

Auriga Research Private Limited

Govt. Approved Test House



No. 136, 6th Cross, 2nd Stage, Yeshwanthpur Industrial Suburb, Bangalore - 560 022 Ph. : +91-080-35229344

Email: admin@aurigaresearch.com, Website: www.aurigaresearch.com

Certificate of Analysis

Information by Customer

Report No. : BG202301250087

Sample

: ARTIFICIAL TEARS

Mfg. By

GLOBAL PHARMA HEALTHCARE PVT. LTD.

Supplied By

GLOBAL PHARMA HEALTHCARE PVT. LTD.

Mfg lic. No. : NS

: NS

Submitted By : GLOBAL PHARMA HEALTHCARE PVT. LTD.

Ref. No.

Address

: NEW NO. 2A, 3RD FLOOR GANGA NAGAR 4TH STREET KODAMBAKKAM, CHENNAI, TAMILNADU- 600024

INDIA

Batch No

Mfg. Date

Expiry Date

Batch Size

Sample Quantity

PCMJ006

APR 2022

MAR 2025

204 Ltr

Date of completion of analysis: 02/03/2023

12 Bottles

Date of start of analysis: 28/01/2023

Sample ID: BG202301250087

Received On:

25/01/2023

Reference to protocol

:- GPHC/SPEC-FP-DRP-A-079-00

Sample not drawn by laboratory.

Description

:- Clear colourless slightly viscous solution

- <parameters></parameters>	<results></results>	<unit></unit>	<req.></req.>	<claim></claim>	<lloq></lloq>	<lower limit=""></lower>	<upper limit></upper 	<method></method>
Content of sodium Carbo	xy methyl cellulose :							
Assay in %	: 99.17	%	90.00 % to 110.00 %					GPHC/STP-FP-DRP -A-079-00
Assay in mg/ml	: 9.92	mg/ml	9.00 mg/ml and 11.00 mg/ml	d 10.0 mg/ml	-	-	-	GPHC/STP-FP-DRP -A-079-00
Total Yeast & Mould count.	: <10 cfu/ml	-	-		-	-	-	USP <61>
Total aerobic	: <10 cfu/ml	-	-		-	-	-	USP <61>
Sterility	: Complies	-	-		-		-	USP <75>
			End of Report					

Report: In the opinion of the undersigned, the sample referred to above is of standard quality as defined in the Act and the rules made thereunder for the reason given below:- of



To verify Report Scan this Code.

(1) Total liability of this laboratory is limited to the invoice amount.
(2) The results listed refer only to the tested sample and applicable parameter. Endorsement of products is neither inferred nor implied.

(3) This report is not to be reproduced wholly or in part and cannot be used as evidence in the court of Law and should not be used in any advertising media without our special Permission on writing.

(4) When the report is without NABL symbol & ULR, it implies that these products & tests are not covered under NABL accredited scope.

40860312023 Svathi. S

Authorized Signatory Note: The result Listed refer only to the tested sample and applicable parameter. Endorsment of products is neither inferred nor implied.

This report is not to be reproduced wholly or in part and cannot be used as evidence in the court of Law and should not be used in advertising media without our special permission in writing. The samples will be destroyed in appropriate time from the date of issue of test certificate unless otherwise specified (In case of non-pershable items only).

RAW DATA SHEET

2038 Book No.:

SI No .: 405358

Booking date: 25 | 01 | 2023 Report No.: Artificial Tears Sample name: 30/01/2023 Analysis Completion Date: 30 0 1 2023 Analysis Started Date:

Test Parameters ASSQ4

Test Method: GRAC 1STR-FR-DRR-A-079-00

Balance ID: ARLIBLED | ANB -012

Equipment/Instrument: ARL (BLEQ (UV -002

Equipment/instrument: NA

Due Date of Calibration: 05 | 02 | 20 2 3

Due Date of Calibration: 29 (03 (2023

Due Date of Calibration: NA

Weight of the Sample:

Diphenyl amine Weighing

1.25146 9 1.25090 9

2 30/01/2023

\$103/02 Pron3

Name Dipheryl amine

Gracial Acetic acid

cone. Hydrochloric acid

B.NO 120418

7393941022

3301021C

make central drug house aualigens

carlo erba

Reagent Preparation: Dissolved 1.25090 g of Diphenyl amine reagent in so ml of colacial acetic acid and then adoled so me of conc. Hydrochloric acid.

Vr 30/01/2023 Performed by (Sign & Date)

603/phro23 Checked By (Sign & Date)

Page 1of 2

Calculation:

Working mode Carboxy muthyl Weighing Date Cellulose Socium 30.01.2023
Time Time 14:14:55
Balance S/N //2/27

Instrument Id:ARL/BLEQ/AWB-012

50.30 mg 50.25 mg

P230T01/2023

6/3/02/2013

standard Details:

Name carboxy methyl cellulose sodicum

B. NO: GRINS1079/21

ralidupto: 12/10/2023

standard Preparation: weighted 50.25 mg of carboxy methyl cellulose Sodium was into a 100 ml volumetric flash, added water, slowly with swirling and then made to volume with same. Mixed well.

Sample Preparation: Pipetted out 5 ml of sample into a 100 ml volumetric flash, addle 100 ml of water

Result: Procedure continued in 81. NO: 405995

Pr 30/01/2023 Performed by (Sign & Date)

Checked By (Sign & Date)

S2 53 102 12023

Page2 of 2

Book No.:

SI No .:

RAW DATA SHEET 2041

405995

01250087 Booking date: 25 (01/2023 Artificial Tears Sample name: Analysis Started Date: 30 (o l (2023 Analysis Completion Date: 30 01 2023

Test Parameters ASSay

Test Method: GRAC 1978 - FR-DRP- A-079-00

Balance ID: NA

Due Date of Calibration: NA

Equipment/Instrument: NA

Due Date of Calibration: NA

Due Date of Calibration: 29 03 2023

Equipment/instrument: ARL | BLEQ | UV -002

Weight of the Sample:

Procedure: Pipetted out each of 2 ml of blank, standard, sample solution in to a test tube and then added 5 ml of reagent and mixed well.

kept at 105 degree for 30 mins.

After that, removed the tubes, cooled to Room temperature. measured the absorbance of the standard and sample preparation at 635 nm

Vr 30/01/2023

Performed by (Sign & Date)

Checked By (Sign & Date)

Page 1of 2

Calculation:

Assay in
$$\%$$
 = Sample Abs × Statusting × upp × Punity "cmc sodium" on as is basis in who standard Abs 100 50 100

= $(0.325 - 0.024)$ × 50.25 × 100 × 99 (0.326 - 0.024) 100 50 × 100

= 0.9917 × 100

Assay in
$$mg/ml = \frac{12}{100} \times LC$$

$$= \frac{99.17}{100} \times 10$$

$$= 9.92 mg/ml$$

Performed by (Sign & Date)

Checked By (Sign & Date)
Page2 of 2





Code : ARLBL/QA/SOP-218
Issue No. : 04
Effective Date : 13 | 0 | 1 | 20 | 20 |
Revision Date : 13 | 10 | 20 | 20 |

REVIEW REPORTS

OF

ANALYTICAL

APPENDIX I

ARLBL/QA/SOP-218/FR-01

Page: 1 of 2

CHECKLIST FOR VERIFICATION OF ANALYTICAL REPORT

A) DETAILS	OF SAMPLE		
Sample Name	Artificial Team	S	
Batch No.	PCM3 006	Date of start of Analysis	30/01/2023
Report No.		Date of Completion of Analysis	30/01/2023
B) DETAILS (DF VE BG202301250087		Observation

SI No	BG202301250087	Obs	bservatio		
SI. No.	Check points	Yes	No	NA	
1	Is the Analyst(s) performed all tests as per the specified Test Method / protocol	V			
2	Are all log entries made in respective equipment log books				
3	Are all entries made in respective Working / Reference Standards usage records	1			
4	Are all Equipment and/or instrument used in the testing are within calibration date				
5	Weight prints for each test is enclosed and are verified	1			
6	Are all calculations verified, found satisfactory		4		
7	All HPLC / LCMS / GC / GCMS / HPTLC Chromatograms and sequence enclosed are reviewed and found satisfactory			~	
8	UV-Vis / IR spectra , Automatic Potentiometric Titrator and TOC graph & data enclosed and found satisfactory	/			
9	ICP-OES / ICP-MS data enclosed and found satisfactory			V	
10	Records / registers / validity of all volumetric solutions are reviewed and found satisfactory			V	
11	Are the unit for results are mentioned in the COC & raw data sheet is matching				
12	Are all pages signed with date in the COC and Raw Data Sheets				
13	Are there any manual integration performed? If yes, provide reason below.			/	
14	Is any incident, deviation or OOS reporting done during the testing		V		
15	Are the respective audit trails checked?				
16	Is there any reprocessed / aborted analysis in audit trail?		/		
17	Are there any duplicate results?		~		
18	Are there any alterations of results?				
19	Are there any deletion of results				
20	Any other observations:		NO)	

Reviewed by / Date:

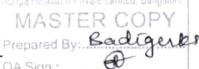
Filename: ARLBL_QA_SOP_218_Issue04

20/1/2023

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AURIGA RESEARCH PRIVATE LIMITED L'Auriga Resparch Private Limited, Bangatore.





Code		ARLBL/QA/SOP-218	
Issue No.	:	04	
Effective Date	1	13/04/2022	
Revision Date	1	13/04/2026	
	-		

Page: 2 of 2

REVIEW	OF	ANALYTICAL Prepared By: Badiger B
REPORTS		QA Sign.:

QUALITY ASSURANCE				
SI. No.	Chark points	Obs	erva	tion
31. NO.	Check points	Yes	No	NA
1	Is test parameters & Method of test mentioned in the COA complying with the TRF			
2	Is the Analyst(s) performed all tests as per specification	/		
3	Is the sample name and batch number entered correctly as mentioned in COC			
4	Weight prints for each test is enclosed and are verified			
5	Are all calculations verified, found satisfactory		-	
6	Are the unit for results are mentioned in the COA, COC & RDS is matching with specification	/	-	
7	Are all pages signed with date in the COC and Raw Data Sheets			
8	Is any incident, deviation or OOS reporting done during the testing			
9	Are the respective audit trails checked?			
10	Is there any reprocessed / aborted analysis in audit trail?			
11	Are there any duplicate results?		1	
12	Are there any alterations of results?		/	
13	Are there any deletion of results			
14	Is all test/s results complying to the release specification	1		

OBSERVATIONS

NA 08/03/2023	SI. No.	Observation No.	Details of observation by reviewer	Observed by sign. With date	Corrective	Action taken
ma 08/03/2023						
				tog 103/20	183	
				MA		

Conclusion: The Analytical Report is found satisfactory in all aspects of compliance.

