

Viva Nylons Ltd ▪ 26 Lunsford Road ▪ Leicester ▪ LE5 0HJ

Teat Laboratory No: 19J7079

FDA Extraction into water, 95%v/v ethanol and ethyl acetate (as specified in CFR 21 §177.1500)

Method(s): FDA extraction tests according to CFR21 section 177.1500 (b) 6.1

Water - Maximum soluble fraction in water 95%v/v

Ethanol - Maximum soluble extraction fraction 95%v/v (ethanol)

Ethyl acetate - Maximum extraction fraction in ethyl acetate

Extraction conditions of 8 hours at reflux were used

Test results: Results are expressed in percentage by weight of extractable materials

Water extraction at reflux					
Sample	Rep 1 (%)	Rep 2 (%)	Rep3 (%)	Mean (%)	Limit (%)
1) 003B	0.53	0.54	0.53	0.53	1.0
2) 003C	0.57	0.55	0.59	0.57	1.0

95%v/v Ethanol extraction at reflux					
Sample	Rep 1 (%)	Rep 2 (%)	Rep3 (%)	Mean (%)	Limit (%)
1) 003B	0.25	0.23	0.25	0.24	2.0
2) 003C	0.29	0.30	0.27	0.29	2.0

95%v/v Ethyl acetate extraction at reflux					
Sample	Rep 1 (%)	Rep 2 (%)	Rep3 (%)	Mean (%)	Limit (%)
1) 003B	0.01	0.02	0.02	0.02	1.0
2) 003C	0.05	0.03	0.03	0.04	1.0