

**Sterilization efficacy Validation test report for
MEDTraceNX's Vaporizer + Sterilizer Product
(Model: STX021)**

Name of the company MEDTraceNX Health OPC Private Limited, Bangalore
Product Name Vaporizer + Sterilizer
Model number STX021 (Multi-color)
Test Registration number 258-2018-10003236-3250
Test Start date 09/10/2018
Test End date 12/10/2018

Test: Study the killing efficacy of food borne pathogens in baby feeding bottles /Baby bottles by **Vaporizer + Sterilizer** product of MEDtraceNX Health OPC Private Limited, Bangalore.

Procedure:

- Bacterial cell concentration of E.coli, Salmonella, Pseudomonas Aeruginosa, is prepared and as per the McFarland standard 1.
- Above cultures is diluted to 1000cfu for the inoculation and same is plated and documented.
- Five to ten ml of the 1000cfu cells is inoculated to baby bottles and inoculated bottles are sterilized in MEDtraceNX's **Vaporizer+Sterilizer** product for the spike recovery. Bottles are exposed to steam for 4, 8 and 10 minutes.
- Treated bottles are plated for the recovery and Log reductions calculated.

Test Results:-

Bacterial cell concentration		Test Results @ Sterilization time (Minutes)		
Testing Bacterial cell	Cfu/ml	4 Minutes	8 Minutes	10 Minutes
E.coli Initial count	6.4x10 ³	< 1 Cfu/ml	< 1 Cfu/ml	< 1 Cfu/ml
Salmonella Initial count	7.9x10 ³	< 1 Cfu/ml	< 1 Cfu/ml	< 1 Cfu/ml
P.aeruginosa Initial count	5.8x10 ³	< 1 Cfu/ml	< 1 Cfu/ml	< 1 Cfu/ml
E.coli Spike recovery	3.1x10 ³	< 1 Cfu/ml	< 1 Cfu/ml	< 1 Cfu/ml
Salmonella Spike recovery	5.7x10 ³	< 1 Cfu/ml	< 1 Cfu/ml	< 1 Cfu/ml
P.Aeruginosa Spike recovery	7.5x10 ³	< 1 Cfu/ml	< 1 Cfu/ml	< 1 Cfu/ml

Test Summary: The data obtained from the above study demonstrates that sterilization process is effective at minimum of 4mins exposure of E.coli, Salmonella and P.aeruginosa to steam generated from **vaporizer + sterilizer** of MEDtraceNX. The validation study reveals that the tested process parameters are effective and adequate to reduce the microbial load of the baby bottles and observed log reduction was 3.0.

Witnessed and Analyzed by:- <i>Balaji</i>	Verified By :-Signature: <i>Bharath M.R.</i>
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Date: 18 October 2018	18 October 2018