Auriga Research Private Limited, Bangalore,

Verified by/ Date:

Filename: ARLBL_QA_SOP_218_Issue04

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Photometric Sample Table

[Summary]

File Information

Parameter File Name: UV\$2023\$JAN - Assay Sodium Filename: Artificial Tears.vphd UV\$2023\$JAN - 13-80-1 -

30-01-2023 18:58:53 Harish HS (Artificial Tears).vphm Carboxy methyl cellulose

Report File Name: Comments: UV\$2023\$JAN -

Date/Time: Analyst:

Instrument Information PDFPhotometric.vrpt

Instrument Type: Model (S/N): Instrument Name: UV-1900 Series ARL-BLEQ-UV-002 UV-1900i (A12535881051)

[Sample Table]

Software Information Software Name: LabSolutions UV-Vis

[Wavelengths]

[Measurement Parameters]

Print Date: 30-01-2023 18:59:20

Type of Measuring Mode:

Instrument Type: Instrument Name: Instrument Information ARL-BLEQ-UV-002 UV-1900 Series

UV-1900i (A12535881051)

Model (S/N):

Repeat: Acquiring Method: [Unknown Sample]

Light Source Switch Wavelength: 340.00 nm Accumulation Time (sec.): Slit Width: [Instrument] 1.0 nm

[Formula]

Measuring Method: Column Name: rounded:

Point (635.00nm)

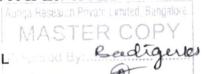
WL635.0

Absorbance

Measurement

Sam	1 Air Blank	2 Blank	3 Standard	4 Sample 01		5 Sample 02	5 Sample 02 6 Sample 03
Sample Name	A	В	0		В	В	
Sample ID	Air Blank	Blank Solution	Carboxy methyl cellulose Sodium		BG202301250087	BG202301250087 BG202301250088	BG202301250087 BG202301250088 BG202301250089
WL635.0	0.000	0.024	0.326		0.325	0.325	0.325 0.324 0.326

dazoloileaz





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: ARLBL/QA/SOP-218
: 04
: 13/04/2022
13/04/2022

REVIEW REPORTS

A)

OF ANALYTICAL

DETAILS OF SAMPLE

APPENDIX II

ARLBL/QA/SOP-218/FR-02

Page: 1 of 2

CHECKLIST FOR VERIFICATION OF MICROBIOLOGY REPORT

Sample	e Name	Artilicial	Tears						
Batch I	No.	Rim Took	Date of start of Analysis	2810	1120	23			
Report	No.		Date of Completion of Analysis	041	04/02/2023				
			•						
B) DET	AILS OF	RG202301250087			01		41		
SI. No.		BO	Check points			erva			
					Yes	No	NA		
1	Is the M	/	_						
2	Is the e								
3	Are all log entries made in respective equipment log books								
4	Weight				/				
5	Are Equ	ate	~						
6	Is the standard and/or sample preparation details entered correctly as per the method								
7	Is print of sterilization cycle enclosed in respective sterilization log book								
8	Is Plate observations made by microbiologists updated in RDS								
9	Are all p	positive and negative c	ontrols recorded for each parameter						
10	Is usage of media consumption recorded in respective media records								
11	Are all pages signed with date in the COC and Raw Data Sheets								
12	Are the unit for results are mentioned in the COC & raw data sheet is matching								
13	Any oth	er observations;	NA OBIETIERS						
							-		

Reviewed by / Date:

Auriga Research Private Limited, Bangalore,

Filename: ARLBL_QA_SOP_218_Issue04

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REVIEW REPORTS OF

ANALYTICAL

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QA Sign.:	D

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Code	:	ARL	BL/C	QA/SOP-218	
ssue No.	:	04			
Effective Date	1:	13	ley	2022	
Revision Date	:	13	lun	12025	

Page: 2 of 2

QUALITY ASSURANCE							
SI. No.	Check points		Observation				
SI. NO.			No	NA			
1	Is test parameters & Method of test mentioned in the COA complying with the TRF	/					
2	Is the Microbiologist(s) performed all tests as per the specified Test Method / protocol	/					
3	Is the sample name and batch number entered correctly as mentioned in COC						
4	Weight prints for each test is enclosed and are verified			/			
5	Are media used and media lot numbers recorded on the controlled RDS						
6	Are all calculations verified and found that there is no error	/					
7	Is all test/s results complying to the release specification						
8	Are all pages signed with date in the COC and Raw Data Sheets						
9	Are the unit for results are mentioned in the COA, COC & RDS is matching with the specification						
10	Is any incident, deviation or OOS reporting done during the testing		/				
11	Is all test results complying to the release specification						

OBSERVATIONS

SI. No.	Observation No.	Details of observation by reviewer	Observed by sign. With date	Corrective	Action taken
			NA toglosla	23	
ema	rks:				

Conclusion: The Microbiology Report is found satisfactory in all aspects of compliance.

Verified by/ Date:

Auriga Research Private Limited, Bangalore,

QA ISSUED

Filename: ARLBL_QA_SOP_218_Issue04

Sign: Date 2001 2023

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MICROBIAL LIMIT TEST OF NON-STERILE PRODUCTS AS PER USP / B.P / PH. EUR / IP AND/OR AS PER CLIENT SPECIFICATIONS

Auriga Research Private Limited, Bangalore
MASTER COPY
Prepared By: May
QA Sign,:

Code	:	ARLBL/MB/STP-013
ssue No.	:	07
Effective Date	:	22/03/2022
Revision Date		23 103 1000

APPENDIX I

ARLBL/MB/STP-013/FR-01

MICROBIAL LIMIT TEST REPORT

Page: 1 of 2

Sample Name	Artificial teas.	Analysis Started Date	28/01/2023
Report No.	B4202301250087	Analysis Completed Date	04/02/2023

SAMPLE PRE-ENRICHMENT (SOLUTION A):
10 -g/mL of sample dissolved in 90 mL of 3c0 M Lot No. Sc0 M - 15 01 20 23-001
1 swab → 10mL of N A Lot No N A
Dilutions can be prepared as per below flow chart A: SCDM-15 01 2023 - 0017
Solution A $(10^{-1})^{01 \text{ m}} \rightarrow 9 \text{ml } (10^{-2}) \rightarrow 9 \text{ml } (10^{-3}) \rightarrow 9 \text{ml } (10^{-4}) \rightarrow 9 \text{ml } (10^{-5}) \rightarrow 9 \text{ml } (10^{-$
Weight Print(s):
\sim_{N_A}
NA \$28/01/2013
SAMPLE PRE-ENRICHMENT (SOLUTION B):
mL of solution A added to mL of SCDM (Solution B);
Lot No. SCDM- Incubate at 30-35°C for 18 – 24 brs / 48 – 72 brs

Filename: ARLBL_MB_STP_013_Issue07

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MICROBIAL LIMIT TEST OF NON-STERILE PRODUCTS AS PER USP / B.P / PH. EUR / IP AND/OR AS PER CLIENT SPECIFICATIONS

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Code ARLBL/MB/STP-013 Issue No. Effective Date 22/03/2022 Revision Date 22/03/2025

Page: 2 of 2

SAMPLE PRE-ENRICHMENT (SOLUTION C): of sample dissolved in mL of SCDM (Solution C), Lot No. SCDM-Incubate at 30-35°C for 18 - 24 hrs. Weight Print(s):

Equipment / Instrument	Equipment / Instrument ID	Calibration Due Date	
Weighing Balance	ARL/BLEQ/AWB— -	NA	
BOD Incubator (20-25°C)	ARL/BLEQ/BOD— 001	01/11/2023	
BIC Incubator (30-35°C)	ARL/BLEQ/BIC- 00/	01/11/2023	
BIC Incubator (30-35°C)	ARL/BLEQ/BIC—		
BIC Incubator (42-44°C)	ARL/BLEQ/BIC-	n/a	
BIC Incubator (37°C)	ARL/BLEQ/BIC—	ULM onloct 2023	
Water Bath (80°C)	ARL/BLEQ/WB-	04/02/2023	

04/03/2013

Analysed By / Date:

Checked By / Date: Oslo212013

Filename: ARLBL_MB_STP_013_Issued7e3earch Private Limited, Bangalos

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Auriga Research Private Limited, Bangalore.
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Prepared By: Man
QA Sign :

Code	1:	ARLBL/MB/STP-013
ssue No.	:	07
Effective Date	1:	22/03/2022
Revision Date		02/02/2025

APPENDIX IV

ARLBL/MB/STP-013/FR-04

TAMC/TBC BY POUR PLATE METHOD

Report No.	BG202301250087	Analysis Started Date	28/01/2023
Culture ID	ATCL 6633	Analysis Completed Date	02/02/2023

PROCEDURE: ______mL of Solution A and each diluent prepared as per flow chart A pipetted into two Petri dishes. Pour 15–20mL of SCDA into Petri dishes in duplicates from each dilution; Lot No. SCDA- &8 | 01 | 20 &3 - 00 0 1 and incubate at 30-35°C for 3-5 days.

FORMULA:

TAMC/TBC → Average No. of colonies obtained x Dilution factor

Calculation for TAMC/Bacteria:

Dilution factor	Plate 1	Plate 2	Average
10-1	Nil	Nil	Nil
10-2	Nil	Nil	Nil
	NA	\$	
		28/01/201	

Negative Control: Growth Observed / Not observed

Positive control: Growth Observed / Not observed

Result: TAMC/TBC _____ cfu /g /mL /swab

Conclusion: The Sample Complies / Does not comply / Not Applicable for TAMC/TBC.

മ_രച്ചിരച്ചിരമാ Analysed By / Date:

Checked By / Date:

05/02/2023

Filename: ARLBL_MB_STP_013_Issue07



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Prepared I	By: Maga
QA Sign	⊕

Code	1:	ARLBL/MB/STP-013
Issue No.	:	07
Effective Date	:	22/03/2022
Revision Date	:	22/02/2020

APPENDIX V

ARLBL/MB/STP-013/FR-05

TYMC BY POUR PLATE METHOD

Report No.	B4202301250087	Analysis Started Date	28/01/2083
Culture ID	ATCG 1663310231	Analysis Completed Date	04/02/2023
	2801.023		

PROCEDURE: ____mL of Solution A and each diluent prepared as per flow chart A pipetted into two Petri dishes in duplicates. Pour 15–20mL of SDCA into Petri dishes in duplicates from each dilution; Lot No. _SDCA- && 0 1 2033 - 000 & ___ and incubate at 20-25°c for 5-7 days.

FORMULA:

TYMC — Average No. of colonies obtained x Dilution factor

Calculation for Yeast and Mold:

Dilution factor	Plate 1	Plate 2	Average
10-1	Nil	Nil	NII
10-2	lin	Nil	Nil
		N	
	NA	+	
	2	16M 14/0212023	

Negative Control: Growth Observed / Not observed

Positive control: Growth Observed / Net observed

Result: TYMC _____ cfu /g /mL /swab

Conclusion: The Sample Complies / Does not comply / Not Applicable for TYMC.

Analysed By / Date: 04/02/1023

Checked By / Date:

05/02/2023

Filename: ARLBL_MB_STP_013_IssueQTriga Research Private Limited, Earlyande.

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STERILITY TESTING FINISHED PRODUCT AND RAW MATERIALS



Code	: ARLBL/MB/STP-004			
Issue No.		08		
Effective Date	1	12/11/2021		
Revision Date	;	12/11/2024		

APPENDIX I

ARLBL/MB/STP-004/FR-01

STERILITY REPORT - MEMBRANE FILTERATION METHOD

at the Tankad	
No. of containers Tested	OTNOS
	road
	Amount of sample used

TEST FOR BACTERIA	TEST FOR FUNGI
	Soya bean Casein Digest Medium Lot no.: \$\(\sigma_{\sigma_1} \) \(\sigma_2 \) \(\sigma_2 \) \(\sigma_3 \) \(-0.017 \)
Incubate at 30-35°C; ARL/BLEQ/BIC- 39 S for 14 days	Incubate at 20-25°C; ARL/BLEQ/BOD- any for 14 days

11100	Date de do	,							
Day	Date	Test Sample	Positive Control	Negative Control	Test Sample	Positive Control	Negative Control	Sign	Remarks
1 st	Hodros	-ve	tre	-ve	-ve	410	-ve	17hortens	2/4
2 nd	Esosper	-16	tue	-00	- ٧ ૯	tre	~ve	12/03/903	ok
3 rd	19loslesz	-ve	tre	-10	-ve	tre	-ve	19/2/1013	Ok
4 th	20/02/2023	~ve	tue	-ve	-ve	tre	-ve	20/02/1013	
5 th	esoficial	~ve	tue	-10	-ve	tuc	-ve	21/07/1013	
6 th	51/07/2012	-ve	tue	-ve	-ve	tre	-ve	Thollow	oh
7 th	Edinger	-ve	tre	-ve	-ve	tre	-ve	23/24/1013	ah
8 th	24/02/2013	-ve	tve	-ve	-ve	tre	-ve	morton	Oh
9 th	72/03/1013	-ve	tre	-ve	-ve	tre	-ve	Troubors	sh
10 th	30/2/2013	-ve	tre	-ve	-ve	tre	-ve	Totozivas	di
11 th	eraskolt &	-ve	tre	~e	ve	tre	-ve	37/03/302	
12 th	walrolse	-16	tre	-ve	-ve	tre	-ve	28/05/2023	sk
13 th	cipalsors	-ve	tre	-Ve	-ve	tre	-Ve	ElalEolio	
14 th	Esalesico	-ve	tre	-ve	-ve	tre	-ve	203/201	A CONTRACTOR OF THE PARTY OF TH

The sample complies / does not complies as per IP / BP / USP / EP / IHS / ISO 11737 -2 / Client Specifications.

