

		YES	NO	PERSON RESPONSIBLE
33	Are there written procedures for the operation and maintenance of the process water supply system? Do these include:			
a	Sanitisation procedures where appropriate?			
b	Specification, including microbiological and chemical limits?			
34	Are filters and UV lights changed as appropriate and records kept?			
35	Is the process water supply system of appropriate sanitary construction i.e. absence of deadlegs and hygienic valves etc?			
36	Are calibration records kept for all ancilliary equipment?			
37	Is the bulk storage of water carried out in a clean and sanitary manner and are all appropriate control measures in place and shown to be effective?			
38	If there is a de-ioniser and/or reverse osmosis unit in the system. Is it sanitised regularly and are records kept?			
39	Is water constantly circulated through the system at a flow rate to minimise microbial growth?			
40	Is all maintenance on the water system recorded?			

		YES	NO	PERSON RESPONSIBLE
41	Is the water tested in accordance with the specified requirement and are the records maintained?			

NUMBER OF QUESTIONS SCORED 'NO'	_____
NUMBER OF QUESTIONS SCORED 'YES'	_____
TOTAL NUMBER OF QUESTIONS	_____
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Section 3: Bulk Manufacturing

		YES	NO	PERSON RESPONSIBLE
42	Does the Bulk Manufacturing Department conduct self-audits and are the results recorded?			
43	Is protective clothing worn in the manufacturing area and is it clean?			
44	Are head coverings, beard coverings and/or gloves worn when required?			
45	Are overalls and head coverings removed before leaving the premises?			
46	Are storage and manufacturing areas well segregated?			
47	Are eating, drinking and smoking prohibited in the manufacturing area?			
48	Does visual observation confirm that there is no evidence of eating, drinking and smoking?			
49	Does the area have a clean and orderly appearance?			
50	Are the doors and windows intact and closed or screened?			
51	Are all openings, holes, or pipe entries through the outside walls, properly sealed or screened?			
52	Is there adequate dust control where necessary?			
a	Are extraction systems regularly maintained and monitored?			
b	Are records kept?			

		YES	NO	PERSON RESPONSIBLE
53	Is manufacturing equipment designed to be of proper construction, with collars around all top coverings and with approved hinges on covers?			
54	Is there a preventative maintenance procedure for all manufacturing equipment and is it followed and documented?			
55	Are temperature measuring and controlling devices calibrated on a regular basis?			
56	Are temperature measuring and controlling devices operational?			
57	Are bulk material meters checked and calibrated on a regular basis?			
58	Is there a suitable range of balances for operating requirements?			
59	Are balances and scales checked and calibrated on a regular basis?			
60	Do the balances show a maximum and minimum loading weight?			
61	Are motors, pipes or other equipment clean and free from oil, chipped or peeling paint?			
62	Are manufacturing kettles and lids clean and undamaged?			
63	Are bulk storage tanks clean, undamaged and suitable for use?			
64	Are all utensils clean and properly stored?			
65	Are hoses properly cleaned and sanitised?			
66	Are all plastic hoses replaced regularly according to use?			

		YES	NO	PERSON RESPONSIBLE
67	Are hoses properly stored off the floor and without loops when not in use?			
68	Is all major equipment distinctively identified?			
69	Is every container (e.g. box, drum, bag) of raw material properly identified and can its status be readily determined?			
70	Are all drum tops clean?			
71	Are all raw material containers closed and intact when not in use?			
72	Are all tanks, kettles and drums properly identified as to content?			
73	Are the current formulations and manufacturing instructions provided to the people producing the batch?			
74	Are all batches manufactured in correctly sized vessels?			
75	Do the manufacturing instructions specify the safety precautions required and are they adhered to?			
76	Is all the necessary batch information recorded for:			
a	Raw material batch numbers?			
b	Raw materials quantities?			
c	Temperature and mixing time controls?			
d	Corrections?			

		YES	NO	PERSON RESPONSIBLE
77	If repeated corrections are necessary are these reported back to R&D?			
78	Are all changes from written procedures documented, justified and signed by an authorised individual?			
79	Are all pre-mixes approved by quality control before use?			
80	Are all changes to formulations authorised by the technical deparment?			
81	Are raw materials used in correct stock rotation?			
82	Are all raw materials marked with an expiry date?			
83	Are all raw materials that have exceeded the expiry date rechecked prior to use according to written procedures?			
84	Are all raw materials stored according to specifications?			
85	Is each raw material weighed into a clean separate container, if it is not added directly to the batch?			
86	Is each raw material intermediate container properly identified when required?			
87	Is the weight of each raw material checked by a second person when required?			
88	Does the process worker record the addition of each raw material to the batch?			
89	If more than one lot of a raw material is used, are both recorded with separate quantities?			

