Auriga Research

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
Ref. No. : NS
Submitted By : GLOBAL PHARMA HEALTHCARE PVT. LTD.
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	12 Bottles

Sample ID : BG202301250087 **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>	<Results>	<Unit>	<Req.>	<Claim>	<LLOQ>	<Lower limit>	<Upper limit>	<Method>
Content of sodium Carboxy 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	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.

*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.

08/03/2023
Suathi.S
Authorized Signatory

Book No.: 2038 Sl No.: 405358

RAW DATA SHEET

Report No.: ARL20230125008	Booking date: 25/01/2023
Sample name: Artificial Tears	
Analysis Started Date: 30/01/2023	Analysis Completion Date: 30/01/2023

Test Parameters: Assay

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

Balance ID: ARL/BLEQ/AWB-012 Due Date of Calibration: 05/02/2023

Equipment/Instrument: ARL/BLEQ/UV-002 Due Date of Calibration: 29/03/2023

Equipment/instrument: NA Due Date of Calibration: NA

Weight of the Sample:

Working mode Diphenyl amine Weighing
Date 30.01.2023
Time 14:11:31
Balance S/N 668671
Instrument Id:ARL/BLEQ/AWB-012

1.25146 g
0.00056 g 1.25090 g
Date 30.01.2023
Time 14:12:56

30/01/2023
Signature

03/02/2023

Name	B.NO	Make
Diphenyl amine	120418	central drug house
Glacial Acetic acid	7393941022	qualigens
conc. Hydrochloric acid	3301021C	Carlo erba

Reagent Preparation : Dissolved 1.25090 g of Diphenyl amine reagent in 50 ml of Glacial acetic acid and then added 30 ml of conc. Hydrochloric acid.

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

03/02/2023
Checked By (Sign & Date)

Calculation:

Working mode: carboxy methyl cellulose Sodium Weighing
Date: 30.01.2023
Time: 14:14:55
Balance S/N: 668671
Instrument Id:ARL/BLEO/AWB-012

50.30 mg 50.25 mg
0.05 mg

Date: 30.01.2023
Time: 14:16:03

30/01/2023
Signature

03/02/2023

standard Details :

Name : Carboxy methyl cellulose Sodium
B.No : GP/WS/079/21
valid upto : 12/10/2023

standard Preparation : Weighed 50.25 mg of carboxy methyl cellulose Sodium WRS into a 100 ml volumetric flask, 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 flask, adde 100 ml of water.

Result : Procedure continued in Sl.No : 405495

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

03/02/2023
Checked By (Sign & Date)

Book No.: 2041 Sl No.: 405995

RAW DATA SHEET

Report No: BG 20230125008 7	Booking date: 25/01/2023
Sample name: Artificial Tears	
Analysis Started Date: 30/01/2023	Analysis Completion Date: 30/01/2023

Test Parameters Assay

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

Balance ID: NA Due Date of Calibration: NA

Equipment/Instrument: NA Due Date of Calibration: NA

Equipment/instrument: ARL/BLEQ/UV-002 Due Date of Calibration: 29/03/2023

Weight of the Sample:

Procedure : Pipetted out each of 2 ml of blanks, 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

30/01/2023

Performed by (Sign & Date)

03/02/2023

Checked By (Sign & Date)

Calculation:

$$\text{Assay in \%} = \frac{\text{Sample Abs}}{\text{Standard Abs}} \times \frac{\text{Std wt in mg}}{100} \times \frac{100}{50} \times \frac{\text{Purity "cmc Sodium" on as is basis in \%}}{100}$$

$$= \frac{(0.325 - 0.024)}{(0.326 - 0.024)} \times \frac{50.25}{100} \times \frac{100}{50} \times \frac{99}{100}$$

$$= 0.9917 \times 100$$

$$= 99.17\ \%$$

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

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

$$= 9.92\ \text{mg/ml}$$

Result : Assay in % = 99.17 %
Assay in mg/ml = 9.92 mg/ml ✓

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

03/02/2023
Checked By (Sign & Date)

CHECKLIST FOR VERIFICATION OF ANALYTICAL REPORT

A) DETAILS OF SAMPLE			
Sample Name	Artificial Tears		
Batch No.	PCMJ006	Date of start of Analysis	30/01/2023
Report No.		Date of Completion of Analysis	30/01/2023

B) DETAILS OF VE

BG202301250087

Sl. No.	Check points	Observation		
		Yes	No	NA
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			✓
10	Records / registers / validity of all volumetric solutions are reviewed and found satisfactory			✓
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:		NO	

Reviewed by / Date: 30/01/2023

Auriga Research Private Limited, Bangalore
QA ISSUED
Sign: Date: 28/01/2023

QUALITY ASSURANCE				
Sl. No.	Check points	Observation		
		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

Sl. No.	Observation No.	Details of observation by reviewer	Observed by sign. With date	Corrective Action taken
			08/03/2023	
Remarks:				

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

08/03/2023

Verified by/ Date:

Auriga Research Private Limited, Bangalore,
QA ISSUED
Sign: Date: 28/04/2023

Photometric Sample Table

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

[Summary]

File Information
Filename: UV2023JAN - 13-80-1 - Artificial Tears.vphd
Parameter File Name: UV2023JAN - Assay Sodium Carboxy methyl cellulose (Artificial Tears).vphm
Analyst: Harish HS
Date/Time: 30-01-2023 18:58:53
Comments:
Report File Name: UV2023JAN - PDFPhotometric.vrpt

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

Software Information
Software Name: LabSolutions UV-Vis
Version: 1.11

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

[Measurement Parameters]

[Wavelengths]
Type of Measuring Mode: Absorbance
rounded: OFF
Column Name: WL635.0
Measuring Method: Point (635.00nm)

