



PASSION. PARTNERSHIP. POSSIBILITIES.

CERTIFICATE OF ANALYSIS AND COMPLIANCE

The following lot(s) have been produced and shipped in accordance with **Title 21CFR § 820 & 210 Current Good Manufacturing Practices (cGMP)**. The characterization data has been measured according to Quality Assurance procedures. Certificates of Analysis is valid until expiration date.

Item Number	852	Lot Number	JT25318
Item	Alcohol Pre Pad	Expiration Date	Aug -2023

TEST	SPECIFICATION		STANDARD OR	RESULT
	MIN	MAX	TEST METHOD	
ASSAY (CH3CH(OH)CH3)	68%	72%	Distillation gravity	Conforms
APPEARANCE	TO PASS TEST		Visual	Conforms
DYE PENETRATION	TO PASS TEST		ASTM 1929	Conforms
PEEL STRENGTH	6N/15mm		ASTM F88	11.22N/15mm
MICROBIAL LIMIT TEST				
TAMC	≤10 ² cfu/g		cUSP<61>	<1 cfu/g
TYMC	≤10 ¹ cfu/g		cUSP<61>	<1 cfu/g
CONTROL BACTERIA				
STAPHYOCOCCUS AUREUS	ABSENT/g		cUSP<62>	ABSENT/g
PSEUDOMONAS AERUGINOSA	ABSENT/g		cUSP<62>	ABSENT/g
BACILLUS CEREUS	ABSENT/g		cUSP<62>	ABSENT/g
BURKHOLDERIA CEPACIA	ABSENT/g		cUSP<62>	ABSENT/g
SOLUTION VOLUME	0.3 g/pad		cUSP<731>	0.35g/pad
SPECIFIC GRAVITY@20 °C	0.872	0.883	cUSP	0.873
ACIDITY LIMIT OF NONVOLATILE RESIDUE	TO PASS TEST		cUSP	Conforms
		5.0mg	cUSP	0.3mg
POUCH SIZE	49x49mm	51x51mm	Caliper	50x50 mm
MANUFACTURE DATE				10-Sep-2018

Should you require any additional information, please contact Dukal Corporation Quality Department at (631)656-3800.

Prepared By;

Megan Quevedo

Quality Assurance and Regulatory Affairs Complaint Specialist