		YES	NO	PERSON RESPONSIBLE
90	Are formulae strictly adhered to?			
91	Is all major equipment that is used, recorded on the batch card/formulation document?			
92	Are the actual theoretical yields determined and differences explained at the conclusion of each appropriate stage of manufacture, processing, packaging or holding of a product?			
93	Are rejected and out-of-specification materials and products identified, controlled and quarantined to prevent their use?			
94	Does quality control approve the reprocessing of out-of-specification bulk material?			
95	Are there procedures available for the reprocessing/blending off of batches?			
96	Is the use of out-of-specification materials authorised and countersigned by the designated persons?			
97	When authorised, is rejected bulk properly disposed of?			
98	Is there a documented procedure for the removal of spillages in a sanitary and timely manner and is it followed?			
99	Are all equipment lubricants used in bulk manufacturing of food grade?			

NUMBER OF QUESTIONS SCORED 'NO' NUMBER OF QUESTIONS SCORED 'YES' TOTAL NUMBER OF QUESTIONS % THAT SCORED 'YES'	_____ _____ _____ _____%
AUDITOR: SIGNATURE: DATE OF AUDIT:	_____ _____ _____

Section 4: Filling & Assembly

		YES	NO	PERSON RESPONSIBLE
100	Does the Filling and Assembly Department conduct self audits and are the results recorded?			
101	Is protective clothing and equipment worn in the manufacturing area and is it clean?			
102	Are head coverings, beard coverings and/or gloves worn when required?			
103	Are overalls and head coverings removed before leaving the premises?			
104	Does the filling area have a clean and orderly appearance?			
105	Is eating, drinking and smoking prohibited in the filling and assembly areas?			
106	Does visual observation confirm that there is no evidence of eating, drinking and smoking?			
107	Are the doors and windows intact and closed or screened?			
108	Are all openings, holes or pipe entries through the outside walls properly sealed or screened?			
109	Is rubbish and waste material properly controlled and disposed in a safe, timely and sanitary manner?			
110	Is the filling equipment designed, constructed and located to facilitate its use, cleaning and maintenance?			

		YES	NO	PERSON RESPONSIBLE
111	Are surfaces which are in contact with the product constructed of materials which have been shown not to affect the product quality?			
112	Is there a preventative maintenance programme, with a schedule for all filling equipment?			
a	Is the schedule adhered to?			
b	Is it documented?			
113	Are motors and other equipment clean and free from oil, chipped or peeling paint?			
114	Are all hoppers and reservoirs for filling equipment kept covered at all times?			
115	Is open filled product protected from above where necessary?			
116	Are labellers, cappers, cartoners and coders kept clean?			
117	Are all utensils intact, clean and sanitary?			
118	Is all major equipment distinctively identified?			
119	Does observation and records show that lines were cleaned and sanitised (where applicable) before the start of filling?			
120	Are clean pumps properly stored and protected?			
121	Are hoses properly stored off the floor?			
122	Are all bottles containing solvents, other liquids or powders, clearly and distinctly marked according to hazard and use?			

		YES	NO	PERSON RESPONSIBLE
123	Are all rubbish containers clean, clearly labelled and covered?			
124	Is there an adequate line start up procedure and is it followed and documented?			
125	Is there an adequate line clearance procedure and is it followed and documented?			
126	Is every container (box, drum, bag etc.) of bulk, packaging material and labels properly identified?			
127	Is the use of out-of-specification componentry authorised and countersigned by the designated persons?			
128	Are all bulk, packaging material and labels approved prior to filling?			
129	Are all bulk drums closed and intact when not in use?			
130	Are measures taken to prevent accidental contamination of bulk product during filling?			
131	Are all packaging materials (e.g. bottles, containers, caps) covered when not in use?			
132	Are filling specifications and quality standards available prior to the start of filling?			
a	Are the filling specifications current?			
b	Do they list the size and type of the equipment required?			
c	Do they list any specific safety requirements?			