[Formula]

[Unknown Sample]
Acquiring Method: Measurement
Repeat: OFF

[Instrument]
Slit Width: 1.0 nm
Accumulation Time (sec.): 0.1
Light Source Switch Wavelength: 340.00 nm

[Sample Table]

	Sample Name	Sample ID	WL635.0
1	Air Blank	Air Blank	0.000
2	Blank	Blank Solution	0.024
3	Standard	Carboxy methyl cellulose Sodium	0.326
4	Sample 01	BG202301250087	0.325
5	Sample 02	BG202301250088	0.324
6	Sample 03	BG202301250089	0.326
7	Sample 04	BG202301250092	0.325

30/01/2023

CHECKLIST FOR VERIFICATION OF MICROBIOLOGY REPORT

A) DETAILS OF SAMPLE			
Sample Name	Artificial Tears		
Batch No.	PCMJ006	Date of start of Analysis	28/01/2023
Report No.		Date of Completion of Analysis	04/02/2023

BG202301250087

B) DETAILS OF VI

Sl. No.	Check points	Observation Yes	No	NA
1	Is the Microbiologist(s) performed all tests as per the specified Test Method / 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 prints for each test is enclosed and are verified			✓
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 mentioned in the COC & raw data sheet is matching	✓		
13	Any other observations: NA 05/02/2023			

05/02/2023

Reviewed by / Date:

QUALITY ASSURANCE				
Sl. No.	Check points	Observation		
		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

Sl. No.	Observation No.	Details of observation by reviewer	Observed by sign. With date	Corrective Action taken
			NA 08/03/2023	

Remarks:

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

08/03/2023

Verified by/ Date:

Auriga Research Private Limited, Bangalore,
QA ISSUED
Sign: Date: 25/01/2023

Sample Name	Artificial tears.	**Analysis Started Date**	28/01/2023
Report No.	BL202301250087	**Analysis Completed Date**	04/02/2023

SAMPLE PRE-ENRICHMENT (SOLUTION A):

10 g/mL of sample dissolved in 90 mL of SCDM Lot No. SCDM-15/01/2023-001H

1 swab ⟶ 10mL of NA Lot No. NA

Dilutions can be prepared as per below flow chart A : SCDM-15/01/2023-001H

Solution A (10^{-1}) $\xrightarrow{01ml}$ 9ml (10^{-2}) ⟶ ~~9ml (10^{-3})~~ ⟶ ~~9ml(10^{-4})~~ ⟶ ~~9ml (10^{-5})~~ ⟶ ~~9ml (10^{-6})~~

Weight Print(s):

NA
28/01/2023

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 hrs / 48 – 72 hrs.

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 28/01/2023

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—	
BIC Incubator (37°C)	ARL/BLEQ/BIC—	NA UCM 04/02/2023
Water Bath (80°C)	ARL/BLEQ/WB—	

UCM 04/02/2023

Analysed By / Date:

Checked By / Date: 05/02/2023

APPENDIX IV **ARLBL/MB/STP-013/FR-04**

TAMC/TBC BY POUR PLATE METHOD

Report No.	BG20230125008T	**Analysis Started Date**	28/01/2023
Culture ID	ATCC 6633	**Analysis Completed Date**	02/02/2023

PROCEDURE: 01 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
10^{-1}	Nil	Nil	Nil
10^{-2}	Nil	Nil	Nil
	NA		
		28/01/2023	

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~~.

02/02/2023
Analysed By / Date:

Checked By / Date: 05/02/2023

APPENDIX V **ARLBL/MB/STP-013/FR-05**

TYMC BY POUR PLATE METHOD

Report No.	BG2023012500087	**Analysis Started Date**	28/01/2023
Culture ID	ATCC T.S 28/01/2023 ~~66331023~~ 1	**Analysis Completed Date**	04/02/2023

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-28/01/2023-0002 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^{-2}	Nil	Nil	Nil
	NA UCM 04/02/2023		

Negative Control: Growth ~~Observed~~ / Not observed

Positive control: Growth Observed / ~~Not observed~~

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

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

Analysed By / Date: FOR UCM 04/02/2023 **Checked By / Date:** 05/02/2023

APPENDIX I ARLBL/MB/STP-004/FR-01

STERILITY REPORT – MEMBRANE FILTERATION METHOD

Product	Artificial tears			Sample Quantity	09 Nos
Report No.	BQ20230125009B7	Batch No.	PCMJ006	No. of containers Tested	07 Nos
Test started on	16/02/2023	Test completed on	02/03/2023	Amount of sample used	10ml

TEST FOR BACTERIA	TEST FOR FUNGI
Fluid Thioglycollate Medium Lot no.: FTM- 13/02/2023-0019	Soya bean Casein Digest Medium Lot no.: SCDM- 13/02/2023-0017
Incubate at 30-35°C; ARL/BLEQ/BIC-005 for 14 days	Incubate at 20-25°C; ARL/BLEQ/BOD-004 for 14 days

