



PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Microbiological results Expression and Release Policy

SOP No.:		Department:	Microbiology
		Effective Date:	
Revision No.:	00	Revision Date:	
Supersede Revision No.:	Nil	Page No.:	1 of 3

1.0 PURPOSE:

To lay down the procedure to express microbiological test results and the test release policy.

2.0 SCOPE:

This is applicable to microbiology lab.

3.0 RESPONSIBILITY:

Microbiology personnels.

4.0 PROCEDURE:

4.1 Microbiological results expression policy

4.1.1 One single bacteria forms into one colony, is known as CFU (colony forming units) in a single plate shall be expressed in units “No’s”.

E.g.: 1, 2, 3.and so on.

4.1.2 If no colony observed it shall be expressed in “Nil” or “0” CFU.

4.1.3 When microbial colonies on set of duplicate plates observed and average results gives in decimals, it shall be rounded off to the nearest higher count. E.g.: When duplicate plate results into 1 & 2 then they will give the average of 1.5, it will be rounded as 2.

4.1.4 When microbial observation to be given in average of the set of results, it shall be first average the set of results with the No. of units taken. Then the results shall be expressed as observed average number.

4.1.5 When a single colony observed in one of the plate and no colony observed in the other plate. Then the results observed in single plate will be averaged and results shall be given as “less than 1” (<1).



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4.1.6 When test performed with diluting the sample and plated. The observed results shall be averaged first. Then the dilution factor shall be multiplied with the average results observed. If no colony is observed in either plate, then report the results as less than the dilution factor.

4.1.7 When diluted and tested sample results show one plate count and the other plate “NIL” CFU. Then average the both results and multiplied with dilution factor.

E.g.: One plate count is 5, the other plate count is 7 and dilution factor 10 then Average will be 6 and results will be

$$“6 \times \text{Dilution factor } 10” = 60 \text{ CFU}$$

E.g.: One plate count is 1, the other plate count is 0 and dilution factor 10 then Average will be 0.5 and results will be

$$“0.5 \times \text{Dilution factor } 10” = 5 \text{ CFU}$$

4.2 Bacterial endotoxin test results expression policy

4.2.1 Bacterial endotoxin test results shall be expressed in “EU” / “IU” units.

4.2.2 The observed bacterial endotoxin test results shall be expressed as it is. When the test performed up to its validation concentration / dilution, then the results shall be of its highest release possibility.

E.g.: For a product the endotoxin limit is of 0.2 EU / mg

$$\text{MVC:} \quad \frac{\text{Lysate sensitivity}}{\text{Endotoxin limit}}$$

$$\text{Test released at:} \quad \frac{\text{Lysate sensitivity}}{\text{Test concentration}}$$

If the test lysate used for the test is 0.06 EU / mL,

MVC will be 0.3 mg / mL.

2 MVC will be 0.6 mg / mL. (MVC x 2)

4 MVC will be 0.12 mg / mL. (MVC x 4) and so on.



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When the test released at its highest possible sensitivity, the results shall express as below

Test shall be release At	MVC	0.2 EU/mg
		2 MVC 0.1 EU/mg
	4 MVC	0.05 EU/mg and so on.

4.3 Microbiological test release policy

- 4.3.1 When microbiological test results are part of release criteria, then the results shall be forwarded to concerned department for proceeding to further steps of the process.
- 4.3.2 These results shall give against the form “Test request slip” Form.
- 4.3.3 When the results shall be given from microbiology section, against SOP for Water, EMP, Media fill reports and other miscellaneous reports, the results shall add into “Respective formats” / “Technical information sheet”- Form.
- 4.3.4 The results sheet shall be duly comprise “Done by” and “Checked by” signatures for its correctness.
- 4.3.5 These results shall be forwarded to concerned department for its further proceedings or for record.

5.0 ANNEXURE / ATTACHMENTS:

None.

6.0 REVISION LOG:

Revision Number	Effective Date	Reason for Revision