Analysed by / Date:

Checked by / Date:

Filename: ARLBL_MB_STP_004_Issue08 Auriga Research Private Limited, Bangalorc.

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Auriga Research Private Limited

Govt. Approved Test House



No. 136, 6th Cross, 2nd Stage, Yeshwanthpur Industrial Suburb, Bangalore - 560 022 Ph. : +91- 080-35229344

Email: admin@aurigaresearch.com, Website: www.aurigaresearch.com

Certificate of Analysis

Information by Customer

Report No. : BG202301250095

Sample

ARTIFICIAL TEARS

Mfg. By

GLOBAL PHARMA HEALTHCARE PVT. LTD.

Supplied By

GLOBAL PHARMA HEALTHCARE PVT. LTD.

Mfg lic. No. : NS

Ref. No.

Address

Submitted By : GLOBAL PHARMA HEALTHCARE PVT. LTD.

: NEW NO. 2A, 3RD FLOOR GANGA NAGAR 4TH STREET KODAMBAKKAM, CHENNAI, TAMILNADU- 600024

Batch Size

Sample Quantity

Batch No

Mfg. Date

Expiry Date

PCMJ013

APR 2022

MAR 2025

204 Ltr

12 Bottles

Sample ID: BG202301250095

Received On:

25/01/2023

Date of start of analysis: 28/01/2023

Date of completion of analysis: 02/03/2023

Reference to protocol

:- GPHC/SPEC-FP-DRP-A-079-00

Sample not drawn by laboratory.

Description

:- Clear colourless slightly viscous solution

- <parameters></parameters>	<results></results>	<unit></unit>	<req.></req.>	<claim></claim>	<lloq></lloq>	<lower limit=""></lower>	<upper limit></upper 	<method></method>
Content of sodium Carbo	oxy methyl cellulose :							
Assay in %	: 97.96	%	90.00 % to 110.00 %					GPHC/STP-FP-DRP -A-079-00
Assay in mg/ml	: 9.80	mg/ml	9.00 mg/ml and 11.00 mg/ml	d 10.0 mg/ml	_	-	-	GPHC/STP-FP-DRP -A-079-00
Total Yeast & Mould count.	: <10 cfu/ml	-	-		-	-	-	USP <61>
Total aerobic microbial count.	: <10 cfu/ml	-	-		-	-	-	USP <61>
Sterility	: Complies	-	-		-	-	-	USP <75>
			End of Papart					

End of Report

Report: In the opinion of the undersigned, the sample referred to above is of standard quality as defined in the Act and the rules made thereunder for the reason given below:- of



To verify Report Scan this Code.

*Terms & Conditions:
(1) Total liability of this laboratory is limited to the invoice amount.

(2) The results listed refer only to the tested sample and applicable parameter. Endorsement of products is neither inferred nor implied.

(3) This report is not to be reproduced wholly or in part and cannot be used as evidence in the court of Law and should not be used in any advertising media

without our special Permission on writing.

(4) When the report is without NABL symbol & ULR, it implies that these products & tests are not covered under NABL accredited scope.

Authorized Signatory

A08/03/2023

COC Employee Wise Report



<Contents of>

4 Sterility

complies



Report Discard After 3 Years

<Req.> <LLOQ/LOD> <Lower L> <Upper L> <Method> NABL

USP <75>

Employee Name	sookta	Depa	artment Name MICRO BIOL	OGY
Product Name	: ARTIFICIAL TEARS		Report No. : BG	202301250095
Client Ref.No	: NS		Received On : 25/	01/2023
			Estimated Time: 5	Day
Batch No	Manufacture Date	Expiry date	Batch Size	Sample Quantity
PCMJ013	APR 2022	MAR 2025	204 Ltr	12 Bottle
Analysis Departme	nt MICRO BIOLOGY, PHARI	MA CHEMICAL	(10022
Analyst &	13/1023		Checked 8	Authorised By
Date of start of ana	lysis 16/02/2023		Date of end	of analysis
Reference To Proto	ence To Protocol GPHC/SPEC-FP-DRP-A-079-00			02/03/2023
Label	NA			
		Sample not drawn by la	aboratory.	

Unit

NA



STERILITY TESTING FINISHED PRODUCT AND RAW MATERIALS



Code	1	ARLBL/MB/STP-004		
Issue No.	:	08		
Effective Date	:	12/11/2021		
Revision Date		12/11/2024		

APPENDIX I

ARLBL/MB/STP-004/FR-01

STERILITY REPORT - MEMBRANE FILTERATION METHOD

Product	Antificial te	are		Sample Quantity	2001 90
Report No.	29002110CSQS	Batch No.	Pcen 2013	No. of containers Tested	2001 FC
Test started on	16/02/2013	Test completed on	02/03/2023	Amount of sample used	low

TEST FOR BACTERIA	TEST FOR FUNGI
	Soya bean Casein Digest Medium Lot no.: Scom-13/02/2023 -0017
Incubate at 30-35°C: ARL/BLEQ/BIC-Qas for 14 days	Incubate at 20-25°C; ARL/BLEQ/BOD- any for 14 days

	bato at es e								
Day	Date	Test Sample	Positive Control	Negative Control	Test Sample	Positive Control	Negative Control	Sign	Remarks
1 st	1 Hostsons	-ve	+16	-ve	-ve	tue	-ve	1462/1017	ok
2 nd	18/02/2013	-46	tue	-16	-16	tre	-10	13/02/3023	sk
3 rd	18/02/2013	-ve	tue	-ve	-10	tre	-ve	19/24/1017	Ole
4 th	Salson	-ve	tve	-ve	-ve	tre	-ve	عامدان	ok
5 th	2/02/202	-10	tve	-ve	-ve	tre	-16	21/2/1013	oh
6 th	27/07/202	-10	tre	-ve	~~	tre	-ve	2262/201	3 Ole
7 th	Eagleoks	-10	tre	-ve	-ve	tue	-ve	12/02/013	oh
8 th	24/02/2017	-16	tre	-10	-ve	tre	-ve	Thousand	ak
9 th	Excless 2	-ve	tue	-ve	-ve	tre	-ve	1562/101-	s ok
O th	26/29/2013	-ve	tve	Ne	-ve	tre	-ve	Todas	
1 th	2402/2017	-16	tue	-Ve	-ve	tre	-ve	31/03/3038	gh
2 th	2402/2013	-ve	tre	-ve	-ve	tre	-ve	18 to 3 box	gh
3 th	0/102/2012	-ve	tre	-ve	-ve	tre	Ve	201/20/10	s Oh
4 th	01/02/5012	-10	tue	Ne	-ve	tre	-ve	ortostos	. Ok

The sample complies / does not complies as per IP / BP / USP / EP / IHS / ISO 11737 -2 / Client Specifications.

Checked by / Date:

Filename: ARLBL_MB_STP_004_Issue08

Auriga Research Private Limited, Bangalore

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Page 17 of 19

RAW DATA SHEET

2038 ook No.:

SI No .:

405354

Report No.: D202301250095 Booking date: 25 loi 2023

Sample name: Artificial Tears

Analysis Started Date: 31 loi 2023

Analysis Completion Date: 31 loi 2023

Test Parameters Assay

Test Method: GPHC ISTP - FP - DRP - A - 079 -00

Balance ID: ARLIBLED AWB -012

Equipment/Instrument: ARL (BLED UV -002

Equipment/instrument: NA

Due Date of Calibration: 05 02 2023

Due Date of Calibration: 29 (03 (2023

Due Date of Calibration: NA

Weight of the Sample:

Working mode Diphenyl amine Weighing Date 31.01.2023
Time 8:52:01
Balance S/N 668671

1.25047 9 1.25037 9

0.0001U g Date

31.01.2023

Pz 31/01/2023

Signature

802/02/2013

Mame

Diphenyl amine

Glacial autic acid

Hydrochlonic acid

B.NO

120418

7393941022

3801021C

make

central drug house

analigens

carlo erba

Reagent Preparation: Dissolved 1.25087 g of Diphenyl amine reagent in so m of Glacial acetic acid and then added so m of conc. Hydrochloric acid.

Performed by (Sign & Date)

Checked By (Sign & Date)

Page 1of 2

Calculation:

Working mode Carboxy methyl Weighing Date cellulose godium 31.01.2023
Time 9:22:34
Balance S/N 688671

Instrument Id:ARL/BLEQ/AWB-012

50.27 mg 50.13 mg

Date Time 31.01.2023 9:24:17

Pz 31/01/2023

Signature

\$10×10×1013

Standard Details:

Name: Carboxy methyl cellulose soddum

B.NO : GPLW8/079/21

valid upto : 12/10/2023

standard Preparation: weighted so 13 mg of carboxy methyl cellulose sodium was into a 100 ml volumetric Hasks, adoled water. Slowly with swirling and then made to volume with water. mixed well.

sample Preparation: Pipetted out 5 ml of sample into a wom! volumetric flash, added no ml of water

Result: Procedure continued in 31-NO: 406143

P2 3/10/2023

Performed by (Sign & Date)

Checked By (Sign & Date)

Page2 of 2

Book No.:

SI No .:

RAW DATA SHEET

2042

406148

DC202301250095 Report No.:

Booking date: 25/01/2023

Sample name:

Artificial Tears

31/01/2023 Analysis Started Date:

Analysis Completion Date: 31 01 2023

Test Parameters

ASSay

Test Method: GIPHC 18TP-FP-DRP-A-079-00

Balance ID:

NA

Due Date of Calibration: MA

Equipment/Instrument: NA

Due Date of Calibration: NA

Equipment/instrument: ARL\BLEQ\UV -002

Due Date of Calibration: 29 (08 2023

Weight of the Sample:

Procedure: Pipetted out each of 2 ml of blank, standard, sample solution in to a test tube and then added 5 ml of reagent and mixed well.

kept at 105 degree for 30 mins.