Day	Date	Test Sample	Positive Control	Negative Control	Test Sample	Positive Control	Negative Control	Sign	Remarks
1st	17/02/2023	-ve	tve	-ve	-ve	tve	-ve	17/02/2023	Ok
2nd	18/02/2023	-ve	tve	-ve	-ve	tve	-ve	18/02/2023	Ok
3rd	19/02/2023	-ve	tve	-ve	-ve	tve	-ve	19/02/2023	Ok
4th	20/02/2023	-ve	tve	-ve	-ve	tve	-ve	20/02/2023	Ok
5th	21/02/2023	-ve	tve	-ve	-ve	tve	-ve	21/02/2023	Ok
6th	22/02/2023	-ve	tve	-ve	-ve	tve	-ve	22/02/2023	Ok
7th	23/02/2023	-ve	tve	-ve	-ve	tve	-ve	23/02/2023	Ok
8th	24/02/2023	-ve	tve	-ve	-ve	tve	-ve	24/02/2023	Ok
9th	25/02/2023	-ve	tve	-ve	-ve	tve	-ve	25/02/2023	Ok
10th	26/02/2023	-ve	tve	-ve	-ve	tve	-ve	26/02/2023	Ok
11th	27/02/2023	-ve	tve	-ve	-ve	tve	-ve	27/02/2023	Ok
12th	28/02/2023	-ve	tve	-ve	-ve	tve	-ve	28/02/2023	Ok
13th	01/03/2023	-ve	tve	-ve	-ve	tve	-ve	01/03/2023	Ok
14th	02/03/2023	-ve	tve	-ve	-ve	tve	-ve	02/03/2023	Ok

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

02/03/2023
Analysed by / Date:

Checked by / Date: 02/03/2023

Auriga Research

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. : NS
Submitted By : GLOBAL PHARMA HEALTHCARE PVT. LTD.
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
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>	<Results>	<Unit>	<Req.>	<Claim>	<LLOQ>	<Lower limit>	<Upper limit>	<Method>
Content of sodium Carboxy 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	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.

*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.

06/03/2023
Swathi.S
Authorized Signatory

COC Employee Wise Report

Auriga Research

Report Discard After 3 Years

Employee Name	sookta	**Department Name**	MICRO BIOLOGY

Product Name : ARTIFICIAL TEARS

Client Ref.No : NS

Report No. : BG202301250095

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 Department MICRO BIOLOGY, PHARMA CHEMICAL

Analyst 02/03/2023

02/03/2023

Checked & Authorised By

Date of start of analysis 16/02/2023

Date of end of analysis 02/03/2023

Reference To Protocol GPHC/SPEC-FP-DRP-A-079-00

Label NA

Sample not drawn by laboratory.

<Contents of>	Result	Unit	<Claim>	<Req.>	<LLOQ/LOD>	<Lower L>	<Upper L>	<Method>	NABL
4 Sterility	Complies	NA	-		-	-	-	USP <75>	

STERILITY REPORT – MEMBRANE FILTERATION METHOD

Product	Artificial tears			Sample Quantity	09 Nos
Report No.	DR20230125009S	Batch No.	PCMJ013	No. of containers Tested	07 Nos
Test started on	16/02/2023	Test completed on	02/03/2023	Amount of sample used	10ml

TEST FOR BACTERIA	TEST FOR FUNGI
Fluid Thioglycollate Medium Lot no.: FTM-13/02/2023-0018	Soya bean Casein Digest Medium Lot no.: SCDM-13/02/2023-0017
Incubate at 30-35°C; ARL/BLEQ/BIC-005 for 14 days	Incubate at 20-25°C; ARL/BLEQ/BOD-004 for 14 days

Day	Date	Test Sample	Positive Control	Negative Control	Test Sample	Positive Control	Negative Control	Sign	Remarks
1st	17/02/2023	-ve	tve	-ve	-ve	tve	-ve	17/02/2023	ok
2nd	18/02/2023	-ve	tve	-ve	-ve	tve	-ve	18/02/2023	ok
3rd	19/02/2023	-ve	tve	-ve	-ve	tve	-ve	19/02/2023	ok
4th	20/02/2023	-ve	tve	-ve	-ve	tve	-ve	20/02/2023	ok
5th	21/02/2023	-ve	tve	-ve	-ve	tve	-ve	21/02/2023	ok
6th	22/02/2023	-ve	tve	-ve	-ve	tve	-ve	22/02/2023	ok
7th	23/02/2023	-ve	tve	-ve	-ve	tve	-ve	23/02/2023	ok
8th	24/02/2023	-ve	tve	-ve	-ve	tve	-ve	24/02/2023	ok
9th	25/02/2023	-ve	tve	-ve	-ve	tve	-ve	25/02/2023	ok
10th	26/02/2023	-ve	tve	-ve	-ve	tve	-ve	26/02/2023	ok
11th	27/02/2023	-ve	tve	-ve	-ve	tve	-ve	27/02/2023	ok
12th	28/02/2023	-ve	tve	-ve	-ve	tve	-ve	28/02/2023	ok
13th	01/03/2023	-ve	tve	-ve	-ve	tve	-ve	01/03/2023	ok
14th	02/03/2023	-ve	tve	-ve	-ve	tve	-ve	02/03/2023	ok

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

02/03/2023
Analysed by / Date:

Checked by / Date: 02/03/2023

Book No.: 2038 Sl No.: 405354

RAW DATA SHEET

Report No.: ARL20230125009[illegible]	Booking date: 25/01/2023
Sample name: Artificial Tears	
Analysis Started Date: 31/01/2023	Analysis Completion Date: 31/01/2023

Test Parameters: Assay

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

Balance ID: ARL/BLEQ/AWB-012 Due Date of Calibration: 05/02/2023

Equipment/Instrument: ARL/BLEQ/UV-002 Due Date of Calibration: 29/03/2023

Equipment/instrument: NA 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
Instrument Id:ARL/BLEQ/AWB-012

1.25047 g
0.00010 g 1.25037 g

Date 31.01.2023
Time 8:53:24

31/01/2023
Signature

03/02/2023

Name	B.NO	Make
Diphenyl amine	120418	central drug house
Glacial acetic acid	7393941022	qualigens
Hydrochloric acid	9801021C	carlo erba

Reagent Preparation: Dissolved 1.25037 g of Diphenyl amine reagent in 50 ml of Glacial acetic acid and then added 30 ml of conc. Hydrochloric acid.

