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STANDARD OPERATING PROCEDURE

TITLE : HANDLING OF OUT OF SPECIFICATION (OOS)	
SOP No. : QA/GEN/11	Page No. : 1 of 7
Revision No. : #01	Supersedes : #00
Effective Date : 02.01.2022	Next Review : 01.01.2027

1. OBJECTIVE

The objective of this SOP is to describe the procedure for investigation & evaluation of laboratory test results that obtained out of specification or acceptance criteria during analysis.

2. SCOPE

This SOP is applicable to the test results, which is out of specification obtained at Quality Control laboratory at this site ONE ASIA NETWORK INDIA PVT.LTD. C-09 (Part) MIDC KHAMGAON.

This procedure is applied to for the test results observed out of specification having acceptance criteria with numerical values for below categories with All chemical, physical, instrumental, analytical and biological tests samples include

- All Raw materials and perfumes.
- Packaging material
- Intermediates/ bulk and Finish products for releasing parameter.
- All periodic retesting results.

Procedure is not applicable for informative parameters like:

- Visual Defects in acceptance criteria.
- Process data / Experimental work that are not part of the registered release specifications.
- Customer complaint.
- Cleaning validation/ verification samples.
- Microbiological testing and Environmental monitoring samples of water samples.
- Calibration and maintenance of equipment's.
- Method validation and method transfer.

3. REQUIREMENTS

- Initial Results of OOS and Evidence.
- Format and Log of Out of specifications results.

	Prepared by	Checked by	Approved by	Authorized by
Sign/ Date	31/12/2021	31/12/2021	01/01/2022	01/01/2022
Name	Sahebuzzamakhan	Suraj Sapkal	Vinod Bhalgaonkar	B.A.shelke

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4. HISTORY

4.1 Rev No. #00

- This SOP is newly prepared.

4.2 Rev No. #01, SOP revised for

- SOP format as per QA/GEN/01.
- Procedure for better understanding.
- Scope change as SOP is applicable for Packaging material.
- Title revised.
- Annexures revised as per revised procedure.

5. PROCEDURE

5.1 This procedure applies to investigate all Out of Specification results as per logic / decision tree as per Format No.: QA/GEN/11/F/01.

5.2 All results generated during testing/ analysis at QC department must be evaluated to determine the Out of Specification results.

5.3 When a test results or unexpected results are obtained which is an Out of Specification (OOS) result, the analyst shall immediately inform to Superior and QC HOD.

5.4 QC associate shall issue the out of specification investigation form as per format No. QA/GEN/11/F/02 from Quality Assurance (QA) department.

5.5 QA shall issue out of specification investigation form with Pre-allocation of OOS number and same shall be log in OOS Log as per format No. QA/GEN/11/F/03.

5.6 Numbering system for OOS shall be as below,

OOS/YYYY/01

Example: OOS/ 2021/01

Where,

OOS - Represents Out of Specification followed by (/),

YYYY– represents the year (i.e. 2021) in four digits followed by (/),

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01 - Serial number of the OOS results.

QC Head shall start investigation with the Laboratory Investigation checklist in the form with Format No. QA/GEN/11/F/02.

5.7 During Investigation and finding root cause/ probable cause of Out of Specification Laboratory result shall be classified in to below Categories but not limited,

- Calculation error and Analyst or laboratory error.
- Sampling Error

5.8 If assignable cause was not identified in Laboratory Investigation checklist QC head shall proceed with the Phase I extended investigation in the extended Investigation part to identify cause of failure at testing.

5.9 Out of Specification investigation (Analytical + extended investigation) must be completed within specified time frame for all commercial batches this shall be not more than 30 working days.

5.10 Out of Specification results that have not been completed within specified time frame shall be pre-approved by QA for extended period and shall be documented.

5.11 Investigation shall be throughout, well documented, and scientifically sound.

5.12 QC In- charge / Head HOD shall lead the investigation team and complete the Investigation of Out of Specification results which obtain during analysis.

5.13 Analyst and an independent reviewer analyze the associated test with calculation & determine if Out of Specification investigation results is due to calculation error and calculation needs repeated/ corrected.