		YES	NO	PERSON RESPONSIBLE
d	Do they stipulate that batch coding must be clear on both the primary and secondary packaging?			
133	Are bottles, caps or other packaging materials falling from the production line discarded?			
134	Is the fill weight checked and maintained within the specified/legal limits?			
135	Is the weight checking equipment calibrated and documented?			
136	Are rejected components and products segregated and properly controlled?			
137	Is there a written procedure for the proper repackaging, control and reconciliation or returns?			
138	Are gloves and hand sterilants available when required?			
139	Is there a documented procedure for the removal of spillages in a sanitary and timely manner and is it followed?			
140	Where appropriate does the opportunity exist for employees to remove their protective clothing prior to entering rest areas?			

NUMBER OF QUESTIONS SCORED 'NO' NUMBER OF QUESTIONS SCORED 'YES' TOTAL NUMBER OF QUESTIONS % THAT SCORED 'YES'	_____ _____ _____ _____%
AUDITOR: SIGNATURE: DATE OF AUDIT:	_____ _____ _____

Section 5: Technical Departments

		YES	NO	PERSON RESPONSIBLE
141	Does the quality unit have the authority and responsibility to approve or reject all materials labelling, bulk and finished goods according to written specifications?			
142	Does the quality unit:			
a	Review product records?			
b	Investigate errors?			
c	Evaluate complaints and investigate them, if required?			
143	Is there a positive release system?			
144	When samples are taken for testing:			
a	Are the containers opened, sampled and resealed according to written procedures, in a way designed to prevent contamination of the contents?			
b	Is sterile equipment and aseptic technique used when necessary?			
c	Are the sample containers labelled with the product name, lot number, date, product container and the name of the person collecting the samples?			
d	Are the sample containers from which the samples have been taken marked ‘sampled’?			
e	Do they consist of at least twice the quantity necessary for all testings?			

		YES	NO	PERSON RESPONSIBLE
145	If the samples are required to be taken from the top and bottom of the container are they maintained and tested separately?			

NUMBER OF QUESTIONS SCORED 'NO'	_____
NUMBER OF QUESTIONS SCORED 'YES'	_____
TOTAL NUMBER OF QUESTIONS	_____
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DATE OF AUDIT:	_____

Section 6: Microbiology Facility

		YES	NO	PERSON RESPONSIBLE
146	Are the calibration/validation records for all appropriate equipment:			
a	Maintained in an orderly and timely fashion?			
b	Readily available?			
147	Is the microbiology facility isolated from other parts of the factory?			
148	Is the microbiology facility suitably lit and ventilated?			
149	Is there a separate handwashing facility?			
150	Is there a requirement for a change of protective clothing when entering and leaving the microbiology laboratory?			
151	Does the area have a clean and orderly appearance?			
152	Are there segregated work areas for aseptic operations?			
153	Is there a copy of the relevant procedures/test methods manual readily available?			
154	Are representative samples:			
a	Taken in accordance with the laboratory manual?			
b	Properly identified, stored and retained?			
155	Are the following tested in accordance with the laboratory manual:			

		YES	NO	PERSON RESPONSIBLE
a	Process water?			
b	Raw materials?			
c	Packaging?			
d	Bulk product?			
e	Finished products?			
156	Are all appropriate control tests carried out in accordance with the laboratory manual?			
157	Are all results recorded clearly and accurately and readily understood?			
158	Is there a documented procedure for acting on out-of-specification results and is it followed?			
159	Are retests carried out on original and additional samples?			
160	Does the microbiology laboratory carry out environmental testing?			

NUMBER OF QUESTIONS SCORED 'NO' NUMBER OF QUESTIONS SCORED 'YES' TOTAL NUMBER OF QUESTIONS % THAT SCORED 'YES'	_____ _____ _____ _____%
AUDITOR: SIGNATURE: DATE OF AUDIT:	_____ _____ _____

Section 7: Laboratory Controls

		YES	NO	PERSON RESPONSIBLE
161	Are there adequate washing facilities?			
162	Does the area have a clean and orderly appearance?			
163	Is there adequate space?			
164	Are there copies of the relevant procedures/test methods readily available and are they followed?			
165	Are representative samples taken:			
a	In accordance with the laboratory manual?			
b	Properly identified, stored and retained?			
166	Are there appropriate acceptance sampling plans?			
167	Is a properly identified reserve sample retained for each lot of active ingredient for the required length of time?			
168	Do laboratory records include:			
a	A description of the sample received for testing with identification of source, quantity, lot number or other distinctive code, date sample was taken and the date sample was received for testing?			
b	Each method used in the testing of the sample and the methods suitably verified under actual conditions of use?			