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

03/02/2023
Checked By (Sign & Date)

Calculation:

Working Mode carboxy methyl cellulose sodium Weighing
Date 31.01.2023
Time 9:22:34
Balance S/N 468671
Instrument Id:ARL/BLER/AWB-012

50.27 mg
0.14 mg 50.13 mg

Date 31.01.2023
Time 9:24:17

31/01/2023
Signature

03/02/2023

Standard Details :

Name : Carboxy methyl cellulose sodium
B.NO : GPLWS/079/21
valid upto : 12/10/2023

Standard Preparation : weighed 50.13 mg of carboxy methyl cellulose sodium WRS into a 100 ml volumetric flask, added water. slowly with swirling and then made to volume with water. mixed well.

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

Result : Procedure continued in Sl.NO : 406143

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

03/02/2023
Checked By (Sign & Date)

Book No.: 2042 Sl No.: 406148

RAW DATA SHEET

Report No.: EC20230125009 5	Booking date: 25/01/2023
Sample name: Artificial Tears	
Analysis Started Date: 31/01/2023	Analysis Completion Date: 31/01/2023

Test Parameters Assay

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

Balance ID: NA Due Date of Calibration: NA

Equipment/Instrument: NA Due Date of Calibration: NA

Equipment/instrument: ARL/BLEQ/UV-002 Due Date of Calibration: 29/03/2023

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

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

23/02/2023
Checked By (Sign & Date)

Calculation:

$$\text{Assay in \%} = \frac{\text{Sample Abs}}{\text{Standard Abs}} \times \frac{\text{Std wt in mg}}{100} \times \frac{100}{50} \times \frac{\text{Purity "CMC Sodium" on as is basis in w/w}}{100}$$

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

$$= 0.9796 \times 100$$

$$= 97.96\ \%$$

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

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

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

Result : Assay in % = 97.96 %

Assay in mg/ml = 9.80 mg/ml ✓

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

31/01/2023
Checked By (Sign & Date)

CHECKLIST FOR VERIFICATION OF ANALYTICAL REPORT

A) DETAILS OF SAMPLE			
Sample Name	Artificial tears		
Batch No.	RM3013	Date of start of Analysis	31/01/2023
Report No.		Date of Completion of Analysis	31/01/2023

B) DETAILS OF VEI BG2023012500 95

Sl. No.	Check points	Observation		
		Yes	No	NA
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			✓
10	Records / registers / validity of all volumetric solutions are reviewed and found satisfactory			✓
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:	NO		

Reviewed by / Date: 23/01/2023

Auriga Research Private Limited, Bangalore
QA ISSUED
Sign: Date: 25/01/2023

QUALITY ASSURANCE				
Sl. No.	Check points	Observation		
		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

Sl. No.	Observation No.	Details of observation by reviewer	Observed by sign. With date	Corrective Action taken
			NA 08/03/2023	
Remarks:				

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

08/03/2023
Verified by/ Date:

Auriga Research Private Limited, Bangalore,
QA ISSUED
Sign: Date: 25/04/2023

Photometric Sample Table

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

[Summary]

File Information
Filename: UV2023JAN - 13-82-1 - Assay sodium carboxy methyl cellulose(Artificial tears).vphd
Parameter File Name: UV2023JAN - Assay Sodium Carboxy methyl cellulose (Artificial Tears).vphm
Analyst: Harish HS
Date/Time: 31-01-2023 14:52:36
Comments:
Report File Name: UV2023JAN - PDFPhotometric.vrpt

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

Software Information
Software Name: LabSolutions UV-Vis
Version: 1.11

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

[Measurement Parameters]

[Wavelengths]
Type of Measuring Mode: Absorbance
rounded: OFF
Column Name: WL635.0
Measuring Method: Point (635.00nm)

[Formula]

[Unknown Sample]
Acquiring Method: Measurement
Repeat: OFF

[Instrument]
Slit Width: 1.0 nm
Accumulation Time (sec.): 0.1
Light Source Switch Wavelength: 340.00 nm

[Sample Table]

	Sample Name	Sample ID	WL635.0
1	Air Blank	Air Blank	0.000
2	Blank	Blank solution	0.023
3	Standard	Carboxy methyl cellulose sodium	0.330
4	Sample 01	BG202301250095	0.326
5	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

31/01/2023

02/03/02/2023

CHECKLIST FOR VERIFICATION OF MICROBIOLOGY REPORT

A) DETAILS OF SAMPLE			
Sample Name	Artificial Tears		
Batch No.	RMJ013	Date of start of Analysis	28/01/2023
Report No.		Date of Completion of Analysis	04/02/2023

B) DETAILS OF VE BG202301250095

Sl. No.	Check points	Observation		
		Yes	No	NA
1	Is the Microbiologist(s) performed all tests as per the specified Test Method / 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 prints for each test is enclosed and are verified			✓
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 mentioned in the COC & raw data sheet is matching	✓		
13	Any other observations: NA			

SL 05/02/2023

Reviewed by / Date:

SL 05/02/2023

Auriga Research Private Limited, Bangalore,
QA ISSUED
Sign: Date: 28/01/2023

QUALITY ASSURANCE				
Sl. No.	Check points	Observation		
		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

Sl. No.	Observation No.	Details of observation by reviewer	Observed by sign. With date	Corrective Action taken
			08/03/2023	

Remarks:

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

08/03/2023

Verified by/ Date:

Auriga Research Private Limited, Bangalore,
QA ISSUED
Sign: Date: 25/04/2023

Sample Name	Artificial tears	**Analysis Started Date**	28/01/2023
Report No.	BG2023012500095	**Analysis Completed Date**	~~01/02/2023~~ 04/02/2023

+0.i LKM 04/02/2023

SAMPLE PRE-ENRICHMENT (SOLUTION A):

10 ~~g~~/mL of sample dissolved in 90 mL of SCDM Lot No. SCDM-15/01/2023-0014

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}) $\xrightarrow{01\ ml}$ 9ml (10^{-2}) ⟶ ~~9ml (10^{-3})~~ ⟶ ~~9ml(10^{-4})~~ ⟶ ~~9ml (10^{-5})~~ ⟶ ~~9ml (10^{-6})~~

Weight Print(s):

NA

28/01/2023

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 hrs / 48 – 72 hrs.

