


OOS Cemical Single Report		 VidyaGxP <small>Data Informs, Wisdom Discerns.</small>	
OOS No. Corporate/24/0031		Record No. 0031	

General Information

Initiator	Manish	Date of Initiation	18-Jun-2024
Record Number	0031	Site/Location Code	Not Applicable
Due Date	2024-06-19	Severity Level	Minor
Initiator Group	CQA	Initiator Group Code	CQA
Short Description	Money is the most important and essential tool of modern economic life. One cannot imagine modern economic life without money. Barter economies or self-sufficient economies are the thing of past and historical significance. Money is the foundation stone m		Assigned To Not Applicable
If Others	If Others *	Is Repeat	yes
Repeat Nature	Repeat Nature	Nature of Change	temporary
Deviation Occurred On	2024-06-20	Source Document Type	Not Applicable
Reference System Document	Not Applicable		
Sample Type	Not Applicable	Product / Material Name	Demo Testing
Market	Demo Testing	Customer	Not Applicable



OOS Camical Initial  
Attachement

S.N.	File
1	<a href="#">multifileupload_8767490.pdf</a>

Info. On Product/ Material

Row#	Item/Product Code	Batch No*.	Mfg.Date	Expiry Date	Label Claim.	Pack Size
1	Demo	123	2024-06-21	2024-06-20	Demo	123
2	Demo	123	2024-06-19	2024-06-19	DEMO	123
3	Demo	123	2024-06-19	2024-06-20	DEMO	123
4	Demo	123	2024-06-20	2024-06-20	DEMO	123
5	Demo	123	2024-06-20	2024-06-20	DEMO	123

Info. On Product/ Material

Row#	Analyst Name	Others (Specify)	In- Process Sample Stage.	Packing Material Type	Stability for
1	Demo	Demo	Demo	Primary	Commercial
2	Demo	Demo	Demo	Secondary	Commercial
3	Demo	Demo	Demo	Tertiary	Pack Evaluation
4	Demo	Demo	Demo	Not Applicable	Not Applicable
5	Demo	Demo	Demo	Secondary	Submission

Details of Stability Study

Row#	AR Number	Condition: Temperature & RH	Interval	Orientation
1	12345	123	asdf	asd
2	1234	1234	asdf	asd
3	1234	1234	asdf	asdfg
4	12345	1234	asd	asdf
5	1234	1234	asdf	asdf

Details of Stability Study

Row#	Pack Details (if any)	Specification No.	Sample Description
1	asdf	1234	asdfg
2	asdf	1245	ASDF
3	asdf	1234	sdf
4	asdf	12345	asdfg
5	asdf	12345	asdf

OOS Details

Row#	AR Number.	Test Name of OOS	Results Obtained	Specification Limit	Details of Obvious Error	Submit By	Submit On
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1	21345	Demo	Demo	1234	Demo	Demo	2024-06-20
2	1234	Demo	Demo	1234	Demo	Demo	Not Applicable
3	234	Demo	Demo	1234	Demo	Demo	Not Applicable
4	2345	Demo	Demo	1234	Demo	Demo	Not Applicable

Preliminary Lab. Investigation TapII

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### Comments

Money is the most important and essential tool of modern economic life. One cannot imagine modern economic life without money. Barter economies or self-sufficient economies are the thing of past and historical significance. Money is the foundation stone

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**Justify if no  
Field Alert**

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Justify if no Analyst Int.

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Phase I  
Investigation  
Required

Not Applicable

## File Attachments

S.N.	File
1	<a href="#">multifileupload_60365486.pdf</a>
2	<a href="#">multifileupload_78898817.pdf</a>

CheckList - Preliminary Lab. Investigation

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## PHASE- I B INVESTIGATION REPORT

S.N.	Question	Response	Remarks
1	Aliquot and standard solutions preserved solutions preserved	Yes	Demo
2	Visual examination (solid and solution) reveals normal or abnormal appearance and solution) reveals normal or abnormal appearance	Yes	Demo
3	The analyst is trained on the method. the method.	Yes	Demo
4	Correct test procedure followed e.g. Current Version of standard testing procedure has been used in testing. followed e.g. Current Version of standard testing procedure has been used in testing.	Yes	Demo
5	Current Validated analytical Method has been used and the data of analytical method validation has been reviewed and found satisfactory. analytical Method has been used and the data of analytical method validation has been reviewed and found satisfactory.	Yes	Demo



