



Test Report

FDA overall migration analysis of Nano4life SiO₂ easy to clean product line.

Test Report : IWTN/W000001267ARLM001

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TEST REPORT

Report Number: IWTN/W000001267ARLM001
Chit Number: ITWI-00000010499A
Receipt Date: 15/07/2014
Lab Book Reference:
File Reference Location: N110/N112
Number of Samples: 2
Method Reference: 21CFR 175:300 table 1 & 2

Samples Submitted

<u>Intertek Sample Reference</u>	<u>Sample Description</u>	<u>Customer Identifier</u>
IWTN/W000001267A-1	Substrate coated in Silicone Dioxide solution	Coated
IWTN/W000001267A-2	Uncoated substrate	Uncoated

Description of Work Required

Ref: 21CFR 175:300 table 1 & 2 FDA Overall Migration

Experimental

50 square inches of sample were exposed by total immersion to 100mL of distilled water, 10% v/v aqueous ethanol, and heptane. Samples undergoing extraction in distilled water, and 10% v/v aqueous ethanol were exposed for 24 hours at 66°C. Samples undergoing heptane extraction underwent exposure at 38°C for 30 minutes. At the end of the exposure period the samples were removed from the extractants. The extractants were filtered and evaporated to dryness. Total extractives were determined gravimetrically.

Results, Interpretation and Opinions

Sample	Extractant	Exposure Time / Hours	Temp / °C	Total extractives / mg/inch ²	Mean total extractives / mg/inch ²
Coated	Distilled water	24	66	0.58	0.60
Coated				0.60	
Coated				0.62	
Uncoated	Distilled water	24	66	0.58	0.55
Uncoated				0.55	
Uncoated				0.54	
Coated	10% v/v Ethanol	24	66	0.60	0.61
Coated				0.63	
Coated				0.61	
Uncoated	10% v/v Ethanol	24	66	0.58	0.61
Uncoated				0.60	
Uncoated				0.64	
Coated	Heptane	0.5	38	0.89	0.85
Coated				0.86	
Coated				0.80	
Uncoated	Heptane	0.5	38	0.99	0.90
Uncoated				0.79	
Uncoated				0.94	

Conclusions

Limit of extractives is 18 mg/inch² for coatings intended for repeat use, and employed other than as a component of a container, as stated in FDA 21 CFR 175:300 paragraph (c),(4). Therefore the mean results for both coated and uncoated samples meet the extractive limit for all extractants and the samples pass the regulations for their intended use in food contact.

Report Authorisation

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