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 28/01/2023

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—	
BIC Incubator (37°C)	ARL/BLEQ/BIC—	NA 1KM 04/02/2023
Water Bath (80°C)	ARL/BLEQ/WB—	

FOR 1KM 04/03/2023

Analysed By / Date:

Checked By / Date: SH 05/02/2023

APPENDIX IV **ARLBL/MB/STP-013/FR-04**

TAMC/TBC BY POUR PLATE METHOD

Report No.	BG2023012500095	**Analysis Started Date**	28/01/2023
Culture ID	ATCC 6633	**Analysis Completed Date**	02/02/2023

PROCEDURE: 01 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
10^{-1}	Nil	Nil	Nil
10^{-2}	Nil	Nil	Nil
	NA		
		02/02/2023	

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~~.

02/02/2023
Analysed By / Date:

Checked By / Date: 05/02/2023

APPENDIX V **ARLBL/MB/STP-013/FR-05**

TYMC BY POUR PLATE METHOD

Report No.	*T.E 28/01/2023 BA2023012950095 ~~Artificial tears~~.	**Analysis Started Date**	28/01/2023
Culture ID	ATCC 10231	**Analysis Completed Date**	04/02/2023

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- 28/01/2023-0002 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^{-2}	Nil	Nil	Nil
		NA UKM 04/02/2023	

Negative Control: Growth Observed / Not observed

Positive control: Growth Observed / ~~Not observed~~

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

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

Analysed By / Date: For UKM 04/02/2023 **Checked By / Date:** 05/02/2023

Auriga Research

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. : NS
Submitted By : GLOBAL PHARMA HEALTHCARE PVT. LTD.
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
PCMJ014	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>	<Results>	<Unit>	<Req.>	<Claim>	<LLOQ>	<Lower limit>	<Upper limit>	<Method>
Content of sodium Carboxy methyl cellulose :								
Assay in %	: 98.61	%	90.00 % to 110.00 %	- -	-	-	-	GPHC/STP-FP-DRP -A-079-00
Assay in mg/ml	: 9.86	mg/ml	9.00 mg/ml and 11.00 mg/ml	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.

*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.

08/03/2023
Sudhir S

Authorized Signatory

STERILITY REPORT – MEMBRANE FILTERATION METHOD

Product	Artificial tears			Sample Quantity	09 Nos
Report No.	BR20230125 0101	Batch No.	PCMJ014	No. of containers Tested	07 Nos
Test started on	16/02/2023	Test completed on	02/03/2023	Amount of sample used	10ml

TEST FOR BACTERIA	TEST FOR FUNGI
Fluid Thioglycollate Medium Lot no.: FTM-13/02/2023-0019	Soya bean Casein Digest Medium Lot no.: SCDM-13/02/2023-0017
Incubate at 30-35°C; ARL/BLEQ/BIC-005 for 14 days	Incubate at 20-25°C; ARL/BLEQ/BOD-004 for 14 days

Day	Date	Test Sample	Positive Control	Negative Control	Test Sample	Positive Control	Negative Control	Sign	Remarks
1st	17/02/2023	-ve	tve	-ve	-ve	tve	-ve	17/02/2023	ok
2nd	18/02/2023	-ve	tve	-ve	-ve	tve	-ve	18/02/2023	ok
3rd	19/02/2023	-ve	tve	-ve	-ve	tve	-ve	19/02/2023	ok
4th	20/02/2023	-ve	tve	-ve	-ve	tve	-ve	20/02/2023	ok
5th	21/02/2023	-ve	tve	-ve	-ve	tve	-ve	21/02/2023	ok
6th	22/02/2023	-ve	tve	-ve	-ve	tve	-ve	22/02/2023	ok
7th	23/02/2023	-ve	tve	-ve	-ve	tve	-ve	23/02/2023	ok
8th	24/02/2023	-ve	tve	-ve	-ve	tve	-ve	24/02/2023	ok
9th	25/02/2023	-ve	tve	-ve	-ve	tve	-ve	25/02/2023	ok
10th	26/02/2023	-ve	tve	-ve	-ve	tve	-ve	26/02/2023	ok
11th	27/02/2023	-ve	tve	-ve	-ve	tve	-ve	27/02/2023	ok
12th	28/02/2023	-ve	tve	-ve	-ve	tve	-ve	28/02/2023	ok
13th	01/03/2023	-ve	tve	-ve	-ve	tve	-ve	01/03/2023	ok
14th	02/03/2023	-ve	tve	-ve	-ve	tve	-ve	02/03/2023	ok

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

02/03/2023
Analysed by / Date:

Checked by / Date: 02/03/2023

Book No.: 2028 Sl No.: 405353

RAW DATA SHEET

Report No.: BQ202301250101	Booking date: 25/01/2023
Sample name: Artificial Tears	
Analysis Started Date: 31/01/2023	Analysis Completion Date: 31/01/2023

