	INNOVA PHARMACTIVE PVT. LTD.		MASTER COPY	
	TEST DATA SHEET			Authorized By / Date :
	Specification No.	IP/QCD/MBS/001(Revision No. 05)		M 27/08/2024
Product Name	Microbiology analysis of Finish Product			Issued By /
Batch No.	CAR 25126			Date : 27/08/2025
A.R. No.	QM25129			Page No. 1 of 7

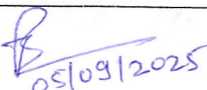
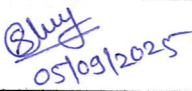
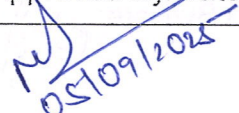
• Test Summary Report


Sampling Date	28/08/2025	Batch size	26.50 kg
Release Date	05/09/2025	Date of Mfg.	AUG 2025
		Date of Retest/Expiry	JUL 2029

Sr.No.	Test	Specification	Result
1.	Total Viable Count		
	A) Total Aerobic Microbial Count (TAMC)	Not more than 1000 CFU/gm	Nil
	B) Total Yeast and Mould Count (TYMC)	Not more than 100 CFU/gm	Nil
2.	Test for Specified organisms		
	A) Escherichia coli	Should be absent/gm of sample	Absent
	B) Salmonella abony	Should be absent/10gms of sample	Absent
	C) Staphylococcus aureus	Should be absent/gm of sample	Absent
	D) Pseudomonas aeruginosa	Should be absent/gm of sample	Absent

CFU- Colony Forming unit

Remarks: The Sample Complies / Does not complies as per the specification No. IP/QCD/MBS/001.

Tested By/Date:	Reviewed By/Date	Approved By/Date
 05/09/2025	 05/09/2025	 05/09/2025

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	Specification No.	IP/QCD/MBS/001(Revision No. 05)		29/09/2025
Product Name	Microbiology analysis of Finish Product			Issued By /
Batch No.	CAR25126			Date : 29/08/2025
A.R. No.	am25129			Page No. 2 of 7

1.0 TOTAL VIABLE COUNT:

A) Total aerobic microbial count(TAMC):

Date: 29/08/2025






Media batch No: BSCDB 131/25

Balance No: IP/QCD/ELB/ 022

Preparation of Sample: 29/08/2025

Take approximate 10 g sample; add to 90ml Soyabean Casein Digest broth with 0.1 % polysorbate 80 (solution A) Shake to dissolve or ensure uniform suspension is formed.

Observation Table for TAMC:

Media Batch No: MSCDA 092/25			Incubator No: IP/QCD/BOD/ 027		
Incubation started on : 29/08/2025			Incubation Completed on: 03/09/2025		
Name of culture used: B. subtilis (BGLM, w4D1)			Instrument No.: IP/QCD/COL/ 045		
Period	Day 1 CFU/gm	Day 2 CFU/gm	Day 3 CFU/gm	Day 4 CFU/gm	Day 5 CFU/gm
SCDA Plate 1	00	00	00	00	00
SCDA Plate 2	00	00	00	00	00
Maximum CFU/gm	00	00	00	00	00
Sign & Date	 30/08/2025	 31/08/2025	 01/09/2025	 02/09/2025	 03/09/2025

CFU/gm of sample:

Total aerobic microbial count(TAMC)/gm= Average No. of colony obtained x dilution factor


Weight of Sample


Total aerobic microbial count(TAMC)/gm= 00 x 90 / 10 = 00 CFU/gm.


