EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Standard operating procedure

Title: Sampling and testing of centrally authorised products – Reports circulation and follow-up procedure		
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1. Purpose

To establish a procedure for the circulation of CAP testing reports issued by the EDQM as part of the sampling and testing programme, and for the organisation and/or coordination of follow-up actions.

2. Scope

This SOP applies to the Compliance and Inspection Sector only, and should be read in conjunction with the documents listed under section 6.

3. Responsibilities

It is the responsibility of each Head of Sector to ensure that this procedure is adhered to within their own sector. The responsibility for the execution of a particular part of this procedure is identified in the right-hand column of section 9.

4. Changes since last revision

Major revision of the SOP and update to reflect the organisational changes in the agency as well as a new corporate identity.

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5. Documents needed for this SOP

Template for checklist for validation of draft CAP reports (X:\Templates\Others\Compliance and Inspection\S&T\Checklist for validation draft CAP testing reports)

Template for Eudralink messages, for the transmission of CAP Testing Report to the Marketing Authorisation Holder (X:\Templates\Others\Compliance and Inspection\S&T\CAP Testing Report to MAH)

Template for Eudralink messages, for the transmission of CAP Testing Report to the Rapporteurs (X:\Templates\Others\Compliance and Inspection\S&T\ CAP Testing Report to Rapps)

Template for Reply Sheet (X:\Templates\Others\Compliance and Inspection\S&T\Reply Sheet)

6. Related documents

Sampling and Testing of Centrally Authorised Products - Objectives and description of the Programme (EMA/INS/S&T/5291/2005)
Operational Units/Inspections/Samptest/c_Procedures/m_General Procedures

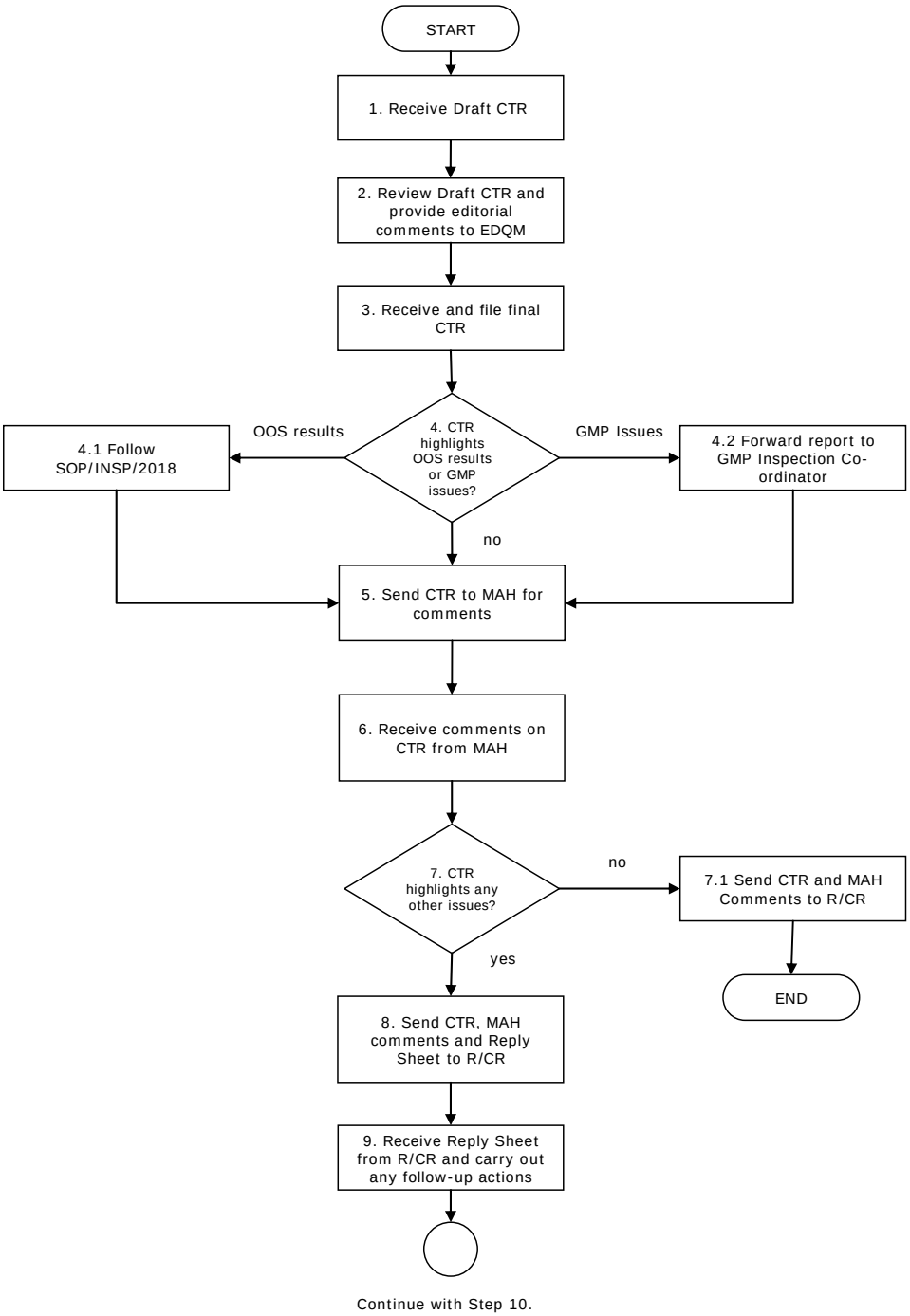
SOP/INSP/2010 – Sampling and testing of centrally authorised products

