



Quality Certificate

VWR® ALCOHOL PREP PAD, STERILE

As per the manufacturer, the below product meets the following criteria:

North American Catalog No:	75856-902
Lot Number:	18030085
Description:	VWR Pad Alcohol Prep St 40gsm 2.79 Cm M
Manufacturing Date:	March 2018
Expiration Date:	February 2021

The product listed above has been manufactured, processed, inspected, and tested in accordance with all requirements of the purchase order and specified on referenced documents.

Furthermore, inspection and test results signify that the items delivered are fully acceptable and in complete conformance to following standards and regulatory requirements:

- US-FDA 21 CFR 211 CGMP for finished pharmaceuticals
- US-FDA 21 CFR 820 CGMP for medical devices
- EN ISO 13485:2012 QMS for medical devices

Listed lot has been tested and passed the manufacturer's internal production standard procedures. When checked, the products also have been validated for sterilization effectiveness according to the following sterilization standards.

- EN ISO 11137-2:2013 Sterilization of health care products- Radiation- Samples taken from the lot were retained at the factory site.



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Sr. No.	Description	Description Specification	Result
1	Appearance/Visual inspection	To Comply With Specification	Complies
2	Length of prep pad	50± 1mm	50.0 mm
3	Width of prep pad	50± 1mm	50.0 mm
4	Length Non-woven	60 ± 2mm	60.0 mm
5	Width of Non-woven	30 ± 2mm	30.0 mm
6	Horizontal Sealing of Prep Pad	≥ 4.0 mm	5.3 mm
7	Vertical Sealing of Prep Pad	≥ 2.5 mm	3.3 mm
8	Filled pouch weight	0.76 ± 0.05g/pc.	0.784 g/pc.
9	Per Pad Solution Weight	0.32 ± 0.05 g/pc.	0.306 g
10	Peel Strength	≥ 6.00N/15mm	27.77 N
11	Dye Penetration	Shall comply as per specification	Complies
12	IPA Content By GC	(68-72) % v/v	70.51 % v/v
13	Microbiological : Bio Burden & Pathogen Test(Before Gamma Irradiation)		
13.1	Total Aerobic Microbial Count	NMT 10 cfu/piece	Nil cfu/piece
13.2	Specified Microorganisms	E.coli, Salmonellaspps, S.aureus, Ps.aeruginosa, Candida, Albicans, Clostridia, Gram negative bile tolerant bacteria Should be Absent.	Absent
14	Irradiation Dose	Irradiation sterilization certificate should pass (VD min 25 KGy-VD max 50.0KGy)	Complies

Signed:

Jamie Ethier
VP Global Quality
VWR, Part of Avantor

Date: November 09, 2018