For SCDA – Positive control : Growth observed/No growth observed

Negative control: Growth observed/No growth observed

Test Sample: Complies / Not Complies with the In-House specification

Tested By/Date: 
03/09/2025

Reviewed By/Date:  05/09/2025

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	Specification No.	IP/QCD/MBS/001(Revision No. 05)		
Product Name	Microbiology analysis of Finish Product			Issued By /
Batch No.	CAR25126			Date : 27/08/2025
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B) Total Yeast and Mould Count: (TYMC)

Date: 29/08/2025

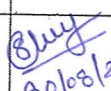
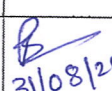
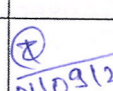
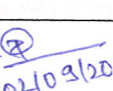
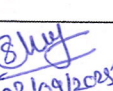
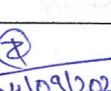
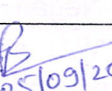
Media batch No: BSCDB 131/25

Balance No: IP/QCD/ELB/ 022

Preparation of Sample: 29/08/2025

Take approximate 10 gm sample; add to 90ml Soyabean Casein Digest broth with 0.1 % polysorbate 80. (Solution A). Shake to dissolve or ensure uniform suspension is formed.

Observation Table for TYMC:

Media Batch No: MSDA 055/25				Incubator No: IP/QCD/BOD/ 039			
Incubation started on : 29/08/2025				Incubation Completed on: 05/09/2025			
Name of culture used: C. abican (C. m4w4D)				Instrument No.: IP/QCD/COL/ 045			
Period	Day 1 CFU/gm	Day 2 CFU/gm	Day 3 CFU/gm	Day 4 CFU/gm	Day 5 CFU/gm	Day 6 CFU/gm	Day 7 CFU/gm
SCDA Plate 1	00	00	00	00	00	00	00
SCDA Plate 2	00	00	00	00	00	00	00
Maximum CFU/gm	00	00	00	00	00	00	00
Sign & Date	 30/08/2025	 31/08/2025	 01/09/2025	 02/09/2025	 03/09/2025	 04/09/2025	 05/09/2025

CFU/gm of sample:

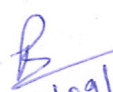
Total Yeast and Mould count (TYMC)/gm = $\frac{\text{Average No. of colony obtained} \times \text{dilution factor}}{\text{Weight of Sample}}$

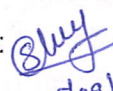
Total Yeast and Mould count(TYMC)/gm = $\frac{00 \times 90}{10} = 00$ CFU/g.


For SDA – Positive control : Growth observed/No-growth observed

Negative control: Growth observed/No growth observed

Test Sample: Complies / Not-Complies with the In-House specification.

Tested By/Date: 
05/09/2025

Reviewed By/Date: 
05/09/2025

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	TEST DATA SHEET		Authorized By / Date : <u>HJ 07/09/2024</u>	
Specification No.	IP/QCD/MBS/001(Revision No. 05)			
Product Name	Microbiology analysis of Finish Product		Issued By / <u>[Signature]</u>	
Batch No.	<u>CAR 25126</u>		Date : <u>27/08/2025</u>	
A.R. No.	<u>QM25129</u>		Page No.	4 of 7

2.0 TEST FOR SPECIFIED ORGANISMS

Sample preparation Date: 29/08/2025

Media Batch No of Soyabean Casein Digest broth: BSCDB 131125

Incubator No: IP/QCD/BOD/ 027 Balance No: IP/QCD/ELB/ 022

Sample preparation for E.coli, Staphylococcus aureus, Pseudomonas aeruginosa

Aseptically transfer 1 g of sample into 9 ml (1:10) of Soyabean Casein Digest broth with 0.1 % polysorbate 80. (Solution B) Homogenize and incubate at 30°C to 35°C for 18 to 24 hours.

A) Escherichia coli :

Selection and Subculture:

After incubation aseptically transfer 1 of (Solution B) into 100 ml of sterile pre-incubated MacConkey Broth (Solution C), and incubate at 42-44°C for 24-48 hrs.

Observation Table 1:

Media Batch No of MacConkey Broth : <u>BMAC 123125</u>		
Incubator No: IP/QCD/BOD/ <u>057</u>		Incubation started on : <u>30/08/2025</u>
Name of Culture used: <u>E.coli (E. coli M12)</u>		Incubation Completed on: <u>01/09/2025</u>
Yellow coloration of media with turbidity		Remarks
Test Sample	Turbidity Present/Absent	<u>complies</u>
Positive control	Turbidity Present/Absent	
Negative control	Turbidity Present/Absent	

After incubation of MacConkey broth subculture it on MacConkey agar plate, invert and incubate the plates at 30°-35°C for 18-72 hrs.