6	Correct sample(s) tested.	Yes ▼	Demo
7	Sample Integrity maintained, correct container is used in testing.maintained, correct container is used in testing.	Yes ▼	Demo
8	Assessment of the possibility that the sample contamination (sample left open to air or unattended) has occurred during the testing/ re-testing procedurepossibility that the sample contamination (sample left open to air or unattended) has occurred during the testing/ re-testing procedure	Yes ▼	Demo
9	All equipment used in the testing is within calibration due period.	Yes ▼	Demo
10	Equipment log book has been reviewed and no any failure or malfunction has been reviewed.	Yes ▼	Demo
11	Any malfunctioning and / or out of calibration analytical instruments (including glassware) is used.	Yes ▼	Demo
12	Whether reference standard / working standard is correct (in terms of appearance, purity, LOD/water content & its storage) and assay values are determined correctly.	Yes ▼	Demo
13	Whether test solution /		

Investigation Conclusion

Summary of Preliminary Investigation	Money is the most important and essential tool of modern economic life. One cannot imagine modern economic life without money. Barter economies or self-sufficient economies are the thing of past and historical significance. Money is the foundation stone m&nbsp;Money is the most important and essential tool of modern economic life. One cannot imagine modern economic life without money. Barter economies or self-sufficient economies are the thing of past and historical significance. Money is the foundation stone m&nbsp;Money is the most important and essential tool of modern economic life. One cannot imagine modern economic life without money. Barter economies or self-sufficient economies are the thing of past and historical significance. Money is the foundation stone m	Root Cause Identified	yes
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OOS Category-Root Cause Ident.

Not Applicable

OOS  
Category  
(Others)

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**CAPA Required.**

yes

**Reference  
CAPA No**

12345

**Delay Justification for Preliminary  
Investigation.**

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## Supporting Attachments

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S.N.	File
1	<a href="#">multifileupload_5862065.pdf</a>

## Preliminary Lab Investigation Review

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Review Comments

Money is the most important and essential tool of modern economic life. One cannot imagine modern economic life without money. Barter economies or self-sufficient economies are the thing of past and historical significance. Money is the foundation stone m Money is the most important and essential tool of modern economic life. One cannot imagine modern economic life without money. Barter economies or self-sufficient economies are the thing of past and historical significance. Money is the foundation stone m Money is the most important and essential tool of modern	Phase II Inv. Required?	yes
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# OOS Review for Similar Nature

## Info. On Product/ Material

Row#	OOS Number	OOS Reported Date	Description of OOS	Previous OOS Root Cause
1	Not Applicable	2024-06-20	Demo	Demo
2	Not Applicable	2024-06-19	Demo	Demo
3	Not Applicable	2024-06-19	Demo	Demo
4	Not Applicable	2024-06-19	Demo	Demo
5	Not Applicable	2024-06-20	Demo	Demo



## Info. On Product/ Material

Row#	CAPA	Closure Date of CAPA	CAPA Requirement	Reference CAPA Number
1	Demo	2024-06-19	yes	12123
2	Demo	2024-06-20	yes	2134
3	Demo	2024-06-20	yes	1234
4	Demo	2024-06-21	yes	1234
5	Demo	2024-06-22	yes	1234

## Phase II Investigation

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**QA Approver  
Comments**

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**Manufact.  
Invest.  
Required?**

Not Applicable

**Manufacturing  
Invest. Type**

Not Applicable

**Audit  
Comments**

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**Hypo/Exp.  
Required.**

yes

**Hypo/Exp.  
Reference**

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## Attachments

S.N.	File
1	Not Applicable

## CheckList - Phase II Investigation

Sr.No.	Question	Response	Remarks
1	Is correct batch manufacturing record used?	<input type="text" value="Yes"/>	Demo
2	Correct quantities of correct ingredients were used in manufacturing?	<input type="text" value="Yes"/>	Demo
3	Balances used in dispensing / verification were calibrated using valid standard weights?	<input type="text" value="Yes"/>	Demo
4	Equipment used in the manufacturing is as per batch manufacturing record?	<input type="text" value="Yes"/>	Demo
5	Processing steps followed in correct sequence as per the BMR?	<input type="text" value="Yes"/>	Demo
6	Whether material used in the batch had any OOS result?	<input type="text" value="Yes"/>	Demo

