

Supplementary Material for

Characterization of genotoxic impurities with LC-QTOF and RP-HPLC methods including different swab methods in cleaning validation

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S.1 Accuracy, Precision and Intermediate Precision

Table S1. PMMA and teflon plate accuracy results of the method

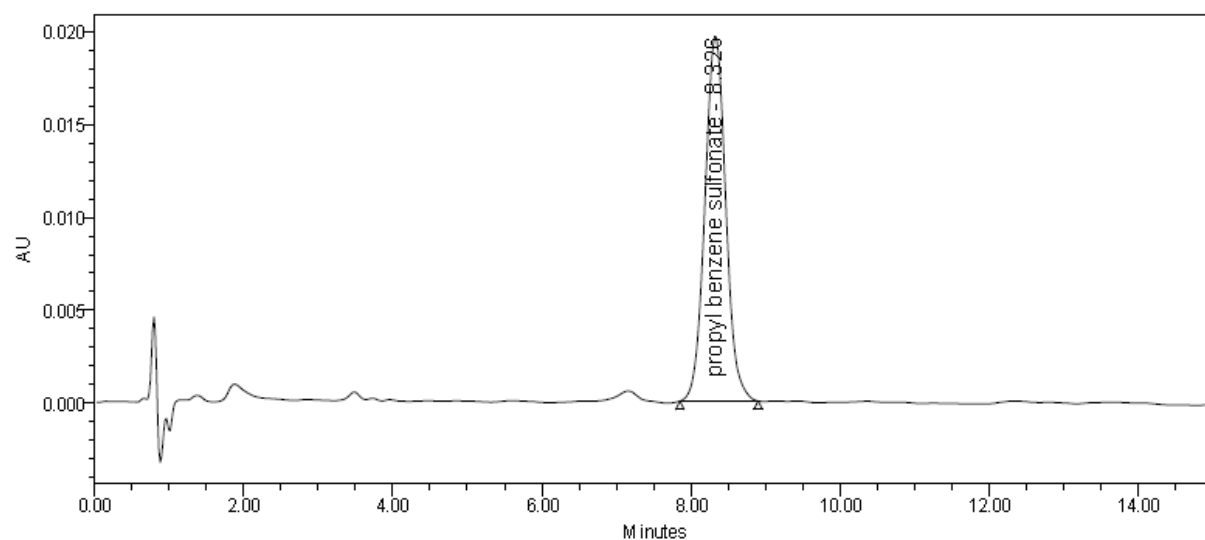
Level	PMMA plate average accuracy, %	RSD, %	Teflon average accuracy, %	RSD, %
LOQ	96.26	1.75	97.74	1.66
80%	93.11	0.13	101.47	0.87
100%	96.01	0.09	94.91	0.22
120%	101.82	0.29	101.79	0.35
200%	101.57	0.13	101.20	0.22

Table S2. POM and glass plate accuracy results of the method

Level	Glass plate average accuracy, %	RSD, %	POM plate average accuracy, %	RSD, %
LOQ	98.24	1.21	97.42	1.81
80%	101.51	0.22	102.65	0.02
100%	96.26	0.34	95.69	0.45
120%	102.21	0.24	102.01	0.11
200%	101.76	0.12	101.78	0.13

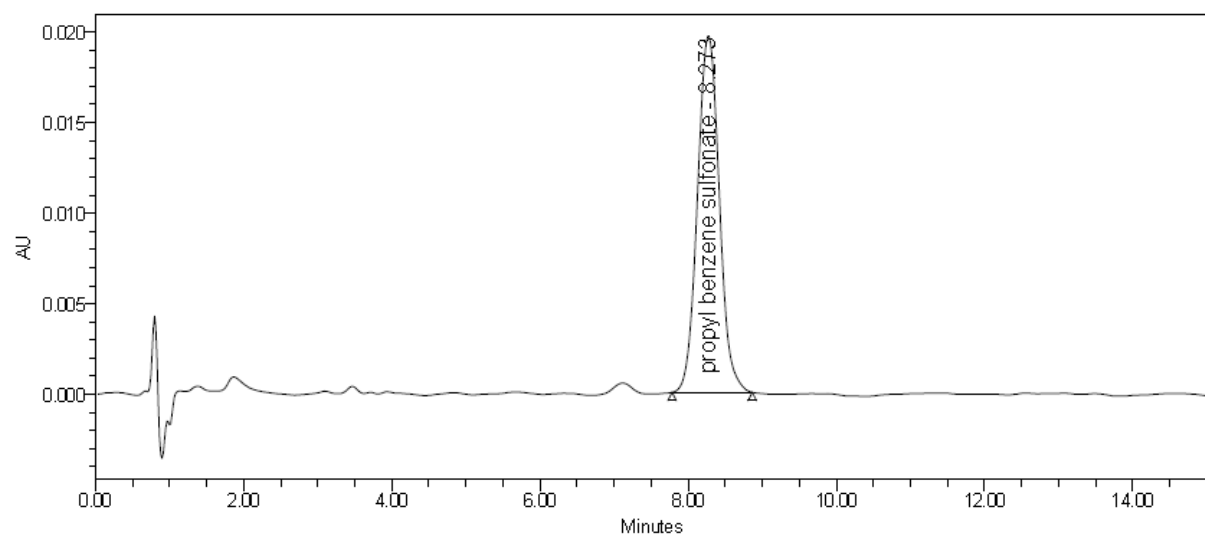
Table S3. Precision and Intermediate Precision results of the method.