Observation table 2:

Media Batch No of MacConkey Agar : <u>MMAC 013125</u>		
Incubator No: <u>IP/QCD/BOD/027</u>		Incubation started on : <u>01/09/2025</u>
Name of Culture used: <u>E.coli (E. coli M12)</u>		Incubation Completed on: <u>04/09/2025</u>
Bright pink smooth mucoid colonies		Remarks
Test Sample	Present/Absent	<u>complies</u>
Positive control	Present/Absent	
Negative control	Present/Absent	

Confirmatory test:

Indole test: Transfer the suspected colonies by means of inoculating loop in the tube containing 5ml of 0.1 % sterile peptone water. Incubate the peptone tube at 30°– 35°C for 18 – 24 hours. After incubation shake and add 0.5ml of Kovac's reagent and allow it to stand for 1 minute.

Observation: Cherry red colour indole ring produced/ not produced.

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	TEST DATA SHEET		Authorized By / Date : <u>M/ 02/09/2025</u>	
Specification No.		IP/QCD/MBS/001(Revision No. 05)		
Product Name	Microbiology analysis of Finish Product		Issued By /	<u>12</u>
Batch No.	<u>CAR25126</u>		Date :	<u>27/08/2025</u>
A.R. No.	<u>QM25129</u>		Page No.	5 of 7

Test Sample: E.coli Present / Absent per gram of the test sample.

Tested By/Date: Ⓟ 04/09/2025

Reviewed By/Date:

Ⓟ 05/09/2025

B) Salmonella abony:

Sample preparation Date: 29/08/2025

Media Batch No of Soyabean Casein Digest broth: BSCDB 131125

Incubator No: IP/QCD/BOD/ 027

Balance No: IP/QCD/ELB/ 022

Sample preparation:

Aseptically transfer 1 g of sample into 9 ml (1:10) Soyabean casein digest broth with 0.1 % polysorbate 80 (solution D). Shake to dissolve and incubate at 30-35°C for 18-24hrs

Selection and Subculture:

After 18 to 24 hours, shake the tube and transfer 0.1ml of (solution D) to 10 ml of Rappaport Vassiliadis Salmonella enrichment broth, and incubate at 30-35°C for 18-24hrs.

Observation Table 1:

Media Batch No of Rappaport Vassiliadis Salmonella enrichment broth: <u>BRVSE 041125</u>		
Incubator No: IP/QCD/BOD/ <u>027</u>		Incubation started on : <u>30/08/2025</u>
Name of Culture used: <u>S.abony (S_a3M1W4D₂)</u>		Incubation Completed on: <u>31/08/2025</u>
Milky turbid appearance		Remarks
Test Sample	Milky turbidity Present/Absent	<u>complies</u>
Positive control	Milky turbidity Present/Absent	
Negative control	Milky turbidity Present/Absent	

After incubation of Rappaport Vassiliadis Salmonella enrichment broth subculture it with the help of inoculating needle on Xylose lysine deoxycholate agar plate, invert and incubate the plates at 30°-35°C for 18-48 hrs.


Observation table 2:

Media Batch No of Xylose lysine deoxycholate agar: <u>MXLDA 122/25</u>		
Incubator No: IP/QCD/BOD/ <u>027</u>		Incubation started on : <u>31/08/2025</u>
Name of Culture used: <u>S.abony (S_a3M1W4D₂)</u>		Incubation Completed on: <u>02/09/2025</u>
Growth of Red with or without black centers colonies observed		Remarks
Test Sample	Present/Absent	<u>complies</u>
Positive control	Present/Absent	
Negative control	Present/Absent	

Confirmatory test:

Triple sugar Iron agar (TSI test): Transfer aseptically the suspected colonies from