After that, removed the tubes, cooled to Room temperature.

measured the absorbance of the standard and sample preparation at 635 nm

Pr 31/01/2023 Performed by (Sign & Date)

Checked By (Sign & Date)

Page 1of 2

Calculation:

Assay in
$$-1$$
 = $\frac{8 \text{ ample Abs}}{8 \text{ standard Abs}} \times \frac{8 \text{ std}}{100} \times \frac{100}{50} \times \frac{\text{Purity "cmc sodium" on as is basis in w/w}}{100}$

$$= \frac{(0.326 - 0.023)}{(0.330 - 0.023)} \times \frac{50.13}{100} \times \frac{100}{50} \times \frac{99}{100}$$

$$= 0.9796 \times 100$$

$$= 97.96 \times 100$$

Assay in
$$mg/ml = \frac{7}{100} \times L.C$$

$$= \frac{97.96}{100} \times 10$$

$$= 9.80 \text{ mg/ml}$$

ANALYTICAL

OF

REVIEW REPORTS





	-	Migra (
Code	1:	ARLBL/QA/SOP-218
ssue No.	:	04
ffective Date	1	13/04/2022
Revision Date	:	13/04/2025

APPENDIX I

ARLBL/QA/SOP-218/FR-01

Page: 1 of 2

CHECKLIST FOR VERIFICATION OF ANALYTICAL REPORT

	OF SAMPLE		
Sample Name	Artificial +	-6 00 Kg	
Batch No.	BW31213	Date of start of Analysis	31/01/2023
Report No.		Date of Completion of Analysis	31/01/2023

	BG202301250095 Check points				
SI. No.	. Check points				
1	Is the Analyst(s) performed all tests as per the specified Test Method / protocol	~			
2	Are all log entries made in respective equipment log books				
3	Are all entries made in respective Working / Reference Standards usage records				
4	Are all Equipment and/or instrument used in the testing are within calibration date				
5	Weight prints for each test is enclosed and are verified	_			
6	Are all calculations verified, found satisfactory	/			
7	All HPLC / LCMS / GC / GCMS / HPTLC Chromatograms and sequence enclosed are reviewed and found satisfactory			/	
8	UV-Vis / IR spectra , Automatic Potentiometric Titrator and TOC graph & data enclosed and found satisfactory				
9	ICP-OES / ICP-MS data enclosed and found satisfactory			V	
10	Records / registers / validity of all volumetric solutions are reviewed and found satisfactory		,	V	
11	Are the unit for results are mentioned in the COC & raw data sheet is matching				
12	Are all pages signed with date in the COC and Raw Data Sheets	-			
13	Are there any manual integration performed? If yes, provide reason below.			~	
14	Is any incident, deviation or OOS reporting done during the testing			,	
15	Are the respective audit trails checked?				
16	Is there any reprocessed / aborted analysis in audit trail?				
17	Are there any duplicate results?				
18	Are there any alterations of results?				
19	Are there any deletion of results		/		
20	Any other observations:		00		
	Auriga Research Drivets Links La				

Reviewed by / Date:

Filename: ARLBL_QA_SOP_218_Issue04

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	-	
Code	1:	ARLBL/QA/SOP-218
ssue No.	:	04
Effective Date	:	13/04/2022
Revision Date	:	13/04/2026

Page: 2 of 2

REVIEW OF ANALYTICAL Prepared By: QA Sign.: QA Sign.:

	QUALITY ASSURANCE					
SI No.						
SI. No. Check points						
1	Is test parameters & Method of test mentioned in the COA complying with the TRF	1				
2	Is the Analyst(s) performed all tests as per specification	/				
3	Is the sample name and batch number entered correctly as mentioned in COC	/				
4	Weight prints for each test is enclosed and are verified					
5	Are all calculations verified, found satisfactory					
6	Are the unit for results are mentioned in the COA, COC & RDS is matching with specification	/				
7	Are all pages signed with date in the COC and Raw Data Sheets					
8	Is any incident, deviation or OOS reporting done during the testing		/			
9	Are the respective audit trails checked?		/			
10	Is there any reprocessed / aborted analysis in audit trail?					
- 11	Are there any duplicate results?					
12	Are there any alterations of results?		/			
13	Are there any deletion of results		/			
14	Is all test/s results complying to the release specification	/				

OBSERVATIONS

SI. No.	Observation No.	Details of observation by reviewer	Observed by sign. With date	Corrective Action taken
			VA 08/03/2023	
			VA	
Rema	ırks:			

Conclusion: The Analytical Report is found satisfactory in all aspects of compliance.

Verified by/ Date:

Auriga Research Private Limited, Bangalore,

Filename: ARLBL_QA_SOP_218_Issue04

Sign: Date 25 or 20 23

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Photometric Sample Table

[Summary]

Filename: File Information Assay sodium carboxy methyl UV\$2023\$JAN - 13-82-1 -

Parameter File Name: UV\$2023\$JAN - Assay Sodium cellulose(Artificial tears).vphd

31-01-2023 14:52:36 Harish HS (Artificial Tears).vphm Carboxy methyl cellulose

Report File Name: Comments: UV\$2023\$JAN -PDFPhotometric.vrpt

Date/Time: Analyst:

Instrument Type: Instrument Name: Instrument Information UV-1900 Series ARL-BLEQ-UV-002

> Software Name: Software Information LabSolutions UV-Vis

Version:

UV-1900 Series

Instrument Type: Model (S/N):

Instrument Name:

Instrument Information UV-1900i (A12535881051) ARL-BLEQ-UV-002

[Unknown Sample]

Repeat: Acquiring Method:

Slit Width: [Instrument] 1.0 nm

Accumulation Time (sec.):

[Measurement Parameters]

Print Date: 31-01-2023 14:53:18

[Wavelengths] Type of Measuring Mode:

Absorbance

rounded: Measuring Method: Column Name: WL635.0 Point (635.00nm)

[Formula]

Measurement

Light Source Switch Wavelength: 340.00 nm

[Sample Table]

	Sample Name	Sample ID	WL635.0
_	Air Blank	Air Blank	0.000
2	Blank	Blank solution	0.023
ω	Standard	Carboxy methyl cellulose sodium	0.330
4	Sample 01	BG202301250095	0.326
Sī	Sample 02	BG202301250101	0.328
6	Sample 03	BG202301250103	0.328
7	Sample 04	BG202301250104	0.328
8	Sample 05	BG202301250105	0.327
9	Sample 06	BG202301250106	0.330

A 3/10/2023

40/00/00x





: ARLBL/QA/SOP-218
: 04
: 13/04/2022
13/04/2022

REVIEW REPORTS

DETAILS OF SAMPLE

OF ANALYTICAL

APPENDIX II

ARLBL/QA/SOP-218/FR-02

Page: 1 of 2

CHECKLIST FOR VERIFICATION OF MICROBIOLOGY REPORT

Sample Name		Artilicial ?	ieary							
Batch I	No.	8m3013	Date of start of Analysis	28	01/208	23				
Report No.							4/02/2023			
B) DETAILS OF VE										
SI. No.	Check points				Observation Yes No NA					
			162	NO	IVA					
1	Is the M protocol		/							
2	Is the equipment, Media, culture details mentioned as per the method									
3	Are all log entries made in respective equipment log books									
4	Weight				~					
5	Are Equipment and/or instrument used in the testing are within calibration date									
6	Is the standard and/or sample preparation details entered correctly as per the method									
7	Is print of sterilization cycle enclosed in respective sterilization log book									
8	Is Plate observations made by microbiologists updated in RDS									
9	Are all positive and negative controls recorded for each parameter									
10	Is usage of media consumption recorded in respective media records									
11	Are all pages signed with date in the COC and Raw Data Sheets				~					
12	Are the	unit for results are mentio	ned in the COC & raw data sheet is matchi	ng	~					
13	Any other observations:									
	_									
			NA OSTONIANS							

Reviewed by / Date:

Filename: ARLBL_QA_SOP_218_Issue04

Auriga Research Private Limited, Bangalore,

QA ISSUED

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REVIEW REPORTS OF

ANALYTICAL

Acrigo Research Private Limited, Bangalore	
MASTER COPY	
Prepared By: Radigertes	
Prepared By: Radigark	

7	1					
Code	1:	ARLBL/QA/SOP-218				
ssue No.	:	04				
Effective Date	:	13	104	12022		
Revision Date	:	13	lun	12025		

Page: 2 of 2

	QUALITY ASSURANCE	1				
SI. No.	Check points					
SI. NO.	Check points	Yes	No	NA		
1	Is test parameters & Method of test mentioned in the COA complying with the TRF	1				
2	Is the Microbiologist(s) performed all tests as per the specified Test Method / protocol					
3	Is the sample name and batch number entered correctly as mentioned in COC	/				
4	Weight prints for each test is enclosed and are verified			/		
5	Are media used and media lot numbers recorded on the controlled RDS					
6	Are all calculations verified and found that there is no error					
7	Is all test/s results complying to the release specification					
8	Are all pages signed with date in the COC and Raw Data Sheets					
9	Are the unit for results are mentioned in the COA, COC & RDS is matching with the specification					
10	Is any incident, deviation or OOS reporting done during the testing		/			
11	Is all test results complying to the release specification					

OBSERVATIONS

H ₀₈ 03 2083	SI. No.	Observation No.	Details of observation by reviewer	Observed by sign. With date	Corrective Action taken
	,				
				A08/03/2083	
				MA	
Remarks:	Rema	rks:			
	Con				

Conclusion: The Microbiology Report is found satisfactory in all aspects of compliance.

Verified by/ Date:

QA ISSUED

Auriga Research Private Limited, Bangalore,

Filename: ARLBL_QA_SOP_218_Issue04 Sign:...

Date 25 loipons

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MICROBIAL LIMIT TEST OF NON-STERILE PRODUCTS AS PER USP / B.P / PH. EUR / IP AND/OR AS PER CLIENT SPECIFICATIONS

Auriga Research Pri	vate Limited, Bangalore.
	RCOPY
Prepared By:	M241-
QA Sign	@

Code	1:	ARLBL/MB/STP-013
ssue No.	:	07
Effective Date	:	22/03/2022
Revision Date	:	22/03/2026

APPENDIX I

ARLBL/MB/STP-013/FR-01

MICROBIAL LIMIT TEST REPORT

Page: 1 of 2

Sample Name	Artifical tears	Analysis Started Date	28/01/2023
Report No.	B4202301250095	Analysis Completed Date	011/02/2023
**************************************		1 OFW	100 H 102/2023

				091		
SAMPLE PRE-EN	IRICHMENT (S	OLUTION A):				
10 g/mL of	sample dissolve	ed in <u>90</u> mL	of SCOM L	ot No. SLDM -	15/01/2023-0	014
1 swab	10mL of	NA	Lot No	NA		
Dilutions can be p	prepared as pe	r below flow cha	art A: SCUM	- 15/01/2023	1-001+	
Solution A (1	0^{-1}) $\xrightarrow{\text{DIM}}$ 9ml	(10 ⁻²) → 9m l (10³) → 9ml(1	10 ⁴) → 9ml (10 ⁻⁵) → 9ml	(10-6
Weight Print(s):						
		NA				
		28/	01/2023			
			12023			
SAMPLE PRE-ENF		LUTION B):				
	mL of s	colution A added	d to	ml of SCRM	(Solution R)	

Auriga Research Private Limited, Bangalore.

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Lot No. SCDM-

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_____. Incubate at 30-35°C for 18 – 24 hrs / 48 – 72 hrs.



MICROBIAL LIMIT TEST OF NON-STERILE PRODUCTS AS PER USP / B.P / PH. EUR / IP AND/OR AS PER CLIENT SPECIFICATIONS

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Code		ARLBL/MB/STP-013
Issue No.	:	07
Effective Date	:	22/03/2012
Revision Date	1:	22/03/2028

Page: 2 of 2

SAMPLE PRE-ENRICHMENT (SOLUTION C):

	of	sample	dissolved	in		mL	of	SCDM	(Solution	C),
Lot No. SCDM-				Inc	ubate at 30-	35°C	for 1	18 – 24 h	rs.	
Weight Print(s):		NA								
		3	8/0.1							
			8/01/2023							

Equipment / Instrument	Equipment / Instrument ID	Calibration Due Date
Weighing Balance	ARL/BLEQ/AWB— -	NA
BOD Incubator (20-25°C)	ARL/BLEQ/BOD— 00)	01/11/2023
BIC Incubator (30-35°C)	ARL/BLEQ/BIC- 001	01/11/2023
BIC Incubator (30-35°C)	ARL/BLEQ/BIC—	1
BIC Incubator (42-44°C)	ARL/BLEQ/BIC—	NA
BIC Incubator (37°C)	ARL/BLEQ/BIC—	IKM enlesses
Water Bath (80°C)	ARL/BLEQ/WB—	04/01/0033

oh/03/2023

Analysed By / Date:

Checked By / Date:

Filename: ARLBL_MB_STP_013_Issue07_Auriga Research Private Limited, Bangalo

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Sign: Date: 12 010013

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MICROBIAL LIMIT TEST OF NON-STERILE PRODUCTS AS PER USP / B.P / PH. EUR / IP AND/OR AS PER CLIENT SPECIFICATIONS



Code	:	ARLBL/MB/STP-013
Issue No.	:	07
Effective Date	1:	22/03/2022
Revision Date	:	22/03/2025

APPENDIX IV

ARLBL/MB/STP-013/FR-04

TAMC/TBC BY POUR PLATE METHOD

Report No.	B4202301250095	Analysis Started Date	28/01/2023
Culture ID	ATCC 6633	Analysis Completed Date	02/01/2023

FORMULA:

TAMC/TBC — Average No. of colonies obtained x Dilution factor

Calculation for TAMC/Bacteria:

Dilution factor	Plate 1	Plate 2	Average
10-1	Nil	Nil	Nil
10-2	Nil	Nil	Nil
	N		
	, ,	8	
		02/02/2023	

Negative Control: Growth Observed / Not observed

Positive control: Growth Observed / Not observed

Result: TAMC/TBC _____cfu /g /mL /swab

Conclusion: The Sample Complies / Does not comply / Not Applicable for TAMC/TBC.

