

Annexure-1
Out of specification
Labrotary investigation form

OOS Investingation Report No. : OOS000009			Date of OOS occurrence : 1-Nov-2017		
A] 008 REPORTING (Tobe completedbyorigina/ analyst)					
Product Name :	Test Formula				
Test Name :	14B-TOLUENE-2,5-DIAMINE (And) THIOGLYCERIN	Batch No. :	B8211111		
Summary of 008 Test Results (state result and specification)					
sdgdfhdhfgghfghgfhghj fghkjhgkg yjhtkgk fffffffffffffffffffffg fdjjddyityjryjureyjjytjykykykytktkk sdgdfhdhfgghfghgfhghj fghkjhgkg yjhtkgk fffffffffffffffffffffg fdjjddyityjryjureyjjytjykykykytktkk sdgdfhdhfgghfghgfhghj fghkjhgkg yjhtkgk fffffffffffffffffffffg fdjjddyityjryjureyjjytjykykykytktkk sdgdfhdhfgghfghgfhghj fghkjhgkg yjhtkgk ff					
Analyst Name :	BDENKAR				
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).				14
1.2	Initial results of Reference sample:				7
1.3	Results of reference sample after retesting in duplicate:				
	Result-1 8	Result-2 4	Average of 1 & 2 6.00	Repeatability NMT 1.3 % 100.00	Formula (Max-Min) X 100/Min
1.4	Difference between initial and re-analysis results of reference sample				
	Initial Results 7	re-analysis results 6.00	Reproducibility NMT 1.5 % 16.67	Formula (Max-Min) X 100/Min	
1.5	Conclusion : sdgdfhdhfgghfghgfhghj fghkjhgkg yjhtkgk fffffffffffffffffffffg fdjjddyityjryjureyjjytjykykykytktkk sdgdfhdhfgghfghgfhghj fghkjhgkg yjhtkgk fffffffffffffffffffffg fdjjddyityjryjureyjjytjykykykytktkk sdgdfhdhfgghfghgfhghj fghkjhgkg yjhtkgk fffffffffffffffffffffg fdjjddyityjryjureyjjytjykykykytktkk sdgdfhdhfgghfghgfhghj fghkjhgkg yjhtkgk ff				
	Guiding rules: If reference sample re analysis result does not confirm initial results: Lab error confirmed. Identify the lab error. <div style="float: right;"> <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No </div>				
	If reference sample re analysis result confirm initial results: Proceed for resampling and reanalysis. <div style="float: right;"> <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No </div>				

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Lab Error

Sr No.	Parameters	Observations	Comments
1	Any Error In Calculation		
2	Any abnormality observed during testing		
3	Was the method discussed with analyst		
4	Correct analytical method used		
5	Analyst was trained to perform the test		
6	Correct glassware used for dilutions		
7	Glassware was properly cleaned		
8	Instruments used are qualified		
9	Instruments used within calibration validity period		
10	Instrument set up & operation as per standard operating procedure.		
11	Correct electrode used		
12	Solution inside electrode is correct		
13	Blank reading is similar as earlier		
14	Any unusual trend in autotitrator graph		
15	Use of appropriate grade of chemicals and reagents within validity period		
16	Water used is same as specified in the method		
17	Correct normality, molarity of volumetric solutions used		
18	Leakage Observed in case of Buchi apparatus.		

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Sr No.	Parameters	Observations	Comments
19	The buchi apparatus is properly dipped in collecting solution		
20	In case of viscometer check viscosity of water using Spindle M1. It should be 29.5+_1 UD at 20 Degree.		
21	Sample and standard preparation is done as per test method		
22	Is any weighing error identified		
23	Is sample properly shaken/sonicated/ warmed as per the test		
24	Any noticeable error is noticed between standard and sample preparation.		
25	Are the sample and standard stored under same environment before testing		
26	Any error in Transcription		
27	Correct column used		
28	Any leakage noticed from column		
29	Correct instrument parameters are used? Like flow rate injection volume		
30	Mobile phase preparation is used as per standard method.		
31	Systems suitability criteria met during testing		
32	Other Findings		
33	Was similar OOS reported for same product		
34	Laboratory error identified? if yes please specify	Yes	

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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		
2	Correction in documents		

Retest Result-1 45	Retest Result-2 47	Average of 1 & 2 46.00	Repeatability NMT 1.3 % 4.44
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Conclusion : OOS Valid

QC Analyst Name : PMORE

Completion Date : 1-Nov-2017

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Re - Sampling

Re-Sampling

1	Result of Retesting			
	Test Result-1 4	Test Result-2 1	Average of 1 & 2 2.50	Repeatability NMT 1.3 % 300.00

QC Analyst Name : AREDDY

Completion Date : 01-Nov-2017

Conclusion :
sdgdfhdhfgghfghgfhghj fghkjhkgk yjhtkgk ffffffffg
fdjjddyitityjryjureyjjytjykytykytktkk
sdgdfhdhfgghfghgfhghj fghkjhkgk yjhtkgk ffffffffg
fdjjddyitityjryjureyjjytjykytykytktkk
sdgdfhdhfgghfghgfhghj fghkjhkgk yjhtkgk ffffffffg
fdjjddyitityjryjureyjjytjykytykytktkk
sdgdfhdhfgghfghgfhghj fghkjhkgk yjhtkgk ff

