REVALIDATION REPORT

OF

EO STERILIZER: ETO-2

(Location-Plant -116, Faridabad)

STARTED DATE : 14.01.2016

COMPLETION DATE : 04.03.2016

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1.0 OBJECTIVES

The objective of revalidation of EO sterilizer is as under:

- Revalidation of the equipment has been planned and executed so that the process of EO sterilization meets its intended use.
- The process has been performed as per intended test plan by running the equipment repeatedly and documenting all relevant information & data.
- The results of the equipment revalidation have been met pre-determined acceptance criteria(s) under normal conditions of operations, and where appropriate for worst-case situations.
- No any variation was observed between the set acceptance criteria and the actual data obtained. Accordingly, the intended use of the equipment has been finalized.
- On the basis of Revalidation data, the Work Instructions (WI) for the equipment have been evaluated for its suitability & found satisfactory.
- The equipment conforms to the complete qualification requirements and shall permit a formal "RELEASE" of the equipment for the use in routine sterilization process.

2.0 SCOPE

The scope of this revalidation is as under:

Sterilization of:

➢ Intravenous Cannula/Catheter with/without safety features
➢ CVC Kit
➢ Spinal Needle
➢ Fistula Needle
➢ 3 way with Extension Tube
➢ Other similar packaged products

The detail of equipment is as under:

Name of Equipment	EO Sterilizer
Equipment No.	2
Equipment Make	Hangzhou Dianda
Location of Equipment	Ground floor Plant 116

3.0 Reference Document

Revalidation Protocol: CVP-STR-038-10, Rev. No.-05

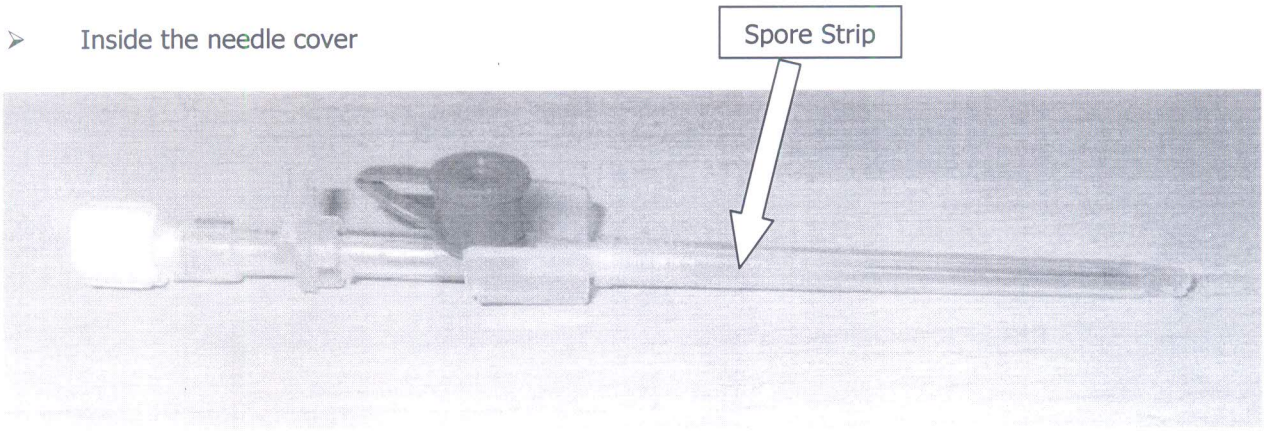
4.0 Definitions

The Ethylene oxide sterilization process uses ethylene oxide as a sterilant to kill viable micro organisms. The ethylene oxide sterilization is suitable for the products which are heat and moisture sensitive.

5.0 Placement of Biological Indicator

The biological indicators are placed within the product inside especially in the areas which are most difficult to sterilize. Although the products are designed in such a way that EO gas reaches to all locations in the product. However the biological indicators are kept in needle cover at the location as mention below-

- Inside the needle cover



6.0 Placement of Biological Indicator at difficult to sterilize locations

A total of 41 biological indicators, 20 temperature sensors and 8 humidity sensors are placed in one revalidation cycle as per the Location chart. Spore strips (BIs), temperature sensors and humidity sensors kept inside the corrugated boxes as well as in chamber.

