





CERTIFICATE OF ANALYSIS

Code : SWTARNA70-P Product : Sterilization Self Seal Pouch Mfg. Date :29.09.2021 Batch Size : 10cmx 27.5cm	Certificate No : SWT- 89 Date of Inspection : 29.09.2021 Batch No : SSP1002909 Expiry date : 09.08.2024
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MATERIALS DESCRIPTION

Paper : Medical Grade Paper 70 GSM	Film : Medical Grade Cast Poly Propylene
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Sr. No	Description of Test	Frequency of Test	Observation	Requirments	Mode of checking
1	Medical Grade Paper GSM	One pouch of every consaginment	70	70 +/- 2 gm	Weighing Balance
2	Medical Grade Paper Thickness		95	95 +/- 2 Micron	Micron Meter
3	CPP Poly GSM		52	52+/- 2 gm	Weighing Balance
4	CPP Poly Thickness		55	55 +/- 2 Micron	Micron Meter
5	Seal Uniformity	On line check during production	Uniform sealing	Should be Uniform sealing	Visual Check
6	Seal Strength	1 hour every lot	R:4.52N/15mm L:3.87N/15mm H:2.92N/15mm	Above 2.5 N/15mm	Tensile Tester (ASTM D 882-97)
7	Seal Width		10 mm	10mm+/-1mm	Vernier Caliper
8	Air bubble in Sealing Area		No Air bubble observed.	Air bubble should not be present.	Visual Check
9	Skip seal (If any)	On line check during production	2 Skip seals	Should be 2 Skip seals	Visual Check
10	Sealing Temprature		185 Deg C	185 +/-2 Deg C	Temprature Controller
11	Sealing Pressure		6.0 Kg	6.0 +/-0.5 Kg	Pressure Controller
12	Sealing Time		1.2 Second	1.2 TO 1.5 Sec	Machine Setup
13	Outer Width Size	Every Pouch	100mm	100mm +/-2mm	Mesuring Scale
14	Inner Width Size		80mm	80mm +/-2mm	Mesuring Scale
15	Total Length of Pouch		275mm	275mm +/-1mm	Machine Setup
16	Sterilization Indicator (Steam)	Every consignment	After sterilization Dark grey turns to Black	After sterilization Dark Grey should turn to Black	Sterilizer (STEAM)
17	Sterilization Indicator (ETO)	Every consignment	After sterilization Greenish turns to Yellow	After sterilization Greenish should turns to Yellow	Sterilizer (ETO)
18	Thum Hole (If any)	On line check during production	Holes not observed	Holes should not be observed	Visual Check
19	Printing Text Matter (If any)		Printing as per approved matter	Printing should be as per approved matter	Visual Check

 PREPARED BY	 CHECKED BY		 RELEASED BY
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