APIC 25 years of promoting patient safety active pharmaceutical ingredients committee

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Registered Starting Material Auditing Guide

Annex 1 – Aide Mémoire

Company :	Auditor(s) :
Location, Country : APIC Guide for Auditing Registered Starting Material Manufacturers	Date of Audit:

Remark: Non-compliance to individual questions does not directly lead to an observation. Risk based principles related to the criticality for the process of the API manufacturer should be taken in consideration.

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Reference [1)]	TOPICS / ISSUE	APPLICABILITY		COMPLIANT			Kind of Documentation**	Commentary	Question posed
		YES	NO	YES	tbi *	No			
3	**Quality Management**								
3.1	**Principles**								
3.11	Is a quality system in place								
3.12	Is there a quality unit(s) that can act independent in releasing or rejecting RSM outside the control of the manufacturing company								
3.2	**Internal Audits**								
3.20	a) Are regular quality audits performed? b) Is there a quality audit schedule? c) Are all relevant departments involved? d) Is the schedule followed?								
3.21	Is the person performing the audit independent from the area audited?								
4	**Personnel**								
4.1	**Personnel Qualifications**								
4.10	a) Are an adequate number of personnel present? b) Is the qualification of personnel sufficient at different levels? c) Are roles and responsibilities defined in writing (procedures or job descriptions)?								
4.11	a) Is regular training conducted? b) Are records of training maintained?								

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		YES	NO	YES	tbi *	No			
4.2	**Personnel Hygiene**								
4.20	a) How is it ensured that personnel practice good sanitation and health habits? b) Did you observe employees having product contact without appropriate personal protection?								
4.21	How is it ensured that no smoking, drinking, chewing and storage of food takes place?								
5	**Buildings and Facilities**								
5.1	**Design and Construction**								
5.10	a) Can cleaning, maintenance and operation be easily performed based on design of equipment and layout of facility? b) Have production and warehouse facilities been designed to prevent contamination or cross contamination? If not, how is contamination prevented?								
5.11	Are defined areas or control systems in place for the following activities: - Receipt, identification, quarantine and release of incoming materials; - Rejected materials; - Sampling of RSM; - Production Operations;								

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		YES	NO	YES	tbi *	No			
	- Laboratory Operations; - Storage of final RSM.								
5.2	**Water**								
5.20	Is the used water demonstrated suitable for intended use?								
5.3	**Containment**								
5.30	Are there measures to prevent contamination and cross-contamination from personnel, materials etc. for example moving materials from one production area to another?								
5.31	Is the production of highly toxic materials, herbicides and pesticides, excluded from RSM equipment and production facilities?								
5.4	**Lighting**								
5.40	Is adequate lighting in place?								
5.5	**Sanitation and Maintenance**								
5.50	Are buildings properly maintained, repaired and cleaned?								
5.51	a) are sewage, refuse, and other waste (e.g.,solids, liquids, or gaseous by-products from manufacturing) in and from buildings and the immediate surrounding area disposed								

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		YES	NO	YES	tbi *	No			
	of in a safe, timely, and sanitary manner?. b) Containers and/or pipes used for waste material managed in order to avoid contamination of the RSM?.								
5.52	Is a suitable pest control system implemented for RSM, product contact materials and packaging materials storage areas?								
6	**Process Equipment**								
6.1	**Design and Construction**								
6.10	Is equipment suitably designed, located and easy to clean and maintain?								
6.11	Is major equipment identified?								
6.12	Are precautions (measures) taken where equipment is opened to prevent contamination? For example, addition of seeds or sampling.								
6.2	**Equipment Maintenance and Cleaning**								
6.20	a) Is a preventive maintenance programme for major equipment in place? b) Is the maintenance Schedule followed?								
6.21	a) Are written procedures for the cleaning of equipment in place?								