Test Parameters Assay

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

Balance ID: NA Due Date of Calibration: NA

Equipment/Instrument: ARL/BLEQ/UV-002 Due Date of Calibration: 29/03/2023

Equipment/instrument: NA Due Date of Calibration: NA

Weight of the Sample:

For Reagent Preparation refer BQ202301250095 - Sl. No: 405354
For Standard Preparation refer BQ202301250095 - Sl. 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 blanks, 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

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

03/02/2023
Checked By (Sign & Date)

Calculation:

$$\text{Assay in \%} = \frac{\text{Sample Abs}}{\text{Standard Abs}} \times \frac{\text{Std wt in mg}}{100} \times \frac{100}{50} \times \frac{\text{Purity "CMC Sodium" on as is basis in w/w}}{100}$$

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

$$= 0.9861 \times 100$$

$$= 98.61\ \%$$

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

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

$$= 9.86\ \text{mg/ml}$$

Result : Assay in % = 98.61 %.
Assay in mg/ml = 9.86 mg/ml ✓

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

31/01/2023
Checked By (Sign & Date)

CHECKLIST FOR VERIFICATION OF ANALYTICAL REPORT

A) DETAILS OF SAMPLE			
Sample Name	Artificial tears		
Batch No.	PAMJ014	**Date of start of Analysis**	31/01/2023
Report No.		**Date of Completion of Analysis**	31/01/2023

B) DETAILS OF BG202301250101

Sl. No.	Check points	Observation		
		Yes	No	NA
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			✓
10	Records / registers / validity of all volumetric solutions are reviewed and found satisfactory			✓
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:			NA

Reviewed by / Date: 31/01/2023

Auriga Research Private Limited, Bangalore
QA ISSUED
Sign: Date: 25/01/2023

QUALITY ASSURANCE				
Sl. No.	Check points	Observation		
		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

Sl. No.	Observation No.	Details of observation by reviewer	Observed by sign. With date	Corrective Action taken
			NA 08/03/2023	
Remarks:				

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

08/03/2023
Verified by/ Date:

Auriga Research Private Limited, Bangalore,
QA ISSUED
Sign: Date: 28/01/2023

Photometric Sample Table

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

[Summary]

File Information
Filename: UV2023JAN - 13-82-1 - Assay sodium carboxy methyl cellulose(Artificial tears).vphd
Parameter File Name: UV2023JAN - Assay Sodium Carboxy methyl cellulose (Artificial Tears).vphm
Analyst: Harish HS
Date/Time: 31-01-2023 14:52:36
Comments:
Report File Name: UV2023JAN - PDFPhotometric.vrpt

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

Software Information
Software Name: LabSolutions UV-Vis
Version: 1.11

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

[Measurement Parameters]

[Wavelengths]
Type of Measuring Mode: Absorbance
rounded: OFF
Column Name: WL635.0
Measuring Method: Point (635.00nm)

[Formula]

[Unknown Sample]
Acquiring Method: Measurement
Repeat: OFF

[Instrument]
Slit Width: 1.0 nm
Accumulation Time (sec.): 0.1
Light Source Switch Wavelength: 340.00 nm

[Sample Table]

	Sample Name	Sample ID	WL635.0
1	Air Blank	Air Blank	0.000
2	Blank	Blank solution	0.023
3	Standard	Carboxy methyl cellulose sodium	0.330
4	Sample 01	BG202301250095	0.326
5	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

31/01/2023

03/02/2023

CHECKLIST FOR VERIFICATION OF MICROBIOLOGY REPORT

A) DETAILS OF SAMPLE			
Sample Name	Artificial Tears		
Batch No.	RMJ 014	Date of start of Analysis	28/01/2023
Report No.		Date of Completion of Analysis	04/08/2023

B) DETAILS OF VE

BG202301250101

Sl. No.	Check points	Observation		
		Yes	No	NA
1	Is the Microbiologist(s) performed all tests as per the specified Test Method / 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 prints for each test is enclosed and are verified			✓
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 mentioned in the COC & raw data sheet is matching	✓		
13	Any other observations: CVA 05/02/2023			

05/02/2023

Reviewed by / Date:

Auriga Research Private Limited, Bangalore,
QA ISSUED
Sign: Date: 28/01/2023

QUALITY ASSURANCE				
Sl. No.	Check points	Observation		
		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

Sl. No.	Observation No.	Details of observation by reviewer	Observed by sign. With date	Corrective Action taken
			08/03/2023 NA	
Remarks:				

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

08/03/2023

Verified by/ Date:

Auriga Research P.V.T. Ltd., Bangalore
QA ISSUED
Sign: Date: 25/01/2023

Sample Name	*T-Eq 28/01/2023 Artificial tears. BG2023012501O1	**Analysis Started Date**	28/01/2023
Report No.	BG2023012501O1	**Analysis Completed Date**	04/02/2023

SAMPLE PRE-ENRICHMENT (SOLUTION A):

10 g/mL of sample dissolved in 90 mL of SCDM Lot No. SCDM-15/01/2023-0014

1 swab ⟶ 10mL of NA Lot No. NA

Dilutions can be prepared as per below flow chart A : SCDM-15/01/2023-0014

Solution A (10^{-1}) $\xrightarrow{01ml}$ 9ml (10^{-2}) ⟶ ~~9ml (10^{-3})~~ ⟶ ~~9ml(10^{-4})~~ ⟶ ~~9ml (10^{-5})~~ ⟶ ~~9ml (10^{-6})~~

Weight Print(s):

NA

28/01/2023

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 hrs / 48 – 72 hrs.

