



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:	17100236
Description:	VWR PAD ALCOHOL PREP ST 40GSM 2.79 CM M
Manufacturing Date:	10/2017
Expiration Date:	09/2020
Irradiation Completion Date:	12/18/2017

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.

The product has been radiation processed with Gamma radiation to a minimum dose of 25 kGy.



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Item	Description	Requirement	Method	Result
1	Appearance/Visual inspection	Match sample	Visual	Complies
2	Average IPA solution content (%v/v)	68-72%	QC-WI-12	69.69
3	Average pouch size (mm)	(50X50) ± 1mm	Scale	50 X 50
4	Average Non-woven size (mm)	(60X30) ± 2mm	Scale	60 X 30
5	Average sealing width (mm)	Horizontal seal (HS) ≥ 4.0 mm	Scale	HS= 6.0 VS= 3.0
		Vertical seal (VS) ≥ 2.5 mm		
6	Average weight per pad (g)	0.76 g ± 0.05	Weight	0.743
7	Average solution weight per pad (g)	0.32 g ± 0.05	Dry loss weight	0.285
8	Average peel strength (N/15mm)	≥ 6.00N/15mm	QC-WI-07 (ASTM F88-09)	15.79
9	Dye penetration	No leakage	(ASTM 1929-2012)	Passes Test
10	Initial Bioburden (Before irradiation) (cfu/Pc)	Total Bacterial Count: NMT 10 cfu/piece	QC-WI-60 /USP 38	01 cfu/Pc
11	Specified organisms	Absence of <i>E. coli</i> , <i>Salmonella</i> spps, <i>S. aureus</i> , <i>Ps. aeruginosa</i> , <i>Candida albicans</i> , <i>Clostridia</i> , gram negative bile tolerant bacteria	QC-WI-61 /USP 38	Not detected
12	Irradiation Dose	Irradiation Sterilization Certificate Pass (VD min 25KGy-VDmax 50.0kGy)	Check the certificate qualified (Released by gamma sterilization Certificate)	Complies

Signed:

Linda K. Shine
 Manager - Supplier Qualification
 Global Compliance
 VWR International LLC

Date: 12/22/2017

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