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	b) Do the procedures give sufficient detail to enable operators to clean each type of equipment in an effective and reproducible manner?								
6.22	a) Is for continuous production or dedicated production facilities the equipment/ facility cleaned at appropriate intervals to prevent build-up or carry-over of contaminants for example degradants? b) Is the cleaning documented?								
6.23	Are non-dedicated equipment and utensils cleaned between productions of different products?								
6.24	a) Are acceptance criteria for residues defined based on the risk of carryover into the next product? b) Are the acceptance criteria based on the risk of carry over into the next product? c) If visual inspection for cleanliness is applied, is the verification supported by analytical data?								
6.3	**Calibration**								
6.30	a) Are instruments critical for the RSM quality calibrated? b) How is critical defined? c) Are written procedure in place?								

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	d) Is the calibration schedule followed? e) Are the records of calibration maintained?								
6.31	Is the calibration done with standards that are traceable to certified standards?								
6.32	a) How is the calibration status of instruments known (label, electronic)? b) How is it ensured that instruments out of calibration are not used?								
6.33	If instruments have been shown out of calibration, are investigations performed to determine if this fact has an impact on the release of the RSM?								
6.4	**Computerized Systems**								
6.40	Are computer systems used for critical activities evaluated to demonstrate the suitability?								
6.41	a) What controls are in place to prevent unauthorized access? b) What controls are in place to prevent and/or track changes to data? c) What controls are in place to prevent and/or track omissions in data? d) How is data protected in cases of system breakdowns? e) Is back-up system provided?								
7.	**Documentation and Records**								

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		YES	NO	YES	tbi *	No			
7.1	**Documentation System and Specifications**								
7.10	a) Is there a written procedure in place describing preparation, review, approval and distribution of all quality related documents? b) Is there a system in place to ensure that only the latest version of the documents in paper or electronic form is in use?								
7.11	a) Is a procedure in place for retaining all appropriate documents? b) Is the retention period specified? c) Are documents promptly retrievable (copies or electronic means acceptable)?								
7.12	Are Good Documentation Practices established and followed; such as - Are corrected entries in documents dated and signed? - Is original entry still readable?								
7.13	Are specifications for raw materials and RSM established?								
7.2	**Master Production Instructions (Master Production and Control Records)**								
7.20	Are Master Production Instructions for the production of the RSM - prepared - dated								

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	- signed - independently checked?								
7.21	Contain Master Production Instructions, at least the following: - name of product - complete list of raw materials - accurate statement of quantities or ratio needed - production location and major equipment to be used - detailed production instructions including sequences, ranges of parameters, sampling instructions, IPC, time limits, expected yield - instructions for storage - sampling								
7.3	**Batch Production Records (Batch Production and Control Records)**								
7.30/7.32/ 7.33	a) Are Batch Production Records checked before issuance for correct version? b) Contains the batch production record: - equipment cleanliness - date(s) and times of completion of each critical step (if appropriate) - identity of major equipment - identification of materials used - actual values								

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		YES	NO	YES	tbi *	No			
	- signatures of the person(s) performing the operation - description of packaging used - deviation/investigation c) In case of continuous production are records available on the control of the process								
7.31	Are the records showing a unique batch number? For continuous production, an identification System should be in place.								
7.4	**Laboratory Control Records**								
7.40	Laboratory records contain: - description of sample including name, batch number and traceable to the batch production record, - reference to test method - cross reference to preparation of reference standards, reagents and/or standard solutions - complete record of raw data - record of all calculations - statement of test result if they comply with specifications - signature and date of person(s) performing the testing								

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	- signature of second person demonstrating review for accuracy, completeness								
7.41	Is there documentation available to support: - modification to test method - calibration of laboratory instruments - OOS evaluations								
7.5	**RSM Batch Documentation Review and Batch Release**								
7.50	Are written procedures available for the handling of batch (laboratory) documentation review and release of the batch?								
7.51	Are all critical deviations, investigations and OOS reviewed as part of the batch record review and before batch release?								
8.	**Materials Management**								
8.1	**General Controls**								
8.10	Are written procedures available for handling of receipt, identification, quarantine, storage, sampling, testing, approval or rejection of materials?								
8.11	Are materials purchased against agreed specifications?								
8.12	Are change(s) of source/supplier of critical raw materials handled according to Change Control system (chap. 14)?								