5.14 If Out of Specification results is due to simple calculation error, then it is corrected and documented and revise results shall submit, if it is not a calculation error/ testing error/ laboratory error then the initial OOS stands confirm/ Valid.

5.15 If laboratory investigations reveals that the Out of Specification results are due to laboratory errors (analyst/instrument/method/reagent/glassware etc.) then the analysis is repeated with original solution/reagents.

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5.16 Repeat the analysis with the same sample by the initial analyst (Failing sample additionally one previous passing batch sample can be considered if applicable) provided that the physical condition of the sample is okay & the sample is adequate for the analysis.

5.17 If the sample is inadequate or insufficient, then perform re-sampling and analyze the sample as per routine procedure.

5.18 Re-sampling to re-test for release is only permissible for the following reasons:

- The Original sample was consumed during testing.
- The Out of Specification investigation results disclose evidence that the original sample was not representative.
- The sample was contaminated or was improperly prepared.

5.19 The re-sampling for re-testing shall be documented & approved by Manager-QA.

5.20 Re-sampling involves analyzing a specimen from any additional unit collected as part of original sampling procedure or new sample collected from the batch.

5.21 Sample shall be tested by original analyst who reported the Out of Specification results, test result & second analyst.

5.22 Repeat analysis shall be performed by other analysts other than one who initially reported the Out of Specification results test result.

5.23 Repeat analysis by another analyst shall be perform with the fresh sample collected by another analyst who is repeating the testing in duplicate to have a set of results.

5.24 Relative standard deviation shall be less than 2% of test results by another analyst if the results are within the specification.

5.25 If the results of all the tests are again Out of Specification by both the analyst, the initial OOS results stand confirm and shall proceed for further investigation.

5.26 If results obtained by two analysts are within specification, then Out of Specification results is Invalid and the average result of another analyst shall be reported for final reporting.

5.27 After reviewing initial investigation, the QC HOD shall investigate the error whether it is due to sampling / Production related error.

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5.28 If the laboratory investigation is not conclusive to investigate the probable cause of OOS, an expanded investigation Phase II must be performed to identify if a non-Process or operator error or a process related error is responsible for the Out of Specification results.

5.29 Phase II investigation shall be performed by production Head (Manufacturing), and the check points shall be verified and update in the associated OOS as per the format No. QA/GEN/11/F/02.

5.30 Complete Investigation shall be done including personnel from QC, production Head (Manufacturing) and QA wherever applicable.

5.31 Investigate the manufacturing process, history of the manufacture of the material under test, results of in-process testing, results of other test conducted on the material, previous history of the material and information from the supplier, including certificate of analysis.

5.32 Hypothesis plan of resampling and testing shall be executed if the assignable cause is not identified in Phase I and Phase II investigation for the OOS confirmation.

5.33 Conclude the hypothesis investigation which will be case specific & must be based on scientific judgment of the information available.

5.34 For the test carried at outside lab QC Head shall investigate the cause in co-ordination with the associated lab and update the details in the OOS format. Supportive evidences shall be collected from outside lab and attached with the Investigation report as evidence.

5.35 All the information available is considered to conclude and to take a decision regarding the validity of the out of specs results, the disposition of the material under test & the actions to be taken.

5.36 CAPA shall be proposed for every OOS, If the out of spec results are due to the analyst error or the manufacturing operator, then the re-training and evaluation of the person involved must be done before further analysis / manufacturing is done by persons are involved.

5.37 The decision is to be taken by GM Operation/ designee after overall review of the investigation. The decision and the action taken are documented.

5.38 All the OOS results shall be discussed periodically in management review meeting.

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5.39 On according the root cause analysis for Out of Specification results corrective action and an effective preventive action shall be initiated and implemented.

6. RESPONSIBILITY

6.1 QC Department

- To analyze and inform the Out of Specification results to QC HOD.
- To confine all the evidences of OOS.
- To re-analyze the material as per the instructions from Investigation outcome.
- Keep all the analytical data generated through investigation as a record.
- QC HOD shall carry out and complete the investigation/ Hypothesis.
- To extend Investigation at outside lab as applicable.