7	All the processing parameters were within the range specified in BMR?	<input type="text" value="Yes"/>	Demo
8	Environmental conditions during manufacturing are as per BMR?	<input type="text" value="Yes"/>	Demo
9	Whether there was any deviation observed during manufacturing?	<input type="text" value="Yes"/>	Demo
10	The yields at different stages were within the acceptable range as per BMR?	<input type="text" value="Yes"/>	Demo
11	All the equipment's used during manufacturing are calibrated?	<input type="text" value="Yes"/>	Demo
12	Whether there is malfunctioning or breakdown of equipment during manufacturing?	<input type="text" value="Yes"/>	Demo
13	Whether the processing equipment was maintained as per preventive maintenance schedule?	<input type="text" value="Yes"/>	Demo
14	All the in-process checks were carried out as per the frequency given in BMR & the results were within acceptance limit?	<input type="text" value="Yes"/>	Demo
15	Whether there were any failures of utilities (like Power, Compressed air, steam etc.) during manufacturing?	<input type="text" value="Yes"/>	Demo

16	Whether other batches/products impacted?	<div>Yes ▼</div>	Demo
17	Any Other	<div>Yes ▼</div>	Demo

**Summary of Phase II Testing**

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### Summary of Exp./Hyp.

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### Summary Mfg. Investigation

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Root Casue Identified.

yes

OOS  
Category-  
Reason  
identified

Not Applicable

Opened



Others (OOS category).

Demo

Details of  
Root Cause

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Impact Assessment.

yes

## Attachments

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S.N.	File
1	<a href="#">multifileupload_43292928.pdf</a>

## Additional Testing Proposal by QA

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**Review Comment.**

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**Additional Test Proposal**      Yes

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**Additional Test Comment.**

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Any Other Actions Required	Yes
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Yes

Additional Testing Attachment

S.N.	File
1	<a href="#">multifileupload_24072033.pdf</a>

OOS Conclusion

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Conclusion Comments.	Specification Limit	12345
<p>Money is the most important and essential tool of modern economic life. One cannot imagine modern economic life without money. Barter economies or self-sufficient economies are the thing of past and historical significance.</p> <p>Money is the foundation stone m&amp;nbsp;Money is the most important and essential tool of modern economic life. One cannot imagine modern economic life without money. Barter economies or self-sufficient economies are the thing of past and historical significance.</p> <p>Money is the foundation stone m&amp;nbsp;Money is the most important and essential tool of modern economic life. One cannot imagine modern economic life without money. Barter economies or self-sufficient economies are the thing of past and historical significance.</p> <p>Money is the foundation stone m Money is the most important and essential tool of modern economic life. One cannot imagine modern economic life without money. Barter economies or self-sufficient economies are the thing of past and historical significance.</p> <p>Money is the foundation stone m&amp;nbsp;Money is the most important and essential tool of modern economic life. One cannot imagine modern economic life without money. Barter economies or self-sufficient economies are the thing of past and historical significance.</p>		



**Results to  
be  
Reported**

Not Applicable

**Final Reportable Results**

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Valid

CAPA Req.    Yes

CAPA Ref No.    ["1"]

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Yes

**Action Item**      **Justification for Delay.**  
**Ref..**

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### Summary of OOS Test Results

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Row#	Analysis Detials	Hypo./Exp./Add.Test PR No.	Results	Analyst Name.	Remarks
1	Demo	Demo	Demo	Demo	Demo
2	Demo	Demo	Demo	Demo	Demo
3	Demo	Demo	Demo	Demo	Demo
4	Demo	Demo	Demo	Demo	Demo
5	Demo	Demo	Demo	Demo	Demo

