



PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

**VALIDATION REPORT FOR EVALUATION OF SAMPLE SIZE FOR MICROBIOLOGICAL
ANALYSIS OF PURIFIED WATER**

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PURIFIED WATER**



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REPORT APPROVAL SHEET

Prepared by

Functional Area	Name	Designation	Signature	Date
Microbiology				

Checked by

Functional Area	Name	Designation	Signature	Date
In charge, Microbiology				
Quality Assurance				

Approved by

Functional Area	Name	Designation	Signature	Date
Head, Quality Control				
Head, Quality Assurance				



VALIDATION REPORT FOR EVALUATION OF SAMPLE SIZE FOR MICROBIOLOGICAL ANALYSIS OF PURIFIED WATER

**Evaluation of Sample size for Microbiological Analysis of Purified Water
DATA SHEET**

Sampling Point Name:

Sampled on & Time:

Analyzed on & Time:

Method of Analysis: Pour Plate Method/Membrane Filtration Technique

Autoclave ID No.:

Media Lot No.:

Sampling Point No.:

Sampled By:

Analyzed By:

Analyzed Sample Quantity:

LAF ID No.:

Incubator ID No.:

Date	Incubation Time	Observation (Sample)				Positive Control	Negative Control	Observed By	Remarks
		Plate – 1	Plate – 2	Plate – 3	Average (Cfu / __ml)				
	After 24 hours								
	After 48 hours								
	After 72 hours								
	After 96 hours								
	After 120 hours								

Checked By:

Date:



**VALIDATION REPORT FOR EVALUATION OF SAMPLE SIZE FOR
MICROBIOLOGICAL ANALYSIS OF PURIFIED WATER**

Summary & Conclusion:

The study for Evaluation of Sample Size for Microbial Analysis of Purified Water carried out for consecutive one month (30 days) on different sampling points. (Purified Water Storage Tank Outlet), (Purified Water Return from Distribution) and (User Point in Coating), using 1 ml sample by pore plate method and 10, 50 and 100 ml sample using Membrane Filtration Technique.

During the study it has been concluded that 10 ml is the suitable sample size to enumerate the microbial counts in Purified Water by using membrane filtration technique because in 10 ml sample the recovery is more accurate as compare to 1 ml by pore plate method. While in 50 ml and 100 ml sample the accurate counting is not possible due to dens growth on the membrane filter.

Hence it is concluded that Membrane Filtration Technique, using 10 ml sample is suitable method for Microbiological Analysis of Purified Water.

Prepared By
Date
(Microbiologist)

Checked By
Date
(Quality Assurance)