Analysed By / Date:

Checked By / Date:

O5/02/2623

Filename: ARLBL_MB_STP_013_Issue07Auriga Research Private Limited, Hangalon COMPANY CONFIDENTIAL
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Sign: Date: 28 01 2023



MICROBIAL LIMIT TEST OF NON-STERILE PRODUCTS AS PER USP / B.P / PH. EUR / IP AND/OR AS PER CLIENT SPECIFICATIONS

Auriga Rese	earch Private I	Limited, Ba	ngalore.
MA:	STER	COL	PY
Prepare	d By: M	94	
QA Sign		9	

Code	1:	ARLBL/MB/STP-013
Issue No.	:	07
Effective Date	1:	22/03/2022
Revision Date	:	22/03/2025

APPENDIX V

ARLBL/MB/STP-013/FR-05

TYMC BY POUR PLATE METHOD

Report No.	202301950095	Analysis Started Date	28/01/2023	The same of
Culture ID	ATCC 10231	Analysis Completed Date	04/02/2023	A

PROCEDURE: ___01 _mL of Solution A and each diluent prepared as per flow chart A pipetted into two Petri dishes in duplicates. Pour 15–20mL of SDCA into Petri dishes in duplicates from each dilution; Lot No. _SDCA- _ 28 | 01 | 20 23 - 000 2 _ and incubate at 20-25°c for 5-7 days.

FORMULA:

TYMC ----- Average No. of colonies obtained x Dilution factor

Calculation for Yeast and Mold:

Plate 1	Plate 2	Average
Nil	Nil	NII
NII	Nil	Nil
	NA	
	1/102/2023	
	NII	Nil Nil

Negative Control: Growth Observed / Not observed

Positive control: Growth Observed / Not observed

Result: TYMC _____ cfu /g /mL /swab

Conclusion: The Sample Complies / Does not comply / Not Applicable for TYMC.

For Unio213017

Analysed By / Date: Checked By / Date:

Checked By / Date: O5/b2/2023

Filename: ARLBL_MB_STP_013_Issue07

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Auriga Research Private Limited

Govt. Approved Test House



No. 136, 6th Cross, 2nd Stage, Yeshwanthpur Industrial Suburb, Bangalore - 560 022 Ph.: +91- 080-35229344

Email: admin@aurigaresearch.com, Website: www.aurigaresearch.com

Certificate of Analysis

Information by Customer

Report No. : BG202301250101

Sample

ARTIFICIAL TEARS

Mfg. By

GLOBAL PHARMA HEALTHCARE PVT. LTD.

Supplied By

GLOBAL PHARMA HEALTHCARE PVT. LTD.

Mfg lic. No. : NS

Ref. No.

Submitted By : GLOBAL PHARMA HEALTHCARE PVT. LTD.

: NS

Address

: NEW NO. 2A, 3RD FLOOR GANGA NAGAR 4TH STREET KODAMBAKKAM, CHENNAI, TAMILNADU- 600024

Sample Quantity

Batch No PCMJ014 Mfg. Date

Expiry Date

Batch Size

APR 2022

MAR 2025

204 Ltr

12 Bottles

Sample ID: BG202301250101

Received On:

25/01/2023

Date of start of analysis: 28/01/2023

Date of completion of analysis: 02/03/2023

Reference to protocol

:- GPHC/SPEC-FP-DRP-A-079-00

Sample not drawn by laboratory.

Description

:- Clear colourless slightly viscous solution

- <parameters></parameters>	<results></results>	<unit></unit>	<req.></req.>	<claim></claim>	<lloq></lloq>	<lower limit=""></lower>	<upper limit></upper 	<method></method>
Content of sodium Carbo	oxy methyl cellulose :							
Assay in %	: 98.61	%	90.00 % to 110.00 %		e 5		į į	GPHC/STP-FP-DRP -A-079-00
Assay in mg/ml	: 9.86	mg/ml	9.00 mg/ml and 11.00 mg/ml	d 10.0 mg/ml	-	-	-	GPHC/STP-FP-DRP -A-079-00
Total Yeast & Mould count.	: <10 cfu/ml		-		-		-	USP <61>
Total aerobic microbial count.	; <10 cfu/ml	-	-		-	-	-	USP <61>
Sterility	: Complies	-	•		-	-	-	USP <75>
			End of Report					

Report: In the opinion of the undersigned, the sample referred to above is of standard quality as defined in the Act and the rules made thereunder for the reason given below:- of



To verify Report Scan this Code.

(1) Total liability of this laboratory is limited to the invoice amount.
(2) The results listed refer only to the tested sample and applicable parameter. Endorsement of products is neither inferred nor implied.

(4) When the report is without NABL symbol & ULR, it implies that these products & tests are not covered under NABL accredited scope.

(3) This report is not to be reproduced wholly or in part and cannot be used as evidence in the court of Law and should not be used in any advertising media without our special Permission on writing.

408/03/2023 Suatrics **Authorized Signatory**

TESTING STERILITY FINISHED PRODUCT AND RAW **MATERIALS**



Code	: ARLBL/MB/STP-004
Issue No.	: 08
Effective Date	: 12/11/2021
Revision Date	: 12/11/2024

APPENDIX I

ARLBL/MB/STP-004/FR-01

STERILITY REPORT - MEMBRANE FILTERATION METHOD

Product	Low filer	tears		Sample Quantity	2001 PO
Report No.	1010 26 10 62 0101	Batch No.	panzory	No. of containers Tested	07 NO8
Test started on	16/05/3013	Test completed on	02/03/2013	Amount of sample used	road

TEST FOR BACTERIA	TEST FOR FUNGI				
Fluid Thioglycollate Medium	Soya bean Casein Digest Medium Lot no.: Scam - 13/01/2023 - 0017				
Incubate at 30-35°C; ARL/BLEQ/BIC-AS for 14 days	Incubate at 20-25°C; ARL/BLEQ/BOD- ooy for 14 days				

11104	loabato at so so si i i i i i i i i i i i i i i i								
Day	Date	Test Sample	Positive Control	Negative Control	Test Sample	Positive Control	Negative Control	Sign	Remarks
1 st	rtosleos	-ve	tve	-ve	-ve	tre	-ve	1464613	
2 nd	13/201200	-ve	tre	-ve	-ve	tre	-ve	15/02/2013	ok
3 rd	crastedes	-ve	tre	-10	-ve	tue	-ve	19/01/1013	31
4 th	20/02/20	-46	tre	-ve	-ve	710	-ve	20/01/10/2	
5 th	शान्त्रीका	-ve	tre	-ve	-Ve.	tre	-ve	201613	
6 th	23/02/2013	-16	tre	-ve	-ve	tue	-ve	22/02/100	
7 th	23/22/2013	-ve	tue	~ve	-ve	tre	-ve	23/2/42	
8 th	eralsolve	-ve	tre	-ve	-ve	tre	-ve	moder	
9 th	22/02/202	-ve	tre	-ve	-ve	tre	-ve	2564613	sh
10 th	sepritors	-12	tue	-ve	-ve	tre	-ve	Stalions	
11 th	Esalegte	-Ve	tre	-ve	-ve	tue	-ve	37/03/3093	
12 th	28/20/2012	-ve	tve	-ve	~ve	tre	-ve	28/00/2018	ok
13 th	alastros	-70	tre	-Ve	~ve	tue	-Ve	era/res	
14 th	02/23/1803	-ve	tre	-ve	~Ve	tre	-ve	S John	

The sample complies / dees not complies as per IP / BP / USP / EP / IHS / ISO 11737 -2 / Client Specifications.

Analysed by / Date:

Checked by / Date: 0105 2013

Filename: ARLBL_MB_STP_004_Issue08; Allniga Research Private Limited, Bangalore

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Sign: Date: M. M. M. S.

RAW DATA SHEET

2028 Book No.:

SI No.: 405353

Réport No.: BC 2 0 2 3 0 1 2 5 0 1 0 1 Booking date: 25 loi 2023

Sample name: Artificial Tears

Analysis Started Date: 31 01 2023

Analysis Completion Date: 31 01 2023

Test Parameters ASSQ4

Test Method: GIPHC (STP - FP - DRP - A-079-00

Balance ID: NA

7111000

Equipment/Instrument: ARLIBLEG | UV - 002

Due Date of Calibration: NA

Due Date of Calibration: 29 (03 2023

Equipment/instrument: NA

Due Date of Calibration: NA

Weight of the Sample:

For Reagent Preparation refer BG 202301250095 - 81-NO: 405354 For Standard Preparation refer BG202301250095 - 81-NO: 405354

sample Preparation: Pipetted out 5 ml of sample into a 100 ml volumetric flask, added 100 ml of water.

Procedure: Pipetted out each of 2 ml of blank, standard, sample solution in to a test tube and then added 5 ml of reagent and mixed well.

kept at 105 degree for 30 mins.

After that, removed the tubes, cooled to Room temperature.

Measured the absorbance of the standard and sample preparation at 635 nm

Performed by (Sign & Date)

Checked By (Sign & Date)

6 62/02/2023

Page 1of 2

Calculation:

Assay in
$$\%$$
 = $\frac{\text{Sample AbS}}{\text{Standard AbS}} \times \frac{\text{Std}}{\text{too}} \times \frac{\text{shd}}{\text{too}} \times \frac{\text{sho}}{\text{soo}} \times \frac{\text{shorthy "cmc Sodium "on as is basis in who too}}{\text{too}}$

$$= \frac{\left(0.328 - 0.023\right)}{\left(0.330 - 0.023\right)} \times \frac{\text{Soi13}}{\text{too}} \times \frac{\text{too}}{\text{so}} \times \frac{99}{\text{too}}$$

$$= 0.9861 \times 100$$

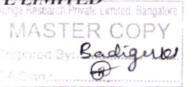
$$= 98.61 \%$$

Assay in mg/ml =
$$\frac{1}{100}$$
 x L.C
= $\frac{98.61}{100}$ x 10
= 9.86 mg/ml

ANALYTICAL

OF

REVIEW **REPORTS**





Code	:	ARLBL/QA/SOP-218
ssue No.	:	04
Effective Date	:	13/04/2022
Revision Date	:	13/04/2012

APPENDIX I

ARLBL/QA/SOP-218/FR-01

Page: 1 of 2

CHECKLIST FOR VERIFICATION OF ANALYTICAL REPORT

A) DE	ETAILS	OF SAMPLE						
Sample	e Name	Artificial tears	ζ.					
Batch	No.	Pant DIG	Date of start of Analysis			202	3	
Report	No.		Date of Completion of Analysis	-	211	011-	2023	
B) DET	AILS O							
SI No	I. No. Check points				Obs	erva	ation	
31. 140.					Yes	No	NA	
1	Is the A	analyst(s) performed all tests as per	the specified Test Method / protoco		~			
2	Are all	log entries made in respective equi	pment log books		/			
3	Are all	entries made in respective Working	/ Reference Standards usage recor	ds				
4	Are all	Equipment and/or instrument used	in the testing are within calibration d	ate				
5	Weight							
6	Are all							
7		.C / LCMS / GC / GCMS / HPTLC Clewed and found satisfactory	Chromatograms and sequence enclo	sed			~	
8	1	/ IR spectra , Automatic Potentiomed and found satisfactory	etric Titrator and TOC graph & data			7		
9	ICP-OES / ICP-MS data enclosed and found satisfactory						V	
10	Record		ric solutions are reviewed and found				V	
11	Are the	unit for results are mentioned in the	e COC & raw data sheet is matching					
12	Are all	pages signed with date in the COC	and Raw Data Sheets					
13	Are the	re any manual integration performe	d? If yes, provide reason below.					
14	Is any i	ncident, deviation or OOS reporting	done during the testing					
15	Are the	respective audit trails checked?						
16	Is there	any reprocessed / aborted analysis	s in audit trail?				,	
17	Are the	re any duplicate results?						
18	Are the	re any alterations of results?					7	
19		re any deletion of results					7	
20	-	er observations:				00	5	

