Annexure-1
Out of specification
Labrotary investigation form

OOS Investigat	[redacted]	**ccurrence :**	25-Sep-2017
A] 008 REPOR			
Product Name :			
Test Name :			B512345
Summary of 008			
kfjalfkad;lfasdkl kkkkkkkkkkkkkk sssssssssssssss sssssssssssssss ssss			fjsdklfjklkkkkkkkkk kkkkkkkkkkkk
Analyst Name :			

B] LABORATORY INVESTIGATION

Sr. No.					
	Cross verification with reference sample (Previous approved FG batch): Not applicable for viscosity/density test				
1.1	Reference sample batch No: (Take about 1 month old batch wherever possible).				23
1.2	Initial results of Reference sample:				23
1.3	Results of reference sample after retesting in duplicate: (Repeatability NMT 3 %)				
	Result-1 5	Result-2 7	Average of 1 &2 6.00	Repeatability 40.00	Formula (Max-Min) X 100/Min
1.4	Difference between initial and re-analysis results of reference sample (Reproducibility NMT 5%)				
	Initial Results 7	re-analysis results 4	Reproducibility 75.00	Formula (Max-Min) X 100/Min	
1.5	**Conclusion :** gfjgfjfgj				
	Guiding rules: If reference sample re analysis result does not confirm initial results: Lab error confirmed. Identify the lab error.				
	If reference sample re analysis result confirm initial results: Proceed for resampling and reanalysis.			☐ Yes	☑ No

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Sr No.	Parameters	Observations	Comments
1	Any Error In Calculation	No	
2	Any abnormality observed during testing	NA	
3	Was the method discussed with analyst	No	
4	Correct analytical method used	No	
5	Analyst was trained to perform the test	No	
6	Correct glassware used for dilutions	No	
7	Glassware was properly cleaned	No	
8	Instruments used are qualified	No	
9	Instruments used within calibration validity period	Yes	
	Instrument Used & ID	**Calibration Due**	
	jk01212	25-Sep-2017	
	jkk	25-Sep-2017	
13	Instrument set up & operation as per standard operating proc	No	
14	Correct electrode used	Yes	
15	Solution inside electrode is correct	Yes	
16	Blank reading is similar as earlier	Yes	
17	Any unusual trend in autotitrator graph	Yes	
18	Use of appropriate grade of chemicals and reagents within v	No	
19	Water used is same as specified in the method	No	
20	Correct normality/ molarity of volumetric solutions used	No	
21	Leakage Observed in case of Buchi apparatus /350px,/150p		
22	The buchi apparatus is properly dipped in collecting solution		
23	In case of viscometer check viscosity of water using Spindle		
24	Sample and standard preparation is done as per test method		
25	Is any weighing error identified		

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26	Is sample properly shaken/sonicated/ warmed as per the tes		
27	Any noticeable error is noticed between standard and sample		
28	Are the sample and standard stored under same environmen		
29	Any error in Transcription		

Chromatography

Sr No.	Parameters	Observation	Comments
1	Correct column used		
2	Any leakage noticed from column		
3	Correct instrument parameters are used? Like flow rate injection volume		
4	Mobile phase preparation is used as per standard method.		
5	Systems suitability criteria met during testing		
6	Other Findings		
7	Was similar OOS reported for same product		
8	Laboratory error identified? if yes please specify		

Note : Action to be followed (In case lab error identified)

Sr No.	Description	Observation	Comments
1	Retesting of same sample by the original analyst in duplicate	Yes	
2	Correction in documents	No	

Retest Result-1	Retest Result-2	Average of 1 & 2	Repeatability NMT 1.3

Conclusion : **QC Analyst Name :** **Completion Date :**

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Re-Sampling

1	Resampling		☑ Yes	☐ No
2	Result of Retesting			
	Test Result-1 6.21	Test Result-2 6.20	Average of 1 & 2 6.21	Repeatability NMT 1.3 0.16

QC Analyst Name : KAIREE

Completion Date : 25-Sep-2017

Conclusion : sffergfergerg

Simulation Testing

Simulation Testing Conclusion :

3	If Reason Identified			
	Retest Result-1	Retest Result-2	Average of 1 & 2	Repeatability NMT 1.3

Quality Control Head Final Remark :

OOS Valid/Invalid : Valid

Proceed for manufacturing investment : No

Head Quality Control : PMORE

Completion Date : 25-Sep-2017

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Manufacturing Investigation

Sr No.	Parameters	Observation	Comments

Summary and conclusion	
Batch File Decision	

UP Manager :

Process Expert :

Quality Head :

Completion Date :