Plate Surface	Precision average, %	Precision RSD, %	Intermediate Precision Average, %	Intermediate Precision RSD, %
PMMA Plate	100.66	0.16	94.88	0.46
Teflon Plate	100.45	0.65	98.26	1.94
Glass Plate	97.25	0.14	96.36	1.86
POM Plate	98.11	0.63	95.68	0.91



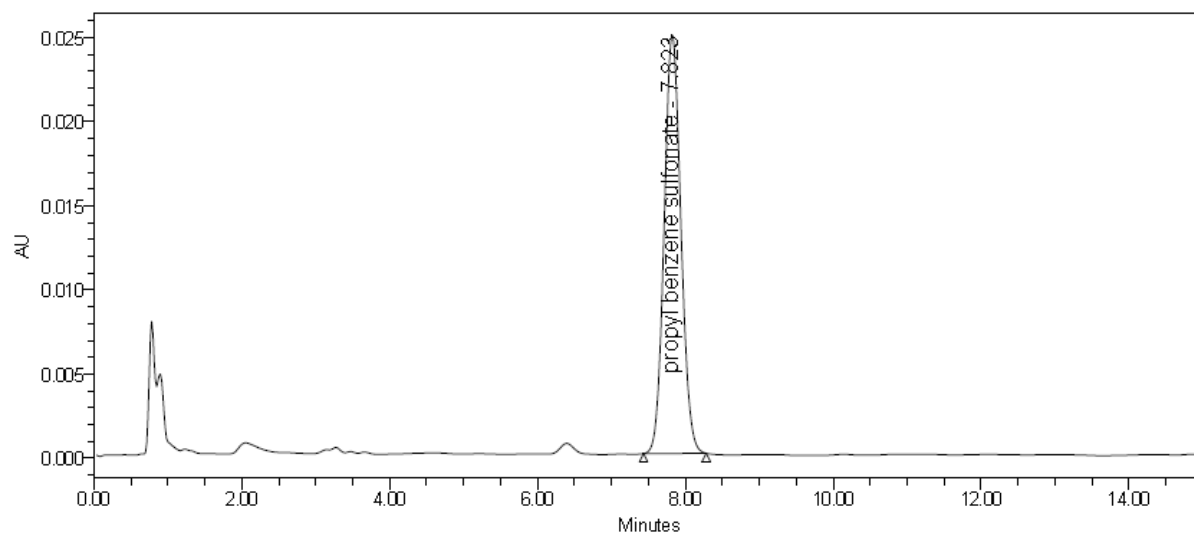
	Peak Name	RT	% Area	Area	Height (μV)	Calculated_Amount
1	propyl benzene sulfonate	8.326	100.00	382595	19658	94.92