6.2 QA Department

- To check the results obtained as Out of Specification results and assignable cause.
- To take decisions and approval for re-analysis / re-testing & intimate to QC dept.
- To take the final decision about the Out of Specification results valid/ invalid.
- To take the decision for the Hold of the material under investigation.
- To co-ordination during investigation wherever applicable.

6.3 Production Department

- Manufacturing Head shall complete Phase II investigation if applicable.
- Production Officer review aspects of manufacturing process that may be cause problem & submit to QA.
- To carry out and co -ordination during investigation as applicable.

6.4 GM Operation/ Designee

- To discuss with QA/QC/Production Dept. regarding the reason of Out of Specification results
- To summon a meeting of all the concerned, so that the recurrence could be avoided in future.
- To Review Investigation out come and authorized closure of OOS.

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7. PRECAUTION

- Reoccurrence of Out of Specification should be avoided in future.
- Investigation shall out come with valid conclusion.
- All the evidence of OOS shall be isolated for the Investigation.
- Out of Specification Log shall be maintained.
- Applicable CAPA shall be implemented prior to closer OOS.

8. REFERENCE / ATTACHMENT

- Logic/Decision Tree (Annexure-I) Format No. QA/GEN/11/F/01- Reference copy
- Out of Specification Investigation Form (Annexure-II) Format No. QA/GEN/11/F/02-Execution Copy- Computerized word copy
- Out of Specification Log (Annexure-III) Format No. QA/GEN/11/F/03- Execution Copy – Bound Book.

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Annexure-I

Quality Assurance Department	Format No. : QA/GEN/11/F/01-R/00
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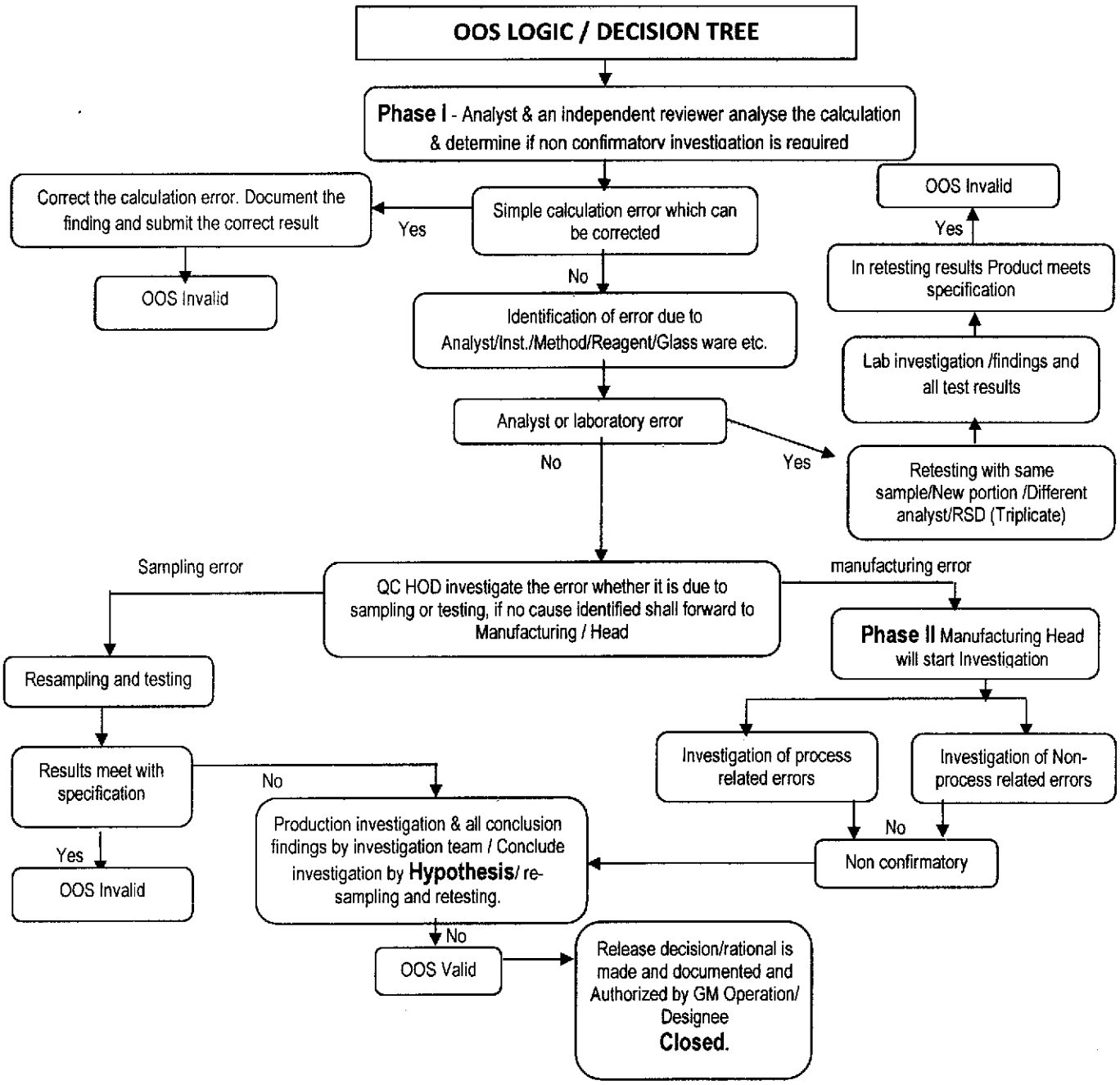