Simulation Testing

1	Required Simulation Testing	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
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Simulation Testing Conclusion :
sdgdfhdhfgghfghgfhghj fghkjhkgk yjhtkgk ffffffffg
fdjjddyitityjryjureyjjytjykytykytktkk
sdgdfhdhfgghfghgfhghj fghkjhkgk yjhtkgk ffffffffg
fdjjddyitityjryjureyjjytjykytykytktkk
sdgdfhdhfgghfghgfhghj fghkjhkgk yjhtkgk ffffffffg
fdjjddyitityjryjureyjjytjykytykytktkk
sdgdfhdhfgghfghgfhghj fghkjhkgk yjhtkgk ff

3	If Reason Identified			
	Retest Result-1 12	Retest Result-2 45	Average of 1 & 2 28.50	Repeatability NMT 1.3 % 275.00

Lab Manager Final Remark :

sdgdfhdhfgghfghgfhghj fghkjhkgk yjhtkgk ffffffffg
fdjjddyitityjryjureyjjytjykytykytktkk
sdgdfhdhfgghfghgfhghj fghkjhkgk yjhtkgk ffffffffg
fdjjddyitityjryjureyjjytjykytykytktkk
sdgdfhdhfgghfghgfhghj fghkjhkgk yjhtkgk ffffffffg
fdjjddyitityjryjureyjjytjykytykytktkk
sdgdfhdhfgghfghgfhghj fghkjhkgk yjhtkgk ff

OOS Valid/Invalid : Valid

Proceed for manufacturing investment :

Lab Manager : PMORE

Completion Date : 1-Nov-2017

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Manufacturing Investigation

Sr No.	Parameters	Observation	Comments
1	Correct method of manufacturing was used?		
2	The dispensing labels on empty poly bags are correct?		
3	Correct quantities of required grade of starting materials were used in manufacturing?		
4	QC approved raw materials were used in manufacturing.		
5	Were the same lots of RM used in other batches of bulk. If yes what is the status of those batches		
6	The RMs were stored properly as per recommended storage conditions.		
7	Weighing balances used in dispensing/verification were calibrated.		
8	Method of manufacturing was validated?		
9	The processing steps were followed in correct sequence as per method of manufacturing.		
10	All the processing parameters were within the range specified in method of manufacturing.		
11	The manufacturing operator was trained.		
12	In which shift the batch was manufactured?		
13	Environmental conditions during manufacturing were as per the limits.		
14	Any deviation from the manufacturing process?		
15	All the monitoring equipment used in the processing were calibrated?		
16	All the processing equipment were maintained as per Preventive maintenance schedule?		
17	Any malfunctioning of equipment or breakdowns during processing?		
18	Any failure of utilities (like power,water,compressed air,steam etc.) associated with the process?		
19	All the in-process checks were performed as per the defined frequency and the results were within acceptance criteria?		

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Manufacturing Investigation

Sr No.	Parameters	Observation	Comments
20	Any significant observation noted during batch Manufacture?		
21	Any other findings (e.g. from review of trend data of previous batches, observations noted during follow up batches etc.) Additional pages can be used for other analysis.		
22	Manufacturing error identified Yes/ NO. If yes, describe the error.	Yes	sdgdfhdhfgghgfhgghgfhghj fjghkjhgkg yjhtkgk fffffffffffffffffffffg fdjjddyityjryjureyjjytjykykykytktkk kykytktkk sdgdfhdhfgghgfhgghgfhghj fjghkjhgkg yjhtkgk fffffffffffffffffffffg fdjjddyityjryjureyjjytjykykykytktkk kykytktkk sdgdfhdhfgghgfhgghgfhghj fjghkjhgkg yjhtkgk fffffffffffffffffffffg fdjjddyityjryjureyjjytjykykykytktkk kykytktkk sdgdfhdhfgghgfhgghgfhghj fjghkjhgkg yjhtkgk ff

Summary and
conclusion

sdgdfhdhfgghgfhgghgfhghj fjghkjhgkg yjhtkgk ffffffffffffffffffffffg
fdjjddyityjryjureyjjytjykykykykytktkk
sdgdfhdhfgghgfhgghgfhghj fjghkjhgkg yjhtkgk ffffffffffffffffffffffg
fdjjddyityjryjureyjjytjykykykykytktkk
sdgdfhdhfgghgfhgghgfhghj fjghkjhgkg yjhtkgk ffffffffffffffffffffffg
fdjjddyityjryjureyjjytjykykykykytktkk

Batch File
Decision

sdgdfhdhfgghgfhgghgfhghj fjghkjhgkg yjhtkgk ffffffffffffffffffffffg
fdjjddyityjryjureyjjytjykykykykytktkk
sdgdfhdhfgghgfhgghgfhghj fjghkjhgkg yjhtkgk ffffffffffffffffffffffg
fdjjddyityjryjureyjjytjykykykykytktkk
sdgdfhdhfgghgfhgghgfhghj fjghkjhgkg yjhtkgk ffffffffffffffffffffffg
fdjjddyityjryjureyjjytjykykykykytktkk
sdgdfhdhfgghgfhgghgfhghj fjghkjhgkg yjhtkgk ff

Manufacturing Incharge :

SARIKA

Process Expert :

MKULKARNI

Lab Manager :

BDENKAR

Completion Date :

01-Nov-2017