Reviewed by / Date

Auriga Research Private Limited, Bangalore,

Filename: ARLBL_QA_SOP_218_Issue04

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REVIEW REPORTS MASTER COPY

ANALYTICAL Prepared By: Badiguts

OA Sign:



Code	: ARLBL/QA/SOP-218
Issue No.	: 04
Effective Date	: 13/04/2022
Revision Date	: 13/04/2026

Page: 2 of 2

QUALITY ASSURANCE						
CI Na	Chaok nainta	Observation				
SI. No.	Check points	Yes	No	NA		
1	Is test parameters & Method of test mentioned in the COA complying with the TRF	/				
2	Is the Analyst(s) performed all tests as per specification	/				
3	Is the sample name and batch number entered correctly as mentioned in COC	/				
4	Weight prints for each test is enclosed and are verified	/				
5	Are all calculations verified, found satisfactory	/				
6	Are the unit for results are mentioned in the COA, COC & RDS is matching with specification	/				
7	Are all pages signed with date in the COC and Raw Data Sheets					
8	Is any incident, deviation or OOS reporting done during the testing		/			
9	Are the respective audit trails checked?					
10	Is there any reprocessed / aborted analysis in audit trail?					
11	Are there any duplicate results?					
12	Are there any alterations of results?					
13	Are there any deletion of results		/			
14	Is all test/s results complying to the release specification					

OBSERVATIONS

		NA OSlo3/2	023	
Remarks:				

Conclusion: The Analytical Report is found satisfactory in all aspects of compliance.

Koslo3/2023 Verified by/ Date:

Auriga Research Private Limited, Bangalore,

Filename: ARLBL_QA_SOP_218_Issue04

Sign: Date 28/0/2023

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Photometric Sample Table

[Summary]

Filename: File Information

UV\$2023\$JAN - 13-82-1 -Assay sodium carboxy methyl

Parameter File Name: UV\$2023\$JAN - Assay Sodium Instrument Information cellulose(Artificial tears).vphd Carboxy methyl cellulose (Artificial Tears).vphm

Harish HS

Instrument Type: Model (S/N):

Instrument Name:

31-01-2023 14:52:36

Date/Time: Analyst:

Report File Name: Comments:

UV\$2023\$JAN -

PDFPhotometric.vrpt

Instrument Type: Instrument Name: UV-1900 Series ARL-BLEQ-UV-002

Instrument Information

Software Name: Software Information

Version:

LabSolutions UV-Vis

ARL-BLEQ-UV-002 UV-1900 Series

UV-1900i (A12535881051)

[Measurement Parameters]

Print Date: 31-01-2023 14:53:18

[Wavelengths]
Type of Measuring Mode:

Column Name: rounded:

Measuring Method:

Point (635.00nm) WL635.0

Absorbance

[Formula]

[Unknown Sample]

Acquiring Method: Repeat:

Measurement

Slit Width: [Instrument]

Accumulation Time (sec.):

1.0 nm

Light Source Switch Wavelength: 340.00 nm

[Sample Table]

	Sample Name	Sample ID	WL635.0
_	Air Blank	Air Blank	0.000
2	Blank	Blank solution	0.023
ω	Standard	Carboxy methyl cellulose sodium	0.330
4	Sample 01	BG202301250095	0.326
Οī	Sample 02	BG202301250101	0.328
6	Sample 03	BG202301250103	0.328
7	Sample 04	BG202301250104	0.328
Φ	Sample 05	BG202301250105	0.327
9	Sample 06	BG202301250106	0.330

Apt 3/10/12023

Gran John



REVIEW REPORTS

A)

OF

DETAILS OF SAMPLE

ANALYTICAL

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Code : ARLBL/QA/SOP-218
Issue No : 04
Effective Date : 13/04/1022
Revision Date : 13/04/1025

APPENDIX II

ARLBL/QA/SOP-218/FR-02

Page: 1 of 2

CHECKLIST FOR VERIFICATION OF MICROBIOLOGY REPORT

Sample	Name	Artilicial Ce	ars				
Batch I	No.	8m3014	Date of start of Analysis	28/0	11202	.3	
Report	No.		Date of Completion of Analysis	DHI	102/2023		
B) DET	AILS OF	F VE					
SI. No.		C	heck points		Obs	erva	tion
31. NO.			neek points		Yes	No	NA
1	Is the M		Il tests as per the specified Test Method	/		,	
2	Is the ed	quipment, Media, culture de	tails mentioned as per the method				
3	Are all le	og entries made in respectiv	e equipment log books		/		
4	Weight	prints for each test is enclos	ed and are verified				/
5	Are Equ	uipment and/or instrument us	sed in the testing are within calibration d	ate			
6	Is the st method		aration details entered correctly as per th	те			
7	Is print of	of sterilization cycle enclose	d in respective sterilization log book				
8	Is Plate	observations made by micro	obiologists updated in RDS		/		
9	Are all p	positive and negative control	s recorded for each parameter		/		
10	Is usage	e of media consumption reco	orded in respective media records				
11	Are all p	pages signed with date in the	e COC and Raw Data Sheets		/		
12	Are the	unit for results are mentione	ed in the COC & raw data sheet is match	ing			
13	Any oth	er observations:					
	_						
			NA CELESTARY				

Reviewed by / Date:

Auriga Research Private Limited. Bangalore,

Filename: ARLBL_QA_SOP_218_Issue04

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REVIEW REPORTS OF

ANALYTICAL

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Prepared By: Radigerte	þ
CA Sign:	

•	1	Con.		
Code	1:	ARL	BL/C	QA/SOP-218
Issue No.	1	04		
Effective Date	1:	13	ley	12022
Revision Date				12025

Page: 2 of 2

	QUALITY ASSURANCE			
CL No	Charle a sinta	Observation		
SI. No.	Check points	Yes	No	NA
1	Is test parameters & Method of test mentioned in the COA complying with the TRF	~		
2	Is the Microbiologist(s) performed all tests as per the specified Test Method / protocol			
3	Is the sample name and batch number entered correctly as mentioned in COC			
4	Weight prints for each test is enclosed and are verified			/
5	Are media used and media lot numbers recorded on the controlled RDS			
6	Are all calculations verified and found that there is no error			
7	Is all test/s results complying to the release specification			
8	Are all pages signed with date in the COC and Raw Data Sheets			
9	Are the unit for results are mentioned in the COA, COC & RDS is matching with the specification			
10	Is any incident, deviation or OOS reporting done during the testing		/	
11	Is all test results complying to the release specification			

OBSERVATIONS

SI. No.	Observation No.	Details of observation by reviewer	Observed by sign. With date	Corrective Action taken
			\$ 08/03/2023	
Rema	ırks:			

Conclusion: The Microbiology Report is found satisfactory in all aspects of compliance.

Auriga Research I

Filename: ARLBL_QA_SOP_218_Issue04

Date 28 loil 2013

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MICROBIAL LIMIT TEST OF NON-STERILE PRODUCTS AS PER USP / B.P / PH. EUR / IP AND/OR AS PER CLIENT SPECIFICATIONS

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	ared By: May1
QA S	ign:

Code	: ARLBL/MB/STP-013
Issue No.	: 07
Effective Date	: 22/03/2022
Revision Date	: 22 103 12035

APPENDIX I

ARLBL/MB/STP-013/FR-01

MICROBIAL LIMIT TEST REPORT

Page: 1 of 2

Sample Name	By 20230125010	Analysis Started Date	28/01/2023
Report No.	BG202301250101	Analysis Completed Date	04loabo23

SAMPLE PRE-ENRICHI	MENT (SOLUTION A):		
10 g/mL of sample	e dissolved in <u>90</u> mL of_	SCDM LOTNO. SCDM	1-15/01/2023-0014
	of NA		
Dilutions can be prepar	ed as per below flow chart A	A:SCDM- 15/01/2023	-001+
Solution A (10 ⁻¹) 01	mℓ → 9ml (10 ⁻²) → 9 ml (10⁻³)) → 9ml(10 ⁻⁴) → 9ml	(10⁻⁵) → 9ml (10 -6
Weight Print(s):			
	NA		
	28/01	12023	
SAMPLE PRE-ENRICHM			
	mL of solution A added to	mL of SCDM	M (Solution B);
Lot No. SCDM-	Incubate at 30	-35°C for 18 – 24 hrs / 48	72 hrs.

Filename: ARLBL_MB_STP_013_Issue07 Auriga Research Private Limited, Bengarote.

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MICROBIAL LIMIT TEST OF NON-STERILE PRODUCTS AS PER USP / B.P / PH. EUR / IP AND/OR AS PER CLIENT SPECIFICATIONS

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Prepared By: May
QA Sign:

Code	: ARLBL/MB/STP-013
Issue No.	: 07
Effective Date	: 22/03/2012
Revision Date	: 22/03/2015

Page: 2 of 2

SAMPLE PRE-ENRICHMENT (SOLUTION C): of sample dissolved in ____ mL of SCDM (Solution C), Lot No. SCDM-. Incubate at 30-35°C for 18 – 24 hrs. Weight Print(s): NA 28/01/2003

Equipment / Instrument	Equipment / Instrument ID	Calibration Due Date
Weighing Balance	ARL/BLEQ/AWB	NA
BOD Incubator (20-25°C)	ARL/BLEQ/BOD— 001	01/11/2023
BIC Incubator (30-35°C)	ARL/BLEQ/BIC— 001	01/11/2023
BIC Incubator (30-35°C)	ARL/BLEQ/BIC—	
BIC Incubator (42-44°C)	ARL/BLEQ/BIC—	NA
BIC Incubator (37°C)	ARL/BLEQ/BIC—	exac
Water Bath (80°C)	ARL/BLEQ/WB-	04/02/2023

FOR 6410212023

Analysed By / Date:

Checked By / Date: OFlb2 2623

Filename: ARLBL_MB_STP_013_Issue07

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Auriga Research Pr	fvate Limited, Bangalore.
MASTI	ER COPY
Prepared By:	Magh
QA Sign.:	€

Code	:	ARLBL/MB/STP-013
Issue No.	:	07
Effective Date	:	22/03/2022
Revision Date	:	22/03/2025

APPENDIX IV

ARLBL/MB/STP-013/FR-04

TAMC/TBC BY POUR PLATE METHOD

Report No.	84202301250101	Analysis Started Date	28/01/2023
Culture ID	ATCC 6633	Analysis Completed Date	02/02/8023

PROCEDURE: _____ mL of Solution A and each diluent prepared as per flow chart A pipetted into two Petri dishes. Pour 15-20mL of SCDA into Petri dishes in duplicates from each dilution; Lot No. SCDA- 28 01 2023 - 000 1 and incubate at 30-35°C for 3-5 days.

FORMULA:

TAMC/TBC Average No. of colonies obtained x Dilution factor

Calculation for TAMC/Bacteria:

Dilution factor	Plate 1	Plate 2	Average
10-1	NII	Nil	Nil
10-2	Nil	N; I	Nil
	NA		
		03/03/203	
		03/03/2033	

Negative Control: Growth Observed / Not observed

Positive control: Growth Observed / Not observed

Result: TAMC/TBC ____ < 10 ___ cfu /g /mL /swab

Conclusion: The Sample Complies / Does not comply / Not Applicable for TAMC/TBC.