		YES	NO	PERSON RESPONSIBLE
c	The weight or measure of sample used for each test, where appropriate?			
d	All data and calculations collected in the course of each test (including all graphs, charts and spectra from laboratory instrumentation) properly identified to show the specific material, container, closure, in-process material, or finished product and lot tested?			
e	The results of tests and how the results compare with established standards of identity, strength, quality and purity?			
f	The signature of the person who performs each test and the date (s) the tests were performed?			
g	The signature of a second person showing that the original records have been reviewed for accuracy, completeness, and compliance with established standards?			
h	Any modification of an established method employed in testing, including the reason for the modification and validation?			
i	The results of testing and standardisation of laboratory reference standards, reagents and standard solutions?			
169	Is there a documented procedure for acting on out-of-specification results?			
170	Are retests carried out on original and additional samples?			

NUMBER OF QUESTIONS SCORED 'NO' NUMBER OF QUESTIONS SCORED 'YES' TOTAL NUMBER OF QUESTIONS % THAT SCORED 'YES'	_____ _____ _____ _____%
AUDITOR: SIGNATURE: DATE OF AUDIT:	_____ _____ _____

Section 8: Research and Development

		YES	NO	PERSON RESPONSIBLE
171	Are there documented working practices?			
172	Is the laboratory suitably lit and ventilated?			
173	Is there a documented procedure for dealing with new raw materials?			
174	Is there a documented procedure for the issue and revision of specifications and methods of manufacture?			
175	Are plant cleaning and sanitisation procedures followed in R&D?			
a	Are documented procedures available?			
b	Are timely and appropriate records maintained?			
176	Do R&D supervise and release initial production batches?			
177	Are all appropriate and relevant tests carried out on all new raw materials and formulations?			
178	Are filling trials conducted under the supervision of R&D?			

NUMBER OF QUESTIONS SCORED 'NO' NUMBER OF QUESTIONS SCORED 'YES' TOTAL NUMBER OF QUESTIONS % THAT SCORED 'YES'	_____ _____ _____ _____%
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Section 9: Complaints and Recalls

		YES	NO	PERSON RESPONSIBLE
179	Are there written procedures for dealing with all consumer complaints and are they in operation?			
180	Are all customer complaint samples tested by the quality department and are the results reviewed?			
181	If the complaint is not investigated, is the reason documented?			
182	Are records of complaints maintained in a separate file?			
183	Are the results of the investigations relayed to operations or other relevant departments as applicable?			
184	Is corrective action taken when necessary?			
185	Is there a written recall procedure readily available to be used if necessary?			

NUMBER OF QUESTIONS SCORED 'NO'	_____
NUMBER OF QUESTIONS SCORED 'YES'	_____
TOTAL NUMBER OF QUESTIONS	_____
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Section 10: Engineering and Maintenance Operations

		YES	NO	PERSON RESPONSIBLE
186	Do all appropriate control and sanitisation procedures apply to all engineering/maintenance work carried out in the facility?			
187	Is manufacturing and processing equipment designed, constructed and located to facilitate its use, cleaning and maintenance?			
188	Is there a written policy on the design of manufacturing and filling equipment which includes:			
a	The requirement that surfaces which come into contact with the product be constructed of materials which will not affect product quality?			
b	Installation procedures?			
c	A requirement for cleaning and sanitisation?			
d	A requirement for the review of existing equipment?			
e	A review by the quality department of new or redesigned equipment/installations?			
189	Are all system faults promptly reported to the engineering department?			
190	Are all engineering faults quickly rectified?			
191	Is there formal consultation/agreement with appropriate departmental managers before commencement of work?			
192	Are engineering tools and equipment kept in a clean and sanitary manner?			

		YES	NO	PERSON RESPONSIBLE
193	Is all equipment removed from the area upon completion and is the area returned to its original condition?			
194	Is there a preventative maintenance procedure, and is it recorded and documented?			
195	Prior to the commencement of any refurbishment, relocation or construction work, are the following people consulted:			
a	Departmental manager?			
b	Technical manager?			
c	Company microbiologist?			
196	Are the workshops and maintenance areas, including stores, maintained in a clean and sanitary manner?			