### Attachments if Any

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S.N.	File
1	<a href="#">multifileupload_30674117.pdf</a>

### Conclusion Review Comments

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**Conclusion**  
**Review**  
**Comments**

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**Action  
Taken on  
Affect.batch**

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Money is the most important and essential tool of modern economic life. One cannot imagine modern economic life without money. Barter economies or self-sufficient economies

**CAPA Req**

Yes

**CAPA  
Reference**

CAPA Reference

Opened



**Justify if No  
Risk  
Assessment**

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**CQ  
Approver**

Demo

## Summary of OOS Test Results

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Row#	Material/Product Name	Batch No.(s) / A.R. No. (s)	Any Other Information	Action Taken on Affec.batch
1	Demo	1234	Demo	Demo
2	Demo	1234	Demo	Demo
3	Demo	1234	Demo	Demo
4	Demo	1234	Demo	Demo
5	Demo	2134	Demo	Demo

## Conclusion Attachment

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S.N.	File
1	<a href="#">multifileupload_6178739.pdf</a>

## OOS QA Review

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Money is the most important and essential tool of modern economic life. One cannot imagine modern economic life without money. Barter economies or self-sufficient economies are the thing of past and historical significance. Money is the foundation stone m&nbsp;Money is the most important and essential tool of modern economic life. One cannot imagine modern economic life without money. Barter economies or self-sufficient economies are the thing of past and historical significance. Money is the foundation stone m&nbsp;Money is the most important and essential tool of modern economic life. One cannot imagine modern economic life without money. Barter economies or self-sufficient economies are the thing of past and historical significance. Money is the foundation stone m&nbsp;Money is the most important and essential tool of modern economic life. One cannot imagine modern economic life without money. Barter economies or self-sufficient economies are the thing of past and historical significance. Money is the foundation stone m&nbsp;Money is the most important and essential tool of modern economic life. One cannot imagine modern economic life without money. Barter economies or self-sufficient economies are the thing of past and historical significance. Money is the foundation stone m

CQ Attachment

S.N.	File
1	<a href="#">multifileupload_44791159.pdf</a>

Batch Disposition

OOS Categoryanalyst\_errorOther'sDemo

Opened

**Material/Batch Release**

release

**Other  
Action  
(Specify)**

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## Other Parameters Results

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## Trend of Previous Batches

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**Stability Data**

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**Process Validation Data**

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## Method Validation

Money is the most important and essential tool of modern economic life.

One cannot imagine modern economic life without money.

Barter economies or self-sufficient economies are the thing of past and historical significance.

Money is the foundation stone

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## Any Market Complaints

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## Statistical Evaluation

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## Risk Analysis for Disposition

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## Conclusion

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## Justify for Delay in Activity

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### Disposition Attachment

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S.N.	File
1	<a href="#">multifileupload_14793660.pdf</a>

### QA Head/designee Approval

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### Approval Comment

Money is the most important and essential tool of modern economic life. One cannot imagine modern economic life without money. Barter economies or self-sufficient economies are the thing of past and historical significance. Money is the foundation stone m&nbsp;Money is the most important and essential tool of modern economic life. One cannot imagine modern economic life without money. Barter economies or self-sufficient economies are the thing of past and historical significance. Money is the foundation stone m&nbsp;Money is the most important and essential tool of modern economic life. One cannot imagine modern economic life without money. Barter economies or self-sufficient economies are the thing of past and historical significance. Money is the foundation stone m&nbsp;Money is the most important and essential tool of modern economic life. One cannot imagine modern economic life without money. Barter economies or self-sufficient economies are the thing of past and historical significance. Money is the foundation stone m&nbsp;Money is the most important and essential tool of modern economic life. One cannot imagine modern economic life without money. Barter economies or self-sufficient economies are the thing of past and historical significance. Money is the foundation stone m&nbsp;Money is the most important and essential tool of modern economic life. One cannot imagine modern economic life without money. Barter economies or self-sufficient economies are the thing of past and historical significance. Money is the foundation stone m

## Approval Attachment

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1	<a href="#"><u>multifileupload_8693005.pdf</u></a>