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

28/01/2023

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–	LKM 04/02/2023
Water Bath (80°C)	ARL/BLEQ/WB–	

For LKM 04/02/2023

Analysed By / Date:

Checked By / Date: SH 05/02/2023

TAMC/TBC BY POUR PLATE METHOD

Report No.	BG2023012501O1	**Analysis Started Date**	28/01/2023
Culture ID	ATCC 6633	**Analysis Completed Date**	02/02/2023

PROCEDURE: 01 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
10^{-1}	Nil	Nil	Nil
10^{-2}	Nil	Nil	Nil
	NA		

02/02/2023

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~~.

02/02/2023
Analysed By / Date:

Checked By / Date: 05/02/2023

APPENDIX V **ARLBL/MB/STP-013/FR-05**

TYMC BY POUR PLATE METHOD

Report No.	BL2023012501O1	**Analysis Started Date**	28/01/2023
Culture ID	ATCC 10231	**Analysis Completed Date**	04/02/2023

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- 28/01/2023-0002 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^{-2}	Nil	Nil	Nil
	NA		
	UKM 04/02/2023		

Negative Control: Growth ~~Observed~~ / Not observed

Positive control: Growth Observed / ~~Not observed~~

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

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

Analysed By / Date: For UKM 04/02/2023 **Checked By / Date:** 05/02/2023

Auriga Research

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
Ref. No. : NS
Submitted By : GLOBAL PHARMA HEALTHCARE PVT. LTD.
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
PCMJ015	APR 2022	MAR 2025	204 Ltr	12 Bottles

Sample ID : BG202301250103 **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>	<Results>	<Unit>	<Req.>	<Claim>	<LLOQ>	<Lower limit>	<Upper limit>	<Method>
Content of sodium Carboxy methyl cellulose :								
Assay in %	: 98.61	%	90.00 % to 110.00 %	- -	-	-	-	GPHC/STP-FP-DRP -A-079-00
Assay in mg/ml	: 9.86	mg/ml	9.00 mg/ml and 11.00 mg/ml	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.

*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.

08/03/2023
Authorized Signatory

Book No.: 2038 Sl No.: 405352

RAW DATA SHEET

Report No.: BG20230125010 3	Booking date: 25/01/2023
Sample name: Artificial Tears	
Analysis Started Date: 31/01/2023	Analysis Completion Date: 31/01/2023

Test Parameters: Assay

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

Balance ID: NA — Due Date of Calibration: NA

Equipment/Instrument: ARL/BLEQ/UV-002 — Due Date of Calibration: 29/03/2023

Equipment/instrument: NA — Due Date of Calibration: NA

Weight of the Sample:

For Reagent Preparation refer BG2023012500 95 - Sl.No: 405354
For standard Preparation refer BG2023012500 95 - Sl.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 into 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

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

03/02/2023
Checked By (Sign & Date)

Calculation:

$$\text{Assay in \%} = \frac{\text{Sample Abs}}{\text{Standard Abs}} \times \frac{\text{Std wt in mg}}{100} \times \frac{100}{50} \times \frac{\text{Purity "cmc Sodium" on as is basis in w/w}}{100}$$

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

$$= 0.9861 \times 100$$

$$= 98.61\ \%$$

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

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

$$= 9.86\ \text{mg/ml}$$

Result : Assay in % = 98.61 %.

Assay in mg/ml = 9.86 mg/ml

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

03/02/2023
Checked By (Sign & Date)

03/02/2023

CHECKLIST FOR VERIFICATION OF ANALYTICAL REPORT

A) DETAILS OF SAMPLE			
Sample Name	Artificial tears		
Batch No.	PEMJ 015	Date of start of Analysis	31/01/2023
Report No.		Date of Completion of Analysis	31/01/2023

B) DETAILS OF VEI

BG202301250103

Sl. No.	Check points	Observation		
		Yes	No	NA
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			✓
10	Records / registers / validity of all volumetric solutions are reviewed and found satisfactory			✓
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:			nil

Reviewed by / Date: 31/01/2023

Auriga Research Private Limited, Bangalore,
QA ISSUED
Sign: Date: 28/01/2023

QUALITY ASSURANCE				
Sl. No.	Check points	Observation		
		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

Sl. No.	Observation No.	Details of observation by reviewer	Observed by sign. With date	Corrective Action taken
			NA 08/03/2023	
Remarks:				

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

08/03/2023
Verified by/ Date:

Auriga Research Private Limited, Bangalore,
QA ISSUED
Sign: Date: 25/01/2023

Photometric Sample Table

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

[Summary]

File Information
Filename: UV2023JAN - 13-82-1 - Assay sodium carboxy methyl cellulose(Artificial tears).vphd
Parameter File Name: UV2023JAN - Assay Sodium Carboxy methyl cellulose (Artificial Tears).vphm
Analyst: Harish HS
Date/Time: 31-01-2023 14:52:36
Comments:
Report File Name: UV2023JAN - PDFPhotometric.vrpt

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

Software Information
Software Name: LabSolutions UV-Vis
Version: 1.11

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

[Measurement Parameters]

[Wavelengths]
Type of Measuring Mode: Absorbance
rounded: OFF
Column Name: WL635.0
Measuring Method: Point (635.00nm)

[Formula]

[Unknown Sample]
Acquiring Method: Measurement
Repeat: OFF

[Instrument]
Slit Width: 1.0 nm
Accumulation Time (sec.): 0.1
Light Source Switch Wavelength: 340.00 nm

[Sample Table]

	Sample Name	Sample ID	WL635.0
1	Air Blank	Air Blank	0.000
2	Blank	Blank solution	0.023
3	Standard	Carboxy methyl cellulose sodium	0.330
4	Sample 01	BG202301250095	0.326
5	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