NUMBER OF QUESTIONS SCORED 'NO'	_____
NUMBER OF QUESTIONS SCORED 'YES'	_____
TOTAL NUMBER OF QUESTIONS	_____
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Section 11: Purchasing and Sub-contract Work

		YES	NO	PERSON RESPONSIBLE
197	Are all **raw materials** purchased according to a specification that has been given to the supplier?			
198	Does the specification contain:			
a	Physical and chemical characteristics?			
b	Strength/purity?			
c	Microbiological specification where applicable?			
d	Storage conditions and shelf life?			
e	Pack size?			
f	Hazard data as applicable?			
g	Requirement for certificate of analysis where applicable?			
199	Are all **components** purchased according to a specification that has been given to the supplier?			
200	Does the specification contain:			
a	A drawing?			
b	Dimensions?			
c	Tolerances?			
d	Physical characteristics?			
e	Specific delivery requirements?			

		YES	NO	PERSON RESPONSIBLE
201	Are all changes in component design approved by relevant departments and are samples supplied to the technical department?			
202	Are all changes in raw materials (including supplier) approved by the technical department?			
203	Do purchasing, in conjunction with the technical department, audit all current and prospective suppliers?			
204	Is there an approved list of suppliers?			
205	Is there a vendor rating system that the purchasing department use?			
206	Is purchasing notified of all rejects as appropriate?			
207	Are all sub-contractors validated and audited prior the commencement of work?			
208	Is all documentation from sub-contractors maintained?			
209	Are sub-contractors reaudited on a regular basis?			
210	Is there a requirement for formal notification from the sub-contractor of any deviation from agreed standards?			

NUMBER OF QUESTIONS SCORED 'NO' NUMBER OF QUESTIONS SCORED 'YES' TOTAL NUMBER OF QUESTIONS % THAT SCORED 'YES'	_____ _____ _____ _____%
AUDITOR: SIGNATURE: DATE OF AUDIT:	_____ _____ _____

Section 12: Information Services

		YES	NO	PERSON RESPONSIBLE
211	Is any computer system routinely calibrated, inspected or checked according to a written programme designed to assure proper performance?			
212	Are programme changes in the computer affecting any product records made and signed only by authorised personnel?			
213	Are input and output programmes and copies checked for accuracy and are such checks documented?			
214	Do all master formula have up-to-date back up files?			
215	Are the computer records maintained and updated promptly?			

NUMBER OF QUESTIONS SCORED 'NO'	_____
NUMBER OF QUESTIONS SCORED 'YES'	_____
TOTAL NUMBER OF QUESTIONS	_____
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AUDITOR:	_____
SIGNATURE:	_____
DATE OF AUDIT:	_____

Section 13: Personnel and Training

		YES	NO	PERSON RESPONSIBLE
216	Are there adequate personnel available to perform, supervise and control all plant activities?			
217	Are management positions or job descriptions available?			
218	Do the job descriptions include:			
a	A description of responsibilities?			
b	The reporting relationship?			
219	Do all new employees undergo an induction programme which includes an explanation on:			
a	Health and safety?			
b	The company's quality policy?			
c	An explanation of the company's health and hygiene policy?			
d	The company's GMP practice?			
220	Is there written policy dealing with hygiene and health?			
221	Does the policy include?			
a	Instructions that clean, appropriate clothing be worn in the manufacturing and processing areas?			
b	Instructions on the practice of the company's sanitation and health requirements?			

		YES	NO	PERSON RESPONSIBLE
c	Instructions that personnel report to management any apparent illness or open lesions that might affect product quality?			
d	A procedure to be followed by management when such illness is reported?			
222	Is the policy explained to the employees at the time of starting and at subsequent training sessions?			
223	Do all departments conduct training relevant to their requirements?			
224	Is there written training procedure which includes:			
a	Designated responsibilities for the training programme?			
b	The preparation of a training schedule?			
c	The training of hourly and management personnel?			
225	Are adequate records kept of all training?			
226	Is training given on a continuing basis?			
227	Is the effectiveness of training monitored?			
228	Does the training cover GMP and plant operations as they relate to employee's specific job functions?			
229	Is there a company induction procedure for:			
a	Employees on short-term contracts?			
b	Contractors employed within the facility?			

		YES	NO	PERSON RESPONSIBLE
c	Sub-contractors?			