Figure S-1 Method precision chromatogram of PMMA plate



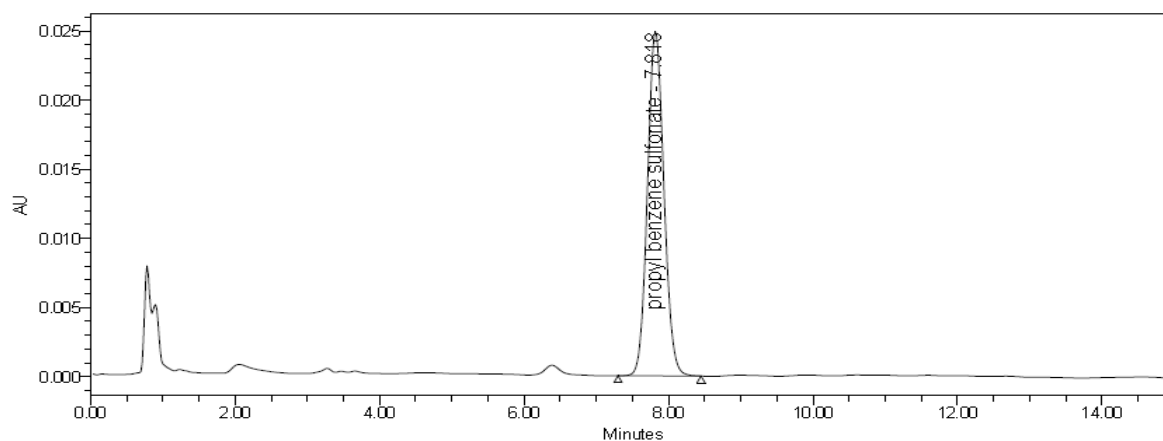
	Peak Name	RT	% Area	Area	Height (μV)	Calculated_Amount
1	propyl benzene sulfonate	8.273	100.00	403719	19686	100.16

Figure S-2 Method precision chromatogram of teflon plate



	Peak Name	RT	% Area	Area	Height (μV)	Calculated_Amount
1	propyl benzene sulfonate	7.823	100.00	390659	24899	97.25

Figure S-3 Method precision chromatogram of glass plate



	Peak Name	RT	% Area	Area	Height (μV)	Calculated_Amount
1	propyl benzene sulfonate	7.818	100.00	393897	24913	98.06

Figure S-4 Method precision chromatogram of POM plate

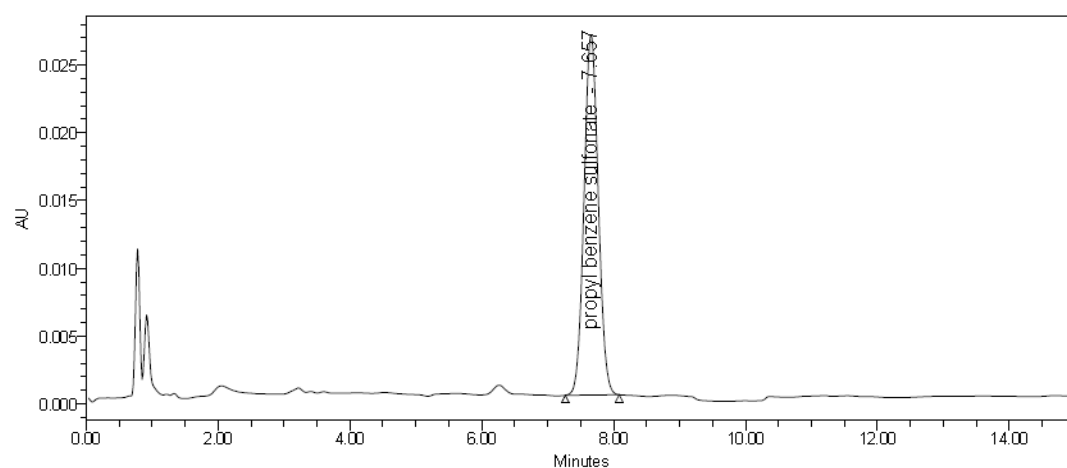
S.1.3 Stability

Table S4. PMMA and teflon plate stability results of the method.

Parameter	Time	Peak Area	% Variation
Stainless steel plate	0 h	392629	-
	24 h (at 5°C)	391691	0.24
	24 h (at 25°C)	391652	0.25
	48 h (at 5°C)	392783	0.75
	48 h (at 25°C)	395148	0.64
Teflon plate	0 h	411530	-
	24 h (at 5°C)	390093	5.21
	24 h (at 25°C)	389848	5.27
	48 h (at 5°C)	389848	7.81
	48 h (at 25°C)	382665	7.01

Table S5. Glass and POM plate stability results of the method.

Parameter	Time	Peak Area	% Variation
Glass plate	0 h	411218	-
	24 h (at 5°C)	389624	5.25
	24 h (at 25°C)	389970	5.17
	48 h (at 5°C)	383298	6.79
	48 h (at 25°C)	383298	6.79
POM plate	0 h	412765	-
	24 h (at 5°C)	386304	6.41
	24 h (at 25°C)	390321	5.44
	48 h (at 5°C)	383298	7.14
	48 h (at 25°C)	388724	5.82



	Peak Name	RT	% Area	Area	Height (μV)	Symmetry Factor	EP Plate Count
1	propyl benzene sulfonate	7.657	100.00	398444	26625	1.05	5957

Figure S-5 System suitability chromatogram