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Annexure-II

Quality Assurance Department	Format No. : QA/GEN/11/F/02-R/00
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OOS No.:	Date of Initiation:
Product / Material Name:	Manufacturer / Supplier :
Batch No. / AR No. :	Qty. / Lot Size:
Mfg. Date:	Exp. Date:
Date of testing:	Analyst Name:
Test performed:	Specification No.:
Description of OOS:	
OOS Reported By: Sign/ Date:	Lab Investigation Allotted to: Sign/ Date:
OOS Investigation started date:	OOS Investigation completed date:

LABORATORY INVESTIGATION

A) Lab Investigation Checklist	**Yes/ No/ NA**
I) Method of analysis review:	
1. Is correct approved specification available and followed?	
2. Was correct method followed for testing?	
3. Were there any deviation?	
4. Were the system suitability criteria defined in the method?	
5. Were negative and positive controls satisfactory?	
II) Raw data and calculation review	
1. Is there any error in raw data documentation?	
2. Is there any calculation error?	
III) Review of equipment / Instrument used	
1. Was the associated instrument calibrated?	
2. Is any calibration error observed in calibration reports?	
3. Was instrument functioning properly as per SOP?	
IV) Sampling review	
1. Is sampling carried out as per SOP?	
2. Is the sample stored properly after analysis?	

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Annexure-II

Quality Assurance Department	Format No. : QA/GEN/11/F/02-R/00
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3. Were there any obvious physical problems with the laboratory sample?	
4. Is the sample quantity sufficient to carry out repeat analysis?	
V) Review of Reagents and standards used	
1. Were correct reagents, solutions, samples and standards used for analysis?	
2. Were reagents, solutions, samples and standards prepared as per SOP?	
3. Is validity within expiry date?	
VI) Review of analyst training	
1. Was the analyst trained for testing procedure and record available?	
2. Was the analyst validated for testing and reported?	
VII) Analyst / Product / Material / Method History Review	
1. Is analyst training record available?	
2. Is material history checked for previous history? If Yes Details of Past history:	
VIII) Any other review: (Separate Annexure can Be attached with Details)	
Lab Investigation summary:	
Is assignable cause relevant to laboratory error?	
Identified Root Cause:	
Deviation raised if any and corrective and preventive action taken:	
Deviation /CAPA No.:	
Whether Phase I Extended Investigation required.	
Whether Phase II investigation recommended:	
Investigation conducted by sign, name & date:	
Investigation approved by QA Head sign & date	