NUMBER OF QUESTIONS SCORED 'NO'	_____
NUMBER OF QUESTIONS SCORED 'YES'	_____
TOTAL NUMBER OF QUESTIONS	_____
% THAT SCORED 'YES'	_____%
AUDITOR:	_____
SIGNATURE:	_____
DATE OF AUDIT:	_____

Section 14: Housekeeping

		YES	NO	PERSON RESPONSIBLE
230	Are there housekeeping procedures readily available for all areas of the whole facility?			
231	Are there adequate sanitary facilities and designated eating and smoking areas, separated from manufacturing areas?			
232	Are all washing facilities clean and orderly?			
233 a	Are the designated eating and smoking areas clean?			
b	Are these regularly inspected?			
c	Are there adequate receptacles for refuse in these areas?			
234	Are the toilets, sinks and hand basins clean and sanitary?			
235	Do the toilets have:			
a	Hot and cold water?			
b	Soap or detergent?			
c	Driers or single service towels?			
d	'Wash hands' signs?			
236	Are the tops of employees lockers clean?			
237	Are drinking fountains clean and are cup dispensers covered?			

		YES	NO	PERSON RESPONSIBLE
238	Do sanitisation procedures apply to work performed by contractors or temporary employees as well as full-time employees?			
239	Are the floors, walls and overhead areas clean and free from leaks and chipped and peeling paint?			
240	Is the internal structure sound and maintained in good decorative order?			
241	Are all ceiling tiles in place, intact and free of water stains?			
242	Are all fans and/or heating units clean?			
243	Is the general appearance in the following areas satisfactory?			
a	Receiving?			
b	Bulk manufacturing?			
c	Filling and assembly?			
d	Other areas?			
244	Are stairways clean and are they adequately lit?			
245	Are the outside material delivery areas clean?			
246	Is sewage and other refuse disposed of in a safe, timely and sanitary manner?			
247	Are there validated pest control procedures in operation together with appropriate documentation?			

		YES	NO	PERSON RESPONSIBLE
248	Are there written sanitising procedures readily available for the following areas?			
a	Raw material weighing?			
b	Bulk manufacture?			
c	Water systems?			
d	Filling and assembly?			
249	Are procedures validated and regularly checked by the laboratory?			
250	Are there individual equipment logs for major equipment, maintenance, cleaning, sanitisation and use?			
251	Do the equipment logs show the date, time, product and lot number of each lot processed?			
252	Do the people performing and verifying the cleaning, sanitisation and maintenance, date and sign the log?			
253	Are the log entries chronological and accurate?			
254	Are sanitisation agents readily available?			
255	Are they approved prior to use by the laboratory?			
256	Are they rotated on a regular basis?			
257	If sanitiser solution is used, is it at the correct concentration and labelled with a date of manufacture and a validated expiry date?			
258	Is the sanitiser used within the expiry date where specified and stored correctly?			

		YES	NO	PERSON RESPONSIBLE
259	Is the presence of cleaning and sanitising residues assayed by chemical or biological means in the laboratory?			
260	Are sanitation and housekeeping supplies and equipment stored away from production materials and manufacturing and processing areas?			
261	Are all cleaning implements (e.g. brushes etc.) of food grade quality?			

NUMBER OF QUESTIONS SCORED 'NO'	_____
NUMBER OF QUESTIONS SCORED 'YES'	_____
TOTAL NUMBER OF QUESTIONS	_____
% THAT SCORED 'YES'	_____%
AUDITOR:	_____
SIGNATURE:	_____
DATE OF AUDIT:	_____

Section 15: Procedures

		YES	NO	PERSON RESPONSIBLE
262	Do all departments have written procedures for their responsibilities and operations?			
263	Are these procedures regularly reviewed and approved by a designated person?			
264	Does each department have its procedures manual readily available?			
265	Are copies of the relevant procedures and revisions circulated to all relevant personnel?			
266	Are obsolete procedures removed when new or revised procedures are issued?			
267	Do procedures contain:			
a	A title?			
b	Scope?			
c	Equipment requirements?			
d	Definitions?			
e	Safety requirements?			
f	Designated responsibilities?			
g	Date of issue and revision level?			
h	Are the easily understood?			

NUMBER OF QUESTIONS SCORED 'NO' NUMBER OF QUESTIONS SCORED 'YES' TOTAL NUMBER OF QUESTIONS % THAT SCORED 'YES'	_____ _____ _____ _____%
AUDITOR: SIGNATURE: DATE OF AUDIT:	_____ _____ _____

Audit Report

Date of audit: _____

Audit site: _____

_____

Company: _____

Address: _____

_____

Tel: _____

Fax: _____

Principle contact: _____

_____

Auditors: _____

_____

Copies to: 1 _____

2 _____

3 _____

4 _____

5 _____

6 _____

Scoring Sheet

Section	Individual Score		% Score
	Number of Questions	Score	
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			
14			
15			
Total number of questions			
% Score			