

Declaration of compliance

Material : FOOD-sil

is in compliance with the regulation FDA 21 CFR 177.260

The sheet complies with the requirements of overall migration limits

Test method :

As established by the FDA 21 CFR 177.2600

Results :

Simulant Used	Time	Temperature	Max. Permissible Limit	Result of 001 Total extractives
Distilled water	7.0 hr(s)	Reflux temperature	20 mg/inch ²	<0,5 mg/inch ²
Distilled water succeeding extraction	2.0 hr(s)	Reflux temperature	1 mg/inch ²	<0,5 mg/inch ²
n-Hexane	7.0 hr(s)	Reflux temperature	175 mg/inch ²	15,4 mg/inch ²
n-Hexane extraction succeeding	2.0 hr(s)	Reflux temperature	4 mg/inch ²	1,4 mg/inch ²

Simulant Used	Time	Temperature	Max. Permissible Limit	Result of 002 Total extractives
Distilled water	7.0 hr(s)	Reflux temperature	20 mg/inch ²	<0,5 mg/inch ²
Distilled water succeeding extraction	2.0 hr(s)	Reflux temperature	1 mg/inch ²	<0,5 mg/inch ²

n-Hexane	7.0 hr(s)	Reflux temperature	175 mg/inch ²	14,4 mg/inch ²
n-Hexane extraction succeeding	2.0 hr(s)	Reflux temperature	4 mg/inch ²	1,2 mg/inch ²

Simulant Used	Time	Temperature	Max. Permissible Limit	Result of 003 Total extractives
Distilled water	7.0 hr(s)	Reflux temperature	20 mg/inch ²	<0,5 mg/inch ²
Distilled water succeeding extraction	2.0 hr(s)	Reflux temperature	1 mg/inch ²	0,7 mg/inch ²
n-Hexane	7.0 hr(s)	Reflux temperature	175 mg/inch ²	12 mg/inch ²
n-Hexane extraction succeeding	2.0 hr(s)	Reflux temperature	4 mg/inch ²	2,8 mg/inch ²

Simulant Used	Time	Temperature	Max. Permissible Limit	Result of 004 Total extractives
Distilled water	7.0 hr(s)	Reflux temperature	20 mg/inch ²	<0,5 mg/inch ²
Distilled water succeeding extraction	2.0 hr(s)	Reflux temperature	1 mg/inch ²	<0,5 mg/inch ²
n-Hexane	7.0 hr(s)	Reflux temperature	175 mg/inch ²	12,6 mg/inch ²
n-Hexane extraction succeeding	2.0 hr(s)	Reflux temperature	4 mg/inch ²	3,0 mg/inch ²

Tecnical manager
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