NA
Ⓟ 02/09/2025

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	TEST DATA SHEET			Authorized By / Date : <u>NA</u> <u>02/09/2025</u>
Specification No.		IP/QCD/MBS/001(Revision No. 05)		
Product Name	Microbiology analysis of Finish Product			Issued By / <u>NA</u>
Batch No.	<u>CAR25126</u>			Date : <u>27/08/2025</u>
A.R. No.	<u>QM25129</u>			Page No. 6 of 7

Xylose lysine deoxycholate agar plate to TSI agar by first stabbing through the center of the slant till the bottom of the tube and then streaking on the surface of the agar slant; incubate the tube at 30°-35°C for 18 to 24 hrs. NA 02/09/2025

Observation: Triple sugar Iron agar slant shows/does not show red slant, yellow butt with gas production and blacking of butt.

Test Sample: Salmonella abony Present / Absent per 10 gram of the test sample

Tested By /Date: NA 02/09/2025

Reviewed By/Date: Bluy 05/09/2025

C) Staphylococcus aureus:

Sample preparation Date: 29/08/2025

Media Batch No of Soyabean Casein Digest broth: BSCDB 131/25

Incubator No: IP/QCD/BOD/ 027

Balance No: IP/QCD/ELB/ 022

Observation Table 1:

Media Batch No of Mannitol salt agar: <u>MMSA 123/25</u>		
Incubator No: IP/QCD/BOD/ <u>027</u>		Incubation started on : <u>30/08/2025</u>
Name of Culture used: <u>S.aureus (Staphylococcus aureus)</u>		Incubation Completed on: <u>02/09/2025</u>
Yellow/White colonies with yellow zones		Remarks
Sample	Present/Absent	<u>complies</u>
Positive control	Present/Absent	
Negative control	Present/Absent	

Confirmatory test:

Coagulase test:

Rehydrate the contents of one vial aseptically with 3 ml sterile purified water. Take 0.5 ml of rehydrated plasma in a test tube. Suspend the suspected colonies in the test tube containing approximately 0.5 ml of rehydrated plasma. Mix gently & incubate at 37°C in incubator or water bath for up to 4 hours.


Observation :

Coagulation is observed/ not observed in the sample preparation. NA 02/09/2025

Test Sample: Staphylococcus aureus Present / Absent per gram of the test sample

Tested By/Date: NA 02/09/2025

Reviewed By/Date: Bluy 05/09/2025

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	Specification No.	IP/QCD/MBS/001(Revision No. 05)		02/09/2025
Product Name	Microbiology analysis of Finish Product			Issued By /
Batch No.	CAR 25126			Date : 27/08/2025
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D) Pseudomonas aeruginosa:

Sample preparation Date: 29/08/2025

Media Batch No of Soyabean Casein Digest broth: BSCDB 131/25

Incubator No: IP/QCD/BOD/ 027

Balance No: IP/QCD/ELB/ 022

Observation Table 1:

Media Batch No of Cetrimide agar: MCA 123/25		
Incubator No: IP/QCD/BOD/ 027	Incubation started on : 30/08/2025	
Name of Culture used: P. aeruginosa (Pa, m410, B)	Incubation Completed on: 02/09/2025	
Greenish colonies, greenish fluorescent under UV light		Remarks
Sample	Present/Absent	complies
Positive control	Present/Absent	
Negative control	Present/Absent	

Confirmatory test:

Oxidase test: Transfer the suspected colonies by means of an inoculating loop on a ready to use oxidase discs (N N- dimethyl-p-phenylenediamine oxalate.)

Observation:

The test is positive if purple colour is produced/ not produced within 5-10 seconds.

Test sample: Pseudomonas aeruginosa Present / Absent per gram of the test sample.

Tested By /Date: 02/09/2025

Reviewed By/Date: 05/09/2025

Raw data are attached with the Test Data Sheet. If applicable.

Comment: No

Conclusion: The above sample Complies / Does not Complies with the tests as per specification No. IP/QCD/MBS/001.

Approved By :

Date:

05/09/2025