7.0 Description of product (Selection of Load)

Process parameter for sterilization of paper/tyvek and PVC/PE film packed product has been validated.

- **Physical Details:**

S. No.	Name of Product	Material of Unit Packaging	Material of Multiunit Packaging	Material of Transit Packaging	Quantity Packed In One Carton
1	IV Cannula	Tyvek/ Medical Grade Paper +PVC /PP+PE Film	Card board paper	Semi craft paper	1000 pcs.
2	CVC Kit	Tyvek + PVC rigid Film	Card board paper	Semi craft paper	100 pcs.
3	Spinal Needle	Medical Grade Paper + PE Film	Card board paper	Semi craft paper	1000 pcs.
4	Fistula Needle	Medical Grade Paper +PP/ PE Film	Card board paper	Semi craft paper	500 pcs.
5	3 way with Extension Tube	Medical Grade Paper +PP/ PE Film	Card board paper	Semi craft paper	400 pcs.

- **Dimensional Details:**

S. No.	Name of Product	Dimension of Unit Packaging	Dimension of Duplex	Dimension of Transit Packaging
1	IV Cannula	142 x 32 mm 135 x 27 mm	170 x 135 x 105 mm (50 pcs.) 170 x 135 x 150 mm (100 pcs.)	545 x 295 x 350 mm 700 x 330 x 180 mm
2	CVC Kit	150 x 200 mm	215 x 202 x 150 mm	850 x 450 x 225 mm
3	Spinal Needle	17.5 x 3.5 mm	170 x 135 x 83 mm	430 x 350 x 290 mm
4	Fistula Needle	460 x 65 mm	615 x 140 x 110 mm	400 x 350 x 385 mm
5	3 way with Extension Tube	230x 950 mm	250 x 230 x 165 mm	855 x 475 x 270 mm

8.0 Process Parameter:

The process parameter is used during revalidation are given below.

S. No.	Parameters	Acceptance Criteria	Observations	
			Empty Run	PQ Runs
(A)	**Pre-Humidification**			
	(i) Time	5 ± 1 Minutes	5 Minutes	5 Minutes
(B)	**Pre- Conditioning**			
	(i) Time	60 ± 2 Minutes	60 Minutes	60 Minutes
	(ii) Chamber Temperature	45°C ± 5°C	47.4 °C - 49.1 °C	42.5 °C - 49.8 °C
	(iii) Chamber Relative Humidity	30%~90%	33 % ~ 40 %	33 % ~ 58 %
(C)	**Conditioning**			
	(i) Initial Vacuum	-0.85±0.01 kg/cm^2	-0.85 kg/cm^2	-0.85 kg/cm^2
	(ii) Vacuum Rate	40 ± 15 Minutes	25 Minutes	25 - 26 Minutes
	(iii) Vacuum Holding Time	10 ± 1 Minutes	10 Minutes	10 Minutes
	(iv) RH Injection Phase	2~5 Minutes	2 Minutes	2 Minutes
	(v) RH Dwell Phase	10 ± 1 Minutes	10 Minutes	10 Minutes
	(vi) Chamber Temperature during Vacuum Hold	45°C ± 5°C	46.7 °C – 48.8 °C	43.2 °C – 49.9 °C
	(vii) Chamber Humidity during Vacuum Hold	30%~90%	32 % ~ 38 %	31 % ~ 53 %
(D)	**Sterilization**			
	(i) EO Pressure Charged	0.54 kg/cm^2 ± 0.05kg/cm^2	0.58 kg/cm^2	0.58 kg/cm^2
	(ii) Weight of EO gas used	48 to 52 kg	50.2 kg	49.9 to 50.4 kg
	(iii) EO gas Inlet Temperature	20°C~60°C	28.2 °C – 43.4 °C	21.2 °C – 33.2 °C
	(iv) Gas Charging Time	45 ± 20 Minutes	46 Minutes	37 - 41 Minutes
	(v) EO Concentration	500 ± 25mg/lit.	502 mg/lit.	499 mg/lit. ~ 504 mg/lit.
	Exposure Phase			
	(vi) Temperature during Exposure	50°C ± 5°C	48.9 °C – 51.2 °C	45.9 °C – 51.9 °C
	(vii) Exposure Time	115, 120 & 240 ± 1 Minute.	240 Minutes.	115, 120, 240 Minutes.
(E)	**Aeration**			
	(i) Gas Discharge phase	-0.85 kg/cm^2 @ 40 ± 15 Minutes.	-0.85 kg/cm^2 @ 43 Minutes.	-0.85 kg/cm^2 @ 41 - 43 Minutes.
	(ii) Air Inlet phase	0 ± 0.05 kg/cm^2	-0.05 kg/cm^2	-0.05 kg/cm^2
	(iii) Air washing phase and Rate	-0.75 kg/cm^2 @ 30 ± 15 Minutes.	-0.75 kg/cm^2 @ 17 Minutes.	-0.75 kg/cm^2 @ 16 - 17 Minutes.
	(iv) Air inlet phase	0 ± 0.05 kg/cm^2	-0.05 kg/cm^2	-0.05 kg/cm^2
	(v) Temperature during aeration	35°C to 60°C	48.5 °C ~ 49.9 °C	39.6 °C ~ 49.7 °C
	(vi) Total Aeration	2 Nos.	2 Nos.	2 Nos.