31/01/2023

03/02/2023

CHECKLIST FOR VERIFICATION OF MICROBIOLOGY REPORT

A) DETAILS OF SAMPLE			
Sample Name	Artificial tears		
Batch No.	RMJ015	**Date of start of Analysis**	28/01/2023
Report No.		**Date of Completion of Analysis**	04/02/2023

B) DETAILS OF VER

BG202301250103

Sl. No.	Check points	Observation		
		Yes	No	NA
1	Is the Microbiologist(s) performed all tests as per the specified Test Method / 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 prints for each test is enclosed and are verified			✓
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 mentioned in the COC & raw data sheet is matching	✓		
13	Any other observations: N/A			

05/02/2023

Reviewed by / Date:

Auriga Research Private Limited, Bangalore,
QA ISSUED
Sign: Date: 20/01/2023

QUALITY ASSURANCE				
Sl. No.	Check points	Observation		
		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

Sl. No.	Observation No.	Details of observation by reviewer	Observed by sign. With date	Corrective Action taken
			08/03/2023	

Remarks:

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

08/03/2023

Verified by/ Date:

Auriga Research Private Limited, Bangalore
QA ISSUED
Sign: Date: 25/01/2023

Sample Name	Artificial tears.	**Analysis Started Date**	28|01|2023
Report No.	BG202301250103	**Analysis Completed Date**	04|01|2023

SAMPLE PRE-ENRICHMENT (SOLUTION A):

10 ml. ~~g/mL~~ of sample dissolved in 90 mL of SCDM Lot No. SCDM- 15\|01\|2023-0014

*T.E 28\|01\|2023

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}) $\xrightarrow{01}$ 9ml (10^{-2}) → 9ml (10^{-3}) → 9ml(10^{-4}) → 9ml (10^{-5}) → 9ml (10^{-6})

Weight Print(s):

NA

28\|01\|2023

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 hrs / 48 – 72 hrs.

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 28/01/2023

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—	04/02/2023
Water Bath (80°C)	ARL/BLEQ/WB—	

FOR 04/02/2023

Analysed By / Date:

Checked By / Date: 05/02/2023

APPENDIX IV **ARLBL/MB/STP-013/FR-04**

TAMC/TBC BY POUR PLATE METHOD

Report No.	BG20230125 0103	**Analysis Started Date**	28/01/2023
Culture ID	ATCC 6633	**Analysis Completed Date**	~~02/01/2023~~ 02/02/2023 *T.G 02/02/2023

PROCEDURE: 01 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
10^{-1}	Nil	Nil	Nil
10^{-2}	Nil	Nil	Nil
	NA		
		02/01/2023	

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~~.

02/01/2023
Analysed By / Date:

Checked By / Date: 05/02/2023

APPENDIX V **ARLBL/MB/STP-013/FR-05**

TYMC BY POUR PLATE METHOD

Report No.	BG2023012S0103	**Analysis Started Date**	28/01/2023
Culture ID	ATCC 10231	**Analysis Completed Date**	04/01/2023

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- 28/01/2023-0002 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^{-2}	Nil	Nil	Nil
		NA LKM 04/02/2023	

Negative Control: Growth ~~Observed~~ / Not observed

Positive control: Growth Observed / ~~Not observed~~

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

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

Analysed By / Date: FOR LKM 04/02/2023

Checked By / Date: 05/02/2023

STERILITY REPORT – MEMBRANE FILTERATION METHOD

Product	Artificial tears			Sample Quantity	09 Nos
Report No.	BR20230125O103	Batch No.	PCMJO1S	No. of containers Tested	07 Nos
Test started on	16/02/2023	Test completed on	02/03/2023	Amount of sample used	10ml

TEST FOR BACTERIA	TEST FOR FUNGI
Fluid Thioglycollate Medium Lot no.: FTM-13/02/2023-0018	Soya bean Casein Digest Medium Lot no.: SCDM-13/02/2023-0017
Incubate at 30-35°C; ARL/BLEQ/BIC-005 for 14 days	Incubate at 20-25°C; ARL/BLEQ/BOD-004 for 14 days

Day	Date	Test Sample	Positive Control	Negative Control	Test Sample	Positive Control	Negative Control	Sign	Remarks
1st	17/02/2023	-ve	tve	-ve	-ve	tve	-ve	17/02/2023	ok
2nd	18/02/2023	-ve	tve	-ve	-ve	tve	-ve	18/02/2023	ok
3rd	19/02/2023	-ve	tve	-ve	-ve	tve	-ve	19/02/2023	ok
4th	20/02/2023	-ve	tve	-ve	-ve	tve	-ve	20/02/2023	ok
5th	21/02/2023	-ve	tve	-ve	-ve	tve	-ve	21/02/2023	ok
6th	22/02/2023	-ve	tve	-ve	-ve	tve	-ve	22/02/2023	ok
7th	23/02/2023	-ve	tve	-ve	-ve	tve	-ve	23/02/2023	ok
8th	24/02/2023	-ve	tve	-ve	-ve	tve	-ve	24/02/2023	ok
9th	25/02/2023	-ve	tve	-ve	-ve	tve	-ve	25/02/2023	ok
10th	26/02/2023	-ve	tve	-ve	-ve	tve	-ve	26/02/2023	ok
11th	27/02/2023	-ve	tve	-ve	-ve	tve	-ve	27/02/2023	ok
12th	28/02/2023	-ve	tve	-ve	-ve	tve	-ve	28/02/2023	ok
13th	01/03/2023	-ve	tve	-ve	-ve	tve	-ve	01/03/2023	ok
14th	02/03/2023	-ve	tve	-ve	-ve	tve	-ve	02/03/2023	ok

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

02/03/2023
Analysed by / Date:

Checked by / Date: 02/03/2023