SOP/INSP/2018 – Dealing with Reports of Defective Medicinal Products

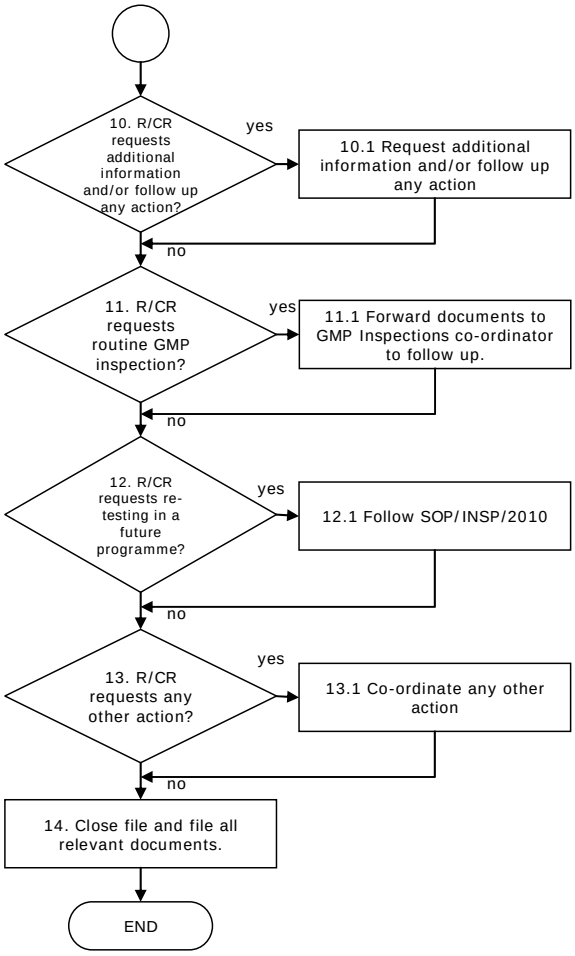
7. Definitions

P-CI:	Compliance and Inspection Sector in the Patient Health Protection Unit
CTR:	CAP testing report (document issued by EDQM for each product tested, containing results of the tests carried out)
DREAM:	Document Records Electronic Archive Management
EDQM:	European Directorate for the Quality of Medicines and HealthCare
GMP:	Good Manufacturing Practices
P-CI coordinator:	Compliance and Inspection Sector staff member who deals with coordination of GMP inspections
MAH:	Marketing Authorisation Holder
OOS:	Out of specification
PTL:	Product Team Leader (for human medicinal products) and Project Manager (for veterinary medicinal products)
PTMQ:	Product Team Member Quality (for human medicinal products)

8. Process map(s)/ flow chart(s)



Continue from Step 9.