PHASE I: EXTENDED INVESTIGATION
Stage I investigation: Retesting
I) Retesting Proposal:
1. Retesting first time (by same chemist on same sample):
2. Name of the chemist:

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Date of retesting:
Retesting results:
2. Retesting 1st time (by another chemist on Fresh sample):
Name of the chemist:
Date of retesting:
1st Retesting results:
3. Retesting 2nd time (by another chemist on Fresh sample):
Name of the chemist:
Date of retesting:
2nd Retesting results:
4. Average results of Another chemist:
5. RSD for Result of another analyst
II) Conclusion and recommendation:
III) Whether Stage II investigation recommended:
IV) If stage II investigation not required, Remarks:
Investigation conducted by name: sign, & date:
Investigation approved by QA Head sign & date

PHASE II: EXTENDED INVESTIGATION AT MANUFACTURING (Applicable only if no assignable cause identified in Phase I Investigation)
BMR & BPR review:
Batch record in line with the original master formula document: Yes / No

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Review of stock of active raw material used in the batch:
Review of dispensing procedures and errors:
Any wrong entries in the BMR & BPR:
Review of any possible errors at the vendor end or the material in the supply chain (RM/PM):
Review of any errors in in-process testing:
Any equipment failure:
Any utility failure:
Any equipment out of calibration:
Review of equipment cleaning:
Environment controls of temperature and pressure:
Whether all critical process parameters were properly controlled:
Review of supersedes batch record with respect to the OOS observation:
Review of validation batch results with respect to the OOS observation:

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Annexure-II

Quality Assurance Department	Format No. : QA/GEN/11/F/02-R/00
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Review of other batches with respect to the OOS observation:
Any incident / deviation report in the same:
Any Other (If applicable):
Extension Approval:
Proposed By (QC HOD): Approved By (QA HOD) Sign Date: Sign Date:
Revised Closure Date:
Cause of Failure Identified:
Investigation carried out by name sign, & date
Investigation approved by QA Head sign & date

Resampling:
If no assignable cause Identified in the Investigation at Manufacturing, then Resampling is recommended by QA Head Resampling Approval by QA Head. Yes / No. (Encircle the selection) QA Head Sign/Date
Stage II Investigation: Resampling and Re-testing
Date of resampling:
Qty Resampled:
Sample Description:
B. No./ Lot No.:

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Quality Assurance Department	Format No. : QA/GEN/11/F/02-R/00
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Test Name:	
Name of Chemist 1: Date of testing: Retesting results:	Name of Chemist 2: Date of testing: Retesting results:
Conclusion and recommendation: Summary of information reviewed, and investigations conducted Comments by QC HOD:	
Prepared By sign, name & date:	

Hypothesis and confirmation:
If no assignable cause Identified in the Investigation at Manufacturing, then hypothesis with resampling and testing is recommended by QA HOD Hypothesis Plan (Separate annexure can be added if required):
Resampling Approval by QA HOD. Yes / No. (Encircle the selection) Sign/Date
Stage II Investigation: Resampling and Re-testing
Date of resampling/ Testing:
Sample Description:
B. No./ Lot No.:
Test Name:

Name of Chemist Date of testing: Retesting results:	
Verified By QC HOD	
Conclusion and recommendation: Summary of information reviewed, and investigations conducted Comments By QA Head:	

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Quality Assurance Department	Format No. : QA/GEN/11/F/02-R/00
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Prepared By sign, name & date:
Conclusion:
Investigation approval Comments by QA HOD: Sign & date:
Investigation Authorization and Final Conclusion: Comments by GM Operation: Sign/Date

Attachments:

1)

2)

3)

4)

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Annexure-

Quality Assurance Department	Format No. : QA/GEN/11/F/03-R/00
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OUT OF SPECIFICATION LOG

Sr. No.	Initiating Department	Short Description	OOS No.	Logged and Issued by Sign/Date	Received By Sign/Date	Target Date (Initial)	Target Closer Date (Extended)	Cause of Failure (Valid/ Invalid)	OOS Closure Date	Remark

31/12/2021