202/02/2023

Analysed By / Date:

Checked By / Date: OSlo2/2023

Filename: ARLBL_MB_STP_013_Issue07, Auriga Research Private Limited, Bangalote,

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MICROBIAL LIMIT TEST OF NON-STERILE PRODUCTS AS PER USP / B.P / PH. EUR / IP AND/OR AS PER CLIENT SPECIFICATIONS

Auriga Research Private L	imited, Bangalore.
MASTER	
Prepared By: Me	41
QA Sign:)

Code	:	ARLBL/MB/STP-013
Issue No.	:	07
Effective Date	1:	22/03/2022
Revision Date	1:	22/2020

APPENDIX V

ARLBL/MB/STP-013/FR-05

TYMC BY POUR PLATE METHOD

Report No.	84202301250101	Analysis Started Date	28/01/2023
Culture ID	ATCC 10231	Analysis Completed Date	04/02/2023

PROCEDURE: ____o__ mL of Solution A and each diluent prepared as per flow chart A pipetted into two Petri dishes in duplicates. Pour 15-20mL of SDCA into Petri dishes in duplicates from each dilution; Lot No. SDCA- 28/01/2023-0002 and incubate at 20-25°c for 5-7 days.

FORMULA:

TYMC Average No. of colonies obtained x Dilution factor

Calculation for Yeast and Mold:

Plate 1	Plate 2	Average
Nil	Nil	Nil
Nil	NII	Nil
NA		
01/21	1	
	Nil	Nil Nil

Negative Control: Growth Observed / Not observed

Positive control: Growth Observed / Not observed

<10 Result: TYMC _ cfu /g /mL /swab

Conclusion: The Sample Complies / Does not comply / Not Applicable for TYMC.

og 244 2023

Analysed By / Date:

Checked By / Date:

Filename: ARLBL_MB_STP_013_Issue0703 Research Private Limited,

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Auriga Research Private Limited

Govt. Approved Test House



No. 136, 6th Cross, 2nd Stage, Yeshwanthpur Industrial Suburb, Bangalore - 560 022 Ph.: +91-080-35229344

Email: admin@aurigaresearch.com, Website: www.aurigaresearch.com

Certificate of Analysis

Information by Customer

Report No. : BG202301250103

Sample

: ARTIFICIAL TEARS

Mfg. By

: GLOBAL PHARMA HEALTHCARE PVT. LTD.

Supplied By

GLOBAL PHARMA HEALTHCARE PVT. LTD.

Mfg lic. No. : NS

Submitted By : GLOBAL PHARMA HEALTHCARE PVT. LTD.

Ref. No.

Address

: NEW NO. 2A, 3RD FLOOR GANGA NAGAR 4TH STREET KODAMBAKKAM, CHENNAI, TAMILNADU- 600024

Sample Quantity

Batch No

Mfg. Date

Expiry Date

Batch Size

PCMJ015

APR 2022

MAR 2025

204 Ltr

Sample ID: BG202301250103

12 Bottles

Date of start of analysis: 28/01/2023

Received On:

25/01/2023

Date of completion of analysis: 02/03/2023

Reference to protocol

:- GPHC/SPEC-FP-DRP-A-079-00

Sample not drawn by laboratory.

Description

:- Clear colourless slightly viscous solution

- <parameters></parameters>	<results></results>	<unit></unit>	<req.></req.>	<claim></claim>	<lloq></lloq>	<lower limit=""></lower>	<upper limit></upper 	<method></method>
Content of sodium Carbo	xy methyl cellulose :							
Assay in %	: 98.61	%	90.00 % to 110.00 %			eī ei		GPHC/STP-FP-DRP -A-079-00
Assay in mg/ml	: 9.86	mg/ml	9.00 mg/ml an 11.00 mg/ml	d 10.0 mg/ml	-	-	-	GPHC/STP-FP-DRP -A-079-00
Total Yeast & Mould count.	: <10 cfu/ml	-	-		-	-	-	USP <61>
Total aerobic microbial count.	: <10 cfu/ml	-	-1		-	-	-	USP <61>
Sterility	: Complies		-		-	-	-	USP <75>
			End of Report					

Report: In the opinion of the undersigned, the sample referred to above is of standard quality as defined in the Act and the rules made thereunder for the reason given below:- of



To verify Report Scan this Code.

(1) Total liability of this laboratory is limited to the invoice amount.
(2) The results listed refer only to the tested sample and applicable parameter. Endorsement of products is neither inferred nor implied.

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to8/03/2023 **Authorized Signatory**

RAW DATA SHEET

2038 Book No.:

Report No.:	B020230	1250	103	Booking date: 25 (01)2023
Sample name:	Artificial	Teans		
Analysis Starte	d Date: 3101/20	23		Analysis Completion Date: 3101(2023

Test Parameters Assay

Test Method: GPHC 1 STP - FP - DRP - A - 079 -00

Equipment/Instrument: ARL BLEQ | UV - 002

Balance ID: NA

Due Date of Calibration: NA

Due Date of Calibration: 29 (03 2023

Equipment/instrument: MA

Due Date of Calibration: NA

Weight of the Sample:

Reagent Preparation refer BG202301250095 -81.NO: 405354 standard Preparation refer BG202301250095 - 81.NO: 405354

sample Preparation: Pipetted out 5 ml of sample into a word volumetric flash, addled worm of water.

Procedure: Pipetted out each of Eml of blank, standard, sample solution into a test tube and then added is me of reagent and mixed well.

kept at 105 degree for 30 mins. After that, removed the tubes, cooled to Room temperature. measured the absorbance of the standard and sample preparation at 635 nm

Varilo1/2023 Performed by (Sign & Date)

Checked By (Sign & Date)

Q 13/02/0023

Page 1of 2

Calculation:

Assay in
$$\frac{7}{5}$$
 = Sample Abs x std wt in mg x 100 x hunity "cme sodium" on as is basis in w/w 100

= $\frac{(0.328 - 0.023)}{(0.330 - 0.023)}$ x $\frac{50.13}{100}$ x $\frac{100}{50}$ x $\frac{99}{100}$

= $\frac{0.9861}{0.9861}$ x $\frac{100}{0.9861}$ x $\frac{99}{100}$

Assay in
$$mg/ml = \frac{7}{100} \times L.C$$

$$= \frac{98.61}{100} \times 10$$

$$= 9.86 mg/ml$$

Result: Assay in 7- = 98.61-7. Assay in my lml = 9.86 mg/ml

Checked By (Sign & Date)

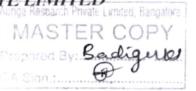
Page2 of 2

(1E \$ 603/02 hors

OF

A) DETAILS OF SAMPLE

REVIEW REPORTS





	-	
Code	: /	ARLBL/QA/SOP-218
Issue No.	: ()4
Effective Date	:	13/04/2022
Revision Date	:	13/04/2025

APPENDIX I

ANALYTICAL

ARLBL/QA/SOP-218/FR-01

Page: 1 of 2

CHECKLIST FOR VERIFICATION OF ANALYTICAL REPORT

Sample	e Name Artificial toos									
Batch I	No.	BW2 016	Date of start of Ar	alysis	31/01	1	102	3		
Report			Date of Completion	n of Analysis	31/01/2023 is 31/01/2023					
B) DET	AILS O	F VEI BG202301250103								
SI. No.						Observation				
51. NO.	Check points					es	No	NA		
1	Is the A	Analyst(s) performed all to	sts as per the specified Test I	Method / protocol	L					
2	Are all	log entries made in respo	ctive equipment log books		0					
3	Are all entries made in respective Working / Reference Standards usage records									
4	Are all Equipment and/or instrument used in the testing are within calibration date									
5	Weight prints for each test is enclosed and are verified				~					
6	Are all calculations verified, found satisfactory				-					
7	All HPLC / LCMS / GC / GCMS / HPTLC Chromatograms and sequence enclosed are reviewed and found satisfactory				ed			0		
8	UV-Vis / IR spectra , Automatic Potentiometric Titrator and TOC graph & data enclosed and found satisfactory									
9	ICP-OES / ICP-MS data enclosed and found satisfactory									
10	Record satisfac		Il volumetric solutions are rev	iewed and found				/		
11	Are the unit for results are mentioned in the COC & raw data sheet is matching				C					
12	Are all pages signed with date in the COC and Raw Data Sheets				-					
13	Are there any manual integration performed? If yes, provide reason below.							/		
14	Is any incident, deviation or OOS reporting done during the testing					/				
15	Are the respective audit trails checked?				~					
16	Is there	any reprocessed / abort	ed analysis in audit trail?				~			
17	Are the	re any duplicate results?								
18	Are the	re any alterations of resu	ts?	7		T				
19	Are the	re any deletion of results	1							
20	Any other observations:						5	0		

Reviewed by / Date:

QA ISSUED

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Date 28 lor/202B

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Prepared By: Badgers



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Issue No.	:	04
Effective Date	:	13/04/2022
Revision Date	:	13/04/2026

Page: 2 of 2

REVIEW	OF	ANALYTICAL Prepared B
REPORTS		QA Sign :

	QUALITY ASSURANCE			
CI No	Charle paints	Obs	Observation	
SI. No.	Check points	Yes	No	NA
1	Is test parameters & Method of test mentioned in the COA complying with the TRF	/		
2	Is the Analyst(s) performed all tests as per specification			
3	Is the sample name and batch number entered correctly as mentioned in COC	/		
4	Weight prints for each test is enclosed and are verified	/		
5	Are all calculations verified, found satisfactory			
6	Are the unit for results are mentioned in the COA, COC & RDS is matching with specification			
7	Are all pages signed with date in the COC and Raw Data Sheets			
8	Is any incident, deviation or OOS reporting done during the testing		/	
9	Are the respective audit trails checked?			
10	Is there any reprocessed / aborted analysis in audit trail?			
11	Are there any duplicate results?		/	
12	Are there any alterations of results?			
13	Are there any deletion of results			
14	Is all test/s results complying to the release specification			

OBSERVATIONS

SI. No.	Observation No.	Details of observation by reviewer	Observed by sign. With date	Corrective	Action taken
			208103/2023		
	1		MGA		

Conclusion: The Analytical Report is found satisfactory in all aspects of compliance.

Verified by/ Date:

Auriga Research Private Limited, Bangalore,

Filename: ARLBL_QA_SOP_218_Issue04

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Photometric Sample Table

Print Date: 31-01-2023 14:53:18

[Summary]

Filename: File Information

cellulose(Artificial tears).vphd UV\$2023\$JAN - 13-82-1 -Assay sodium carboxy methyl

(Artificial Tears).vphm Harish HS Carboxy methyl cellulose

UV\$2023\$JAN - Assay Sodium

Parameter File Name:

31-01-2023 14:52:36

Date/Time: Analyst:

Comments:

Report File Name:

UV\$2023\$JAN -

PDFPhotometric.vrpt

Instrument Information

Instrument Name: Instrument Type: ARL-BLEQ-UV-002 UV-1900 Series

> Software Name: Software Information

Instrument Information Instrument Name: UV-1900 Series

LabSolutions UV-Vis

ARL-BLEQ-UV-002

UV-1900i (A12535881051)

Instrument Type: Model (S/N):

[Measurement Parameters]

rounded: [Wavelengths] Type of Measuring Mode:

Measuring Method: Column Name:

Point (635.00nm) WL635.0 Absorbance

[Formula]

Repeat: Acquiring Method: [Unknown Sample]

Measurement

Slit Width: [Instrument]

1.0 nm

Accumulation Time (sec.):

Light Source Switch Wavelength: 340.00 nm

[Sample Table]

	Sample Name	Sample ID	WL635.0
_	Air Blank	Air Blank	0.000
2	Blank	Blank solution	0.023
ω	Standard	Carboxy methyl cellulose sodium	0.330
4	Sample 01	BG202301250095	0.326
σ.	Sample 02	BG202301250101	0.328
0	Sample 03	BG202301250103	0.328
7	Sample 04	BG202301250104	0.328
Φ	Sample OF	BG202301250105	0.327
0	Sample Of	BG202301250106	0.330
(Campio		