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		YES	NO	YES	tbi *	No			
8.2	**Receipt and Quarantine**								
8.20	a) Upon receipt are incoming materials visually examined for - correct labelling - container damage? b) Are materials held under quarantine until released for use? c) How is this done?								
8.21	Are incoming materials assessed for compliance with the specifications, tested if appropriate, and released prior to use?								
8.22	a) Are Incoming materials released before mixed with existing bulk stocks? b) Is a system in place to prevent discharging materials wrongly in bulk stocks?								
8.3	**Storage**								
8.30	Is material stored in a manner to prevent degradation, contamination and cross-contamination?								
8.31	Are fibre drums, bags and boxes stored off the floor?								
8.32	In case materials is stored outdoors: - Do labels remain legible? - Are the containers cleaned before opening?								

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	- Is a process in place?								
8.33	How are rejected materials handled?								
9	**Production and In Process Controls**								
9.1	**Production Operations**								
9.10	Are raw materials handled to prevent contamination or cross-contamination?								
9.11	Are the raw materials before use verified against the specified raw materials in the batch record?								
9.12	Are written procedures established to document and evaluate critical deviations?								
9.13	Are materials to be reprocessed or reworked controlled to prevent unauthorized use?								
9.14	a) Is there a system in place to prohibit blending of OOS batches? b) If blending is performed: - Is the homogeneity established? - Is full traceability to the individual batches documented|? - Is there a customer agreement in case of OOS blending								
9.2	**In-process Sampling and Controls**								
9.20	If IPC's are established, are these documented?								
9.3	**Contamination Control**								

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9.30	What measures are taken in production to prevent contamination of the RSM?								
9.31	Are higher precautions in place in the final stages of the manufacturing of the RSM?								
10.	**Packaging and Identification Labelling of RSM**								
10.1	**Packaging Materials**								
10.21/9.22	Is the primary and functional secondary packaging material verified and documented at receipt against specifications?								
10.2	**Packaging and Labelling Operations**								
10.20	Are the labelling operations performed in a way to prevent mix-ups?								
10.21	Are written procedures in place ensuring that correct packaging materials and labels are used?								
10.22	Indicate the labels at least? - name or identifying code of product - batch number - name and address of the manufacturer - storage conditions, when such information is critical to assure quality								
11.	**Storage and Distribution**								
11.1	**Warehousing Procedures**								

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11.10	a) Are facilities for the storage of all materials available supporting the claimed storage conditions (e.g. temperature, humidity)? b) Are records of the storage conditions kept?								
11.2	**Distribution Procedures**								
11.20	How is it ensured that RSMs are not distributed before release?								
11.21	How are transportation conditions assured so that the quality of the product will not be adversely affected?								
12	**Laboratory Controls**								
12.1	**General Controls**								
12.10	Are adequate laboratory facilities available?								
12.11	Are sampling and testing procedures in place?								
12.12	Are there specifications set for the RSM? Do they include a control of the impurities?								
12.13	Are the test methods suitable for their intended use?								
12.14	Are the laboratory controls followed and documented at the time of performance?								
12.15	Are deviations documented?								
12.16	Are all OOS results evaluated and documented?								
12.17	a) Are reference standards stored under appropriate conditions?								

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	b) Is the reference standard appropriately tested to establish the identity and purity?								
12.2	**Testing of RSM**								
12.20	Are appropriate laboratory tests conducted on a representative sample of each batch to determine conformance to specifications?								
12.3	**Certificates of Analysis**								
12.30	Are authentic Certificates of Analysis issued for each batch of RSM?								
12.40/12.41	Does the Certificate of Analysis contain?: - name of RSM - batch number - date of manufacturing - expiry date, if applicable - retest date, if applicable - date and signature of authorized personnel - name and address of the manufacturing site								
12.42	On the Certificate of Analysis, are all tests performed listed, together with acceptance limits and numerical results obtained?								
12.43	a) If Certificate of Analysis is issued by agents or brokers that performed re-testing, are the name and address of the laboratory that performed								