9.0 Testing of biological indicator

After completion of sterilization cycle, all the biological indicator (spore strips) are inoculated in Soyabean Casein Digest Medium Previously sterilized at 121° C for 15 minutes and kept at 30-35° C in BOD incubator for 7 days. The media is monitored daily for any growth of microorganism and the result is complying with the test plan.

10.0 Product Package Testing

Product is tested randomly for the effect of sterilization on packaging condition, printing matter, sealing or any other effect due to temperature & humidity. The effect of sterilization is not having any detrimental effect on the functioning of product as well as on package.

11.0 Product Functional Testing:

The functional testing has been performed that cycles having exposure phase of 120 minutes and 240 minutes during revalidation and analysed the effect of sterilization processes (temperature, humidity, Ethylene oxide gas and vacuum pressure) on product. The product which passes under sterilization process is complies all test acceptance criteria during finish product testing. No significant impact of sterilization process observed on product functionality during finish product testing. The results are satisfactory and met with acceptance criteria. The functional testing data is attached with report for 120 minutes and 240 minutes of exposure during revalidation.

12.0 Ethylene Oxide Residual Testing

The sterilized samples are sent to an external agency for EO residual testing and the concentration of Ethylene Oxide and ECH is in compliance with the EN ISO 10993-7:2008 standard.

13.0 LAL testing (Bacterial Endotoxin Testing)

10 sterilized samples from the EO sterilized product load have been tested for bacterial endotoxin test using Gel-clot method and are complying with the test plan.

14.0 Product sterility Testing

20 sterilized samples from the EO sterilized product load have been tested for sterility test and are complying with the test plan.

15.0 Deviation Report

No any deviation observed from the acceptance criteria of the specific check point.

16.0 Summary for Revalidation record of EO sterilizer- 2

S. No.	Exposure Time	Physical parameter	Number of BI used	Number of BIs showing growth	Observation
1	115 minutes	Satisfactory	40	Nil	No Growth
2	120 minutes	Satisfactory	40	Nil	No Growth
3	120 minutes	Satisfactory	40	Nil	No Growth
4	120 minutes	Satisfactory	40	Nil	No Growth
5	240 minutes	Satisfactory	40	Nil	No Growth
6	240 minutes	Satisfactory	40	Nil	No Growth

17.0 Conclusion:

As indicated from the results of above summary it is concluded that the complete kill of biological indicators (BIs) is observed at **120 minutes (Half Cycle)** and the routine cycle can be taken with **240 minutes'** exposure time with same physical parameters.
Since packaging material is same for all products therefore we will use same sterilization cycle parameter for other products.

The sterilization cycle has not indicated any negative impacts on product or product package.

18.0 APPROVAL OF REVALIDATION REPORT

The report has been prepared, checked, and approved by the undersigned:

	DEPARTMENT	NAME	DESIGNATION	SIGNATURE	DATE
PREPARED BY	Quality Assurance	Kamal gaur	Sr. Officer		02.03.2016
	Quality Control	Sumit Verma	Sr. Microbiologist		02.03.2016

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APPROVED BY	Quality Assurance	SS Rawat	General Manager		04.03.2016