9. Procedure

Step	Action	Responsibility
1	Receive draft CTRs from EDQM. EMA receives on an on-going basis the electronic copies of the draft CTRs from EDQM, with the request to provide editorial comments.	Assistant
2	Review draft CTRs and provide editorial comments to EDQM within two weeks. Save draft CTRs in DREAM under: OperationalUnits/Inspections/Samptest/e.Programmes/Year/3_Reports/Draft reports.	Assistant
3	Receive final CTRs from EDQM. EMA receives on an on-going basis the electronic copies of the final CTRs from EDQM. Save draft CTRs in DREAM under: OperationalUnits/Inspections/Samptest/e.Programmes/Year/3_Reports/Final reports.	Assistant
4	Does CTR highlight OOS results or GMP issues? OOS results: go to Step 4.1 GMP issues: go to Step 4.2 No OOS or GMP issues: go to Step 5	Assistant
4.1	CTR identifies out of specification results. Follow SOP/INSP/2018 “Dealing with reports of defective medicinal products”. MAH, Rapporteur, Co-Rapporteur, Supervisory Authorities and EMA Product Team Members are informed during the procedure. Go to Step 5.	Scientific Administrator
4.2	CTR identifies GMP issues (that could be dealt by an inspection of the relevant manufacturing site). Forward the report to the P-CI coordinator if manufacturing site is in a third country or to the relevant Supervisory Authority if manufacturing site is in the EEA. Go to Step 5.	Assistant
5	Send CTR to MAH by Eudralink using the text in the template “Template for Eudralink messages, for the transmission of CAP Testing Report to the Marketing Authorisation Holder”. Ask the MAH to comment on the content and/or the conclusions of the report. 2 weeks deadline to reply.	Assistant
6	Receive comments from MAH. Save MAH comments in DREAM under: OperationalUnits/Inspections/Samptest/e.Programmes/Year/4_Circulation and follow up.	Assistant
7	Does CTR highlight any other issues? No: go to Step 7.1 Yes: go to Step 8	Assistant
7.1	CTR does not highlight any issue.	Assistant

Step	Action	Responsibility
	On receipt of the MAH comments (or after the deadline has expired), forward: • CTR • MAH comments (if any) to the Rapporteurs by Eudralink using the text in the template "Template for Eudralink messages, for the transmission of CAP Testing Report to the Rapporteurs". The documents are for information and filing (we do not foresee to receive any comments from Rapporteurs). 2 weeks deadline to reply. On expiry of deadline close the file.	
8	CTR highlights other issues (technical, scientific, editorial). On reception of the MAH comments (or after the deadline has expired), forward: • CTR • MAH comments (if any) • Reply Sheet to the Rapporteurs. The Rapporteurs are asked to provide advice in relation to possible follow-up actions (steps 10-13). 4 weeks deadline to reply.	Assistant
9	Receive Reply Sheet from Rapporteurs and carry out any follow-up action. These can be taken on the basis of the Rapporteurs' advice and/or after liaison with PTL/PTMQ (when the R/CR did not provide any response).	Assistant
10	Rapporteur requests the MAH to provide any additional information and/or to take any follow-up action? No: go to Step 11 Yes: go to Step 10.1	Assistant
10.1	Contact the MAH to provide additional information and/or to take any follow-up action (e.g. submit a variation, update SOP) MAH to be contacted: • directly by the P-CI Or • by the PTL/PTQM Continue with step 11.	Assistant
11	Rapporteur requests the issue(s) highlighted in the CTR to be included in next routine GMP inspection? No: go to Step 12 Yes: go to Step 11.1	Assistant
11.1	Forward correspondence to P-CI coordinator, with the request to follow-up. Continue with step 12.	Assistant
12	Rapporteur requests to include product in a future Sampling and Testing Programme? No: go to Step 13 Yes: go to Step 12.1	Assistant
12.1	Include the product in one of the next years' Sampling and Testing	Assistant

Step	Action	Responsibility
	Programmes. Follow SOP/INSP/2010. Continue with step 13.	
13	Rapporteur requests any other action ? No: go to Step 14 Yes: go to Step 13.1	Assistant
13.1	Organise/co-ordinate the action (e.g. organise ad hoc inspection of the manufacturing site; re-testing of the product as a matter of urgency, meeting with Rapporteurs) and report as appropriate. Continue with step 14.	Assistant
14	Save all relevant documents in DREAM. Close the file.	Assistant

10. Records

Electronic copies of documents related to each programme are filed in electronic folders in DREAM under: Operational Units/Inspections/Samptest/e.Programmes/YYYY.