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	the tests and the name and address of the original manufacturing site indicated? b) Is a copy of the original Certificate of Analysis added?								
12.4	**Expiry and Retest Dating**								
12.40	Are expiry/retest dates supported by documented data?								
12.5	**Reserve/Retention Samples**								
12.50	Are reserve samples stored for the predefined period?								
12.51	Are reserve samples stored in same packaging system or more protective than the marketed?								
13	**Process VALIDATION**								
13.10	Is there documented evidence available to support the processes (production process, analytical method, equipment, cleaning, etc.) consistency, robustness and reproducibility of the current processes?								
14	**Change Control**								
14.10	Is a formal change control system in place capable of evaluating all changes that may affect the production and control of the RSM?								
14.11	Are all changes potentially impacting the quality of the RSM								

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	- Managed by the system? - And communicated to the customer(s)?								
15	**REPROCESSING AND REWORK OF MATERIALS**								
15.1	**General**								
15.10	a) Are RSM failing to meet established specifications identified as such and quarantined? b) How are reprocessed and reworked batches identified?								
15.11	a) Is rework performed under change control? b) Is there an approved process description for the rework?								
15.2	**Recovery of Materials and Solvents**								
15.20	Do procedures exist for the recovery of materials?								
15.21	Do the recovered materials meet specifications for their intended use?								
15.22	Is the use of recovered solvent, mother liquors and other recovered materials adequately documented?								
15.3	**Returns**								
15.30	Are returned RSMs identified and quarantined?								
15.30/15.31	Are records of returned goods available containing - name and address of the consignee								

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	- RSM batch number and quantity - Reason of return - Disposition decision of the RSM								
15.33	In case there is doubt on the quality of the returned goods are appropriate actions taken. (reprocess-rework-destruction)?								
16.	**Complaints**								
16.10	Is a written procedure available describing the handling of complaints?								
16.11	Are the records of complaints retained?								
17	**Contract Manufacturers (including Laboratories)**								
17.10	How is the contract manufacturer evaluated to ensure compliance of the specific operations?								
17.11	a) Is there a written contract (agreement) with the contract manufacturer? b) Are the roles and responsibilities defined in detail?								
17.12	Is subcontracting by the contract manufacturer excluded? If not, how is it ensured that the contract giver is involved in prior evaluation of the subcontractor?								

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17.13	a) How is it ensured that the contract giver is informed about all intended changes of the contract manufacturer to the process? b) Does the contract giver approve all significant changes?								
18	**Specific Guidance for APIs Manufactured by Fermentation**								
18.1	**General**								
18.13	a) What measures are taken for the processes to ensure that raw materials (media, buffer components) are no source of microbiological contamination? b) If applicable, are the bioburden and/or endotoxins controlled at appropriate stages of production?								
18.14	Which controls are in place in the different stages of manufacturing to assure RSM quality?.								
18.15	Which equipment and environmental controls are used to minimize contamination? Are adequate acceptance criteria for quality and frequencies for monitoring set at the various steps of production?								
18.16	Are the following controls taken into account?: - Control of the critical operating								

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	parameters during fermentation; - Monitoring of the process ; - Harvest and purification procedures protect the RSM from contamination (particularly of a microbiological nature) and from loss of quality; - Monitoring of bioburden and, where needed, endotoxin levels at appropriate stages of production.								
18.17	Is removal of media components, product related impurities and contamination demonstrated?								
18.2	**Fermentation**								
18.20	Are closed and contained systems used when aseptic additions are needed? If open vessels are used which measures and controls are used to minimise risk of contamination?								
18.21	If use of open equipment can cause microbial contamination which environmental controls are done?								
18.22	Are personnel handling the cultures appropriately gowned?								
18.23	Are critical operating parameters monitored?								

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18.24	Is the fermentation equipment cleaned and sanitized/sterilized after use?								
18.25	Is culture media sterilized before use?								
18.26	Are procedures in place to detect contamination and to determine necessary action? Is the impact of the contamination evaluated?								
18.27	Are records of contamination maintained?								
18.28	Is multi-purpose equipment sufficiently tested to minimize contamination?								
18.3	**Harvesting, Isolation and Purification**								
18.30	Are harvesting steps performed in equipment and areas designed to minimize risk of contamination?								
18.31	Can the harvesting and purification procedures assure that the RSM is recovered with consistent quality?								
18.32	a) Is all equipment cleaned properly and sanitized after use? b) If equipment is used for multiple products are additional controls and testing conducted?								
18.33	Is purification performed under controlled environmental conditions if open systems are used?								

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