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OF

DETAILS OF SAMPLE

REVIEW

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Effective Date	: 13/04/2022
Revision Date	13/04/2022

REPORTS APPENDIX II

ARLBL/QA/SOP-218/FR-02

Page: 1 of 2

CHECKLIST FOR VERIFICATION OF MICROBIOLOGY REPORT

Sample	e Name	Artilicial to	072				
Batch !	No.	210 Ems	Date of start of Analysis	28/0	1/202	-3	
Report	No.		Date of Completion of Analysis				
B) DET	AILS OF	VER BG202301250103					
SI. No.		202001220103	Check points		Obs	erva	tion
SI. NO.			Oneck points		Yes	No	NA
1	Is the M		all tests as per the specified Test Method	1			
2	Is the e	quipment, Media, culture d	letails mentioned as per the method		~		
3	Are all I	og entries made in respec	tive equipment log books		/		
4	Weight	prints for each test is enclo	osed and are verified				
5	Are Equ	ipment and/or instrument	used in the testing are within calibration d	ate			
6	Is the st method		paration details entered correctly as per the	те			
7	Is print	of sterilization cycle enclos	ed in respective sterilization log book		/		
8	Is Plate	observations made by mid	crobiologists updated in RDS				
9	Are all p	positive and negative contr	ols recorded for each parameter				
10	Is usage	e of media consumption re	corded in respective media records				
11	Are all p	pages signed with date in t	he COC and Raw Data Sheets				
12	Are the	unit for results are mention	ned in the COC & raw data sheet is match	ing			
13	Any oth	er observations:					
			NA SIL OBTORIUS				

Reviewed by / Date:

Auriga Research Private Limited, Bangalore,

Filename: ARLBL_QA_SOP_218_Issue04

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REVIEW REPORTS

OF

ANALYTICAL

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Prepared By: Radigerte
GA Sign:

Code	: ARLBL/QA/SOP-218
Issue No.	: 04
Effective Date	13/04/2022
Revision Date	13/04/2022

Page: 2 of 2

	QUALITY ASSURANCE			
SI. No.	No.			
SI. NO.	. Check points		No	NA
1	Is test parameters & Method of test mentioned in the COA complying with the TRF	/		
2	Is the Microbiologist(s) performed all tests as per the specified Test Method / protocol			
3	Is the sample name and batch number entered correctly as mentioned in COC			
4	Weight prints for each test is enclosed and are verified			V
5	Are media used and media lot numbers recorded on the controlled RDS			
6	Are all calculations verified and found that there is no error			
7	Is all test/s results complying to the release specification			
8	Are all pages signed with date in the COC and Raw Data Sheets			
9	Are the unit for results are mentioned in the COA, COC & RDS is matching with the specification			
10	Is any incident, deviation or OOS reporting done during the testing		/	
11	Is all test results complying to the release specification			

OBSERVATIONS

SI. No.	Observation No.	Details of observation by reviewer	Observed by sign. With date	Corrective	Action taken
			t. 102/2022		
		N	Solo3/2013		
ema	rks:				

Conclusion: The Microbiology Report is found satisfactory in all aspects of compliance.

Auriga Research Fi

Verified by/ Date:

Filename: ARLBL_QA_SOP_218_Issue04

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MICROBIAL LIMIT TEST OF NON-STERILE PRODUCTS AS PER USP / B.P / PH. EUR / IP AND/OR AS PER CLIENT SPECIFICATIONS

Auriga Research Priva	te Limited, Bangalore.
MASTE	RCOPY
Prepared By:	Post
QA Sign:	6

Code	1:	ARLBL/MB/STP-013
ssue No.	:	07
Effective Date	1:	22/03/2012
Revision Date	:	22/03/2026

APPENDIX I

ARLBL/MB/STP-013/FR-01

MICROBIAL LIMIT TEST REPORT

Page: 1 of 2

Sample Name	Artificial tears.	Analysis Started Date	28/01/2023
Report No.	84202301250103	Analysis Completed Date	04/01/2023

SAMPLE PRE-ENRICHMENT (SOLUTION A):
10 $\frac{M}{g/m}$ of sample dissolved in $\frac{90}{NA}$ Lot No. SCDM- 15 01 2023 - 0014 1 swab $\frac{100}{NA}$ Lot No. NA
1 swab → 10mL of NA Lot No NA
Dilutions can be prepared as per below flow chart A: SCDM- 15 01 2023 - 0017
Solution A $(10^{-1}) \xrightarrow{0.1} 9 \text{ml } (10^{-2}) \xrightarrow{} 9 \text{ml } (10^{-3}) \xrightarrow{} 9 \text{ml } (10^{-4}) \xrightarrow{} 9 \text{ml } (10^{-5}) \xrightarrow{} 9 \text{ml } (10^{-6})$
Weight Print(s):
NA .
NA 8/01/2023
SAMPLE PRE-ENRICHMENT (SOLUTION B):
mL of solution A added to mL of SCDM (Solution B);
Lot No. <u>SCDM-</u> . Incubate at 30-35°C for 18 – 24 hrs / 48 – 72 hrs.

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MICROBIAL LIMIT TEST OF NON-STERILE PRODUCTS AS PER USP / B.P / PH. EUR / IP AND/OR AS PER CLIENT SPECIFICATIONS

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Prepared By: May
QA Sign:

Code	1:	ARLBL/MB/STP-013
Issue No.	1	07
Effective Date	:	22/03/2012
Revision Date	:	22/03/2025

Page: 2 of 2

SAMPLE PRE-ENRICHMENT (SOLUTION C): ___ of sample dissolved in ____ mL of SCDM (Solution C), Lot No. SCDM-_____. Incubate at 30-35°C for 18 – 24 hrs. Weight Print(s): 08/01/2023

Equipment / Instrument	Equipment / Instrument ID	Calibration Due Date
Weighing Balance	ARL/BLEQ/AWB—	NA
BOD Incubator (20-25°C)	ARL/BLEQ/BOD— 001	011112023
BIC Incubator (30-35°C)	ARL/BLEQ/BIC- 00 1	01/11/2023
BIC Incubator (30-35°C)	ARL/BLEQ/BIC—	
BIC Incubator (42-44°C)	ARL/BLEQ/BIC-	NA
BIC Incubator (37°C)	ARL/BLEQ/BIC—	04/102/2023
Water Bath (80°C)	ARL/BLEQ/WB-	

FOR UCA 2023

Analysed By / Date:

Checked By / Date: O5/02/2023

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Filename: ARLBL_MB_STP_013_Issue07UIQ3_Research Private Limited, Bangalote





Code	: ARLBL/MB/STP-013	
Issue No.	: 07	
Effective Date	: 22/03/2022	
Revision Date	: 22/03/2025	

MICROBIAL LIMIT TEST OF NON-STERILE PRODUCTS AS PER USP / B.P / PH. EUR / IP AND/OR AS PER CLIENT SPECIFICATIONS

APPENDIX IV

ARLBL/MB/STP-013/FR-04

TAMC/TBC BY POUR PLATE METHOD

Report No.	B4202301250103	Analysis Started Date	28/01/2023	
Culture ID	ATCC 66 33	Analysis Completed Date	02/01/2023	* T. E &

PROCEDURE: ___O I __mL of Solution A and each diluent prepared as per flow chart A pipetted into two Petri dishes. Pour 15-20mL of SCDA into Petri dishes in duplicates from each dilution; Lot No. SCDA- 28 01 2023- 0001 and incubate at 30-35°C for 3-5 days.

FORMULA:

TAMC/TBC -Average No. of colonies obtained x Dilution factor

Calculation for TAMC/Bacteria:

Dilution factor	Plate 1	Plate 2	Average
lo-'	Nil	Nil	Nil
10-7	Nil	Nil	Nil
	2010		
	NA	8	
		02/01/20	1 1

Negative Control: Growth Observed / Not observed

Positive control: Growth Observed / Not observed

<10 Result: TAMC/TBC ___ cfu /g /mL /swab

Conclusion: The Sample Complies / Does not comply / Not Applicable for TAMC/TBC.

02/01/2023 Analysed By / Date:

Checked By / Date: OF 102 2 223

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MICROBIAL LIMIT TEST OF NON-STERILE PRODUCTS AS PER USP / B.P / PH. EUR / IP AND/OR AS PER CLIENT SPECIFICATIONS

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Prepa	ared By: May
QA S	ign.:

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Issue No.	:	07
Effective Date	:	22/03/2022
Revision Date	:	22/02/2025

APPENDIX V

ARLBL/MB/STP-013/FR-05

TYMC BY POUR PLATE METHOD

Report No.	BG202301250103	Analysis Started Date	28/01/2023
Culture ID	ATLL 10231	Analysis Completed Date	04/01/2023

PROCEDURE: 0 I mL of Solution A and each diluent prepared as per flow chart A pipetted into two Petri dishes in duplicates. Pour 15-20mL of SDCA into Petri dishes in duplicates from each dilution; Lot No. SDCA- 28 01 2023-0002 and incubate at 20-25°c for 5-7 days.

FORMULA:

TYMC Average No. of colonies obtained x Dilution factor

Calculation for Yeast and Mold:

Dilution factor	Plate 1	Plate 2	Average
10-1	Nil	Nil	Nil
10-9	Nil	Nil	NII
		NA	
		04/02/2022	

Negative Control: Growth Observed / Not observed

Positive control: Growth Observed / Not observed

Result: TYMC

Conclusion: The Sample Complies / Does not comply / Not Applicable for TYMC.

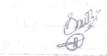
Analysed By / Date:

Checked By / Date: 812

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Sign: Date: 28 0/1023

STERILITY TESTING OF FINISHED PRODUCT AND RAW MATERIALS



APPENDIX I

ARLBL/MB/STP-004/FR-01

STERILITY REPORT - MEMBRANE FILTERATION METHOD

Product	t possificial	eans		Sample Quantity	2001 90	
Report No.	136705301520103	Datah Na	PCMJOIS	No. of containers Tested	ZON FO	
Test started on	16/05/2023	Test completed on	02/20/2013	Amount of sample used	lom	

TEST FOR BACTERIA	Soya bean Casein Digest Medium Lot no.: Scom-13/02/2023 - 0017			
Incubate at 30-35°C; ARL/BLEQ/BIC-09 for 14 days	Incubate at 20-25°C; ARL/BLEQ/BOD-004 for 14 days			

								1	
Day	Date	Test Sample	Positive Control	Negative Control	Test Sample	Positive Control	Negative Control	Sign	Remarks
1 st	czarkotti	-ve	tre	-ve	- ve	tre	-ve	1762/1013	soh
2 nd	18/02/2013	-ve	tue	-ve	-ve	tre	-10	18/03/2033	Oh
3 rd	esaskolpi	-10	tre	-ve	-16	tre	ve	19/01/10/2	ok
4 th	esaleolos	-10	tue	-ve	-ve	tre	-ve	टीजीका	Oh
5 th	esasteolis	-ve	tre	-ve	-ve	tve	-ve	Mortions	
6 th	esasteoles	-ve	tre	-ve	-ve	tre	-ve	Tibelion	ole
7 th	crasheoles	-ve	tre	-ve	-ve	tre	-ve	13/2/1013	sole
8 th	Elastrolys	-ve	tre	-ve	-ve	tre	-ve	2462/20	sk
9 th	edochos	-ve	tre	-ve	-ve	tue	-ve	Telps /	s sh
10 th		-ve	tue	-ve	-ve	tue	-ve	Horners	عار
11 th		-ve	tre	-ve	~ve	tre	-ve	23/03/3033	
12 th		-ve	tre	-ve_	-ve	tre	-ve	Seosleolse	
13 th		-ve	tve	-ve	-ve	tre	-ve	Erapearo	ملر
14 th		-ve	tve	-14	-ve	tre	-ve	Secolina Second	1

The sample complies / does not complies as per IP / BP / USP / EP / IHS / ISO 11737 -2 / Client Specifications.

Analysed by / Date:

Checked by / Date:

103/2013

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