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Supplementary materials to:

The Questionable Quality Profile of Food Supplements: The Case of Red Yeast Rice Marketed Products

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Table S1. Experimental condition and specification of mass uniformity assay prescribed by Ph. Eur. 11. Ed.

Dosage Form	Average Mass	Percent deviation
Tablets (uncoated and film-coated)	Not more than 80 mg	10
	More than 80 mg and less than 250 mg	7.5
	250 mg or more	5
Capsules	Less than 300 mg	10
	300 mg or more	7.5

Table S2. Experimental conditions and specification for pharmacopeial disintegration test.

	European Pharmacopoeia 11	
Dosage form	**Immersion liquid/disc**	**Maximum time of Disintegration**
Uncoated tablets	Purified water (35-39°C) with disc	15 min
Coated tablets	Purified water (35-39°C) with disc [a]	30 min (film-coated) 60 min (other coatings)
Gastro-resistant tablets	HCl 0.1 M (35-39°C) without disc and then	Intact after not less than 1h
	Phosphate buffer solution pH 6.8 (35-39°C) with disc [b]	60 min
Hard capsules	Purified water or HCl 0.1 M [c]	30 min
Soft capsules	Purified water or HCl 0.1 M with disc [d]	30 min

[a] If any of the tablets has not disintegrated, the test is repeat on a further 6 tablets, replacing water R with 0.1 M hydrochloric acid.
[b] If the tablets are not compliant to the test, due to disc adherence, the test should be repeated without discs.
[c] The use of discs is required if the capsules float in the immersion liquid.
[d] If the sof capsule adheres to the disc, it can be omitted.

Table S3. Stock solutions composition.

Salt solution	Stock concentration (mol/L)	SSF (pH 7)		SGF (pH 3)		SIF (pH 7)	
		mL of Stock added to prepare 0.4 L (mL)	Final salt concentration in sample (mmol/L)	mL of Stock added to prepare 0.4 L (mL)	Final salt conc. in sample (mmol/L)	mL of Stock added to prepare 0.4 L (mL)	Final salt conc. in sample (mmol/L)
KCl	0.5	15.1	15.1	6.9	6.9	6.8	6.8
KH_2PO_4	0.5	3.7	1.35	0.9	0.9	0.8	0.8
$NaHCO_3$	1	6.8	13.68	12.5	25	42.5	85
NaCl	2	-	-	11.8	47.2	9.6	38.4
$MgCl_2(H_2O)_6$	0.15	0.5	0.15	0.4	0.12	1.1	0.33
$NH_4(CO_3)_2$	0.5	0.06	0.06	0.5	0.5	-	-
$CaCl_2(H_2O)_2$	0.3	-	1.5	-	0.15	-	0.6

Abbreviations: SSF: simulated salivary fluid, SGF: simulated gastric fluid, and SIF: simulated intestinal fluid.

Table S4. Information relevant for the study reported on the label of FS.

Sample	Dosage form category	Single unit weight [a] (mg)	Number of AIs	AIs (Monacolin K) (mg)	Inactive ingredients (mg)
#1	Film-coated tablet	400	7	290 (-) [d]	110
#2	Film-coated tablet	1000	2	539 (1.45) [b]	471
#3	Film-coated tablet	1100	3	615 (10) [b]	385
#4	Film-coated tablet	1340	4	1004 (5) [b]	336
#5	Film-coated tablet	983	6	780 (-) [c]	203
#6	Uncoated tablet	1000	1	667 (-) [d]	333
#7	Uncoated tablet	550	5	320 (10) [b]	230
#8	Uncoated tablet	Not reported	8	739 (10) [b]	-
#9	Uncoated tablet	330	1	200 (10) [b]	130
#10	Hard shell capsule	450	2	238.7 (10) [b]	211
#11	Hard shell capsule	500	2	280 (10) [b]	220
#12	Hard shell capsule	450	6	213 (2.2) [b]	237
#13	Softgels	1600	8	1063 (10) [b]	537
#14	Softgels	1777	4	658 (5) [b]	1120

[a] Calculated from the ratio between the total weight declared on the label and the number of dosage form units.

[b] Reported on the label as monacolin K.

[c] Reported on the label as monacolins.

[d] Not specified.

AI= Active ingredient.

Note. Following COMMISSION REGULATION (EU) 2022/860, the use of monacolins from red yeast rice is allowed at levels of less than 3 mg per portion of the product recommended for daily consumption.

Table S5. Inactive ingredients listed on the RYR FS label.

		Film-coated tablets				Uncoated tablets				
		#1	**#2**	**#3**	**#4**	**#5**	**#6**	**#7**	**#8** [a]	**#9**
Tablet/tablet core	Microcrystalline cellulose	X	X	X [b]	X [b]	X	X [b]	X	-	X [b]
	Starch						X		-	
	Maltodextrines from Maize		X						-	
	Calcium Carbonate						X		-	
	Cross-linked sodium carboxymethylcellulose		X	X	X	X			-	
	Silicon dioxide		X	X	X	X	X	X	-	X
	Magnesium salts of fatty acids	X [c]	X	X	X	X	X	X	-	X
	Carminic Acid				X				-	
	Titanium dioxide (E. 171) [d]		X	X					-	
	Iron oxide red			X					-	
	Iron oxide black								-	
	Iron oxides and iron hydroxides		X		X				-	
Coating	Hydroxypropyl methyl cellulose	X	X	X					-	
	Hydroxypropylcellulose					X			-	
	Polyvinyl alcohol			X					-	
	Polyvinylpyrrolidone					X			-	
	Microcrystalline cellulose	X	X	X	X	X				
	Talc		X		X	X			-	
	Polyethylene glycol		X		X				-	
	Glycerol			X					-	
	Stearic acid	X							-	
	Polysorbate 80				X				-	
	Niacin (nicotinamide/vitamin B3)				X				-	
	Shellac					X			-	

[a] The label does not report the ingredient list.
[b] Reported as "cellulose" in the ingredient list.
[c] Reported as "vegetable magnesium stearate" in the ingredient list.
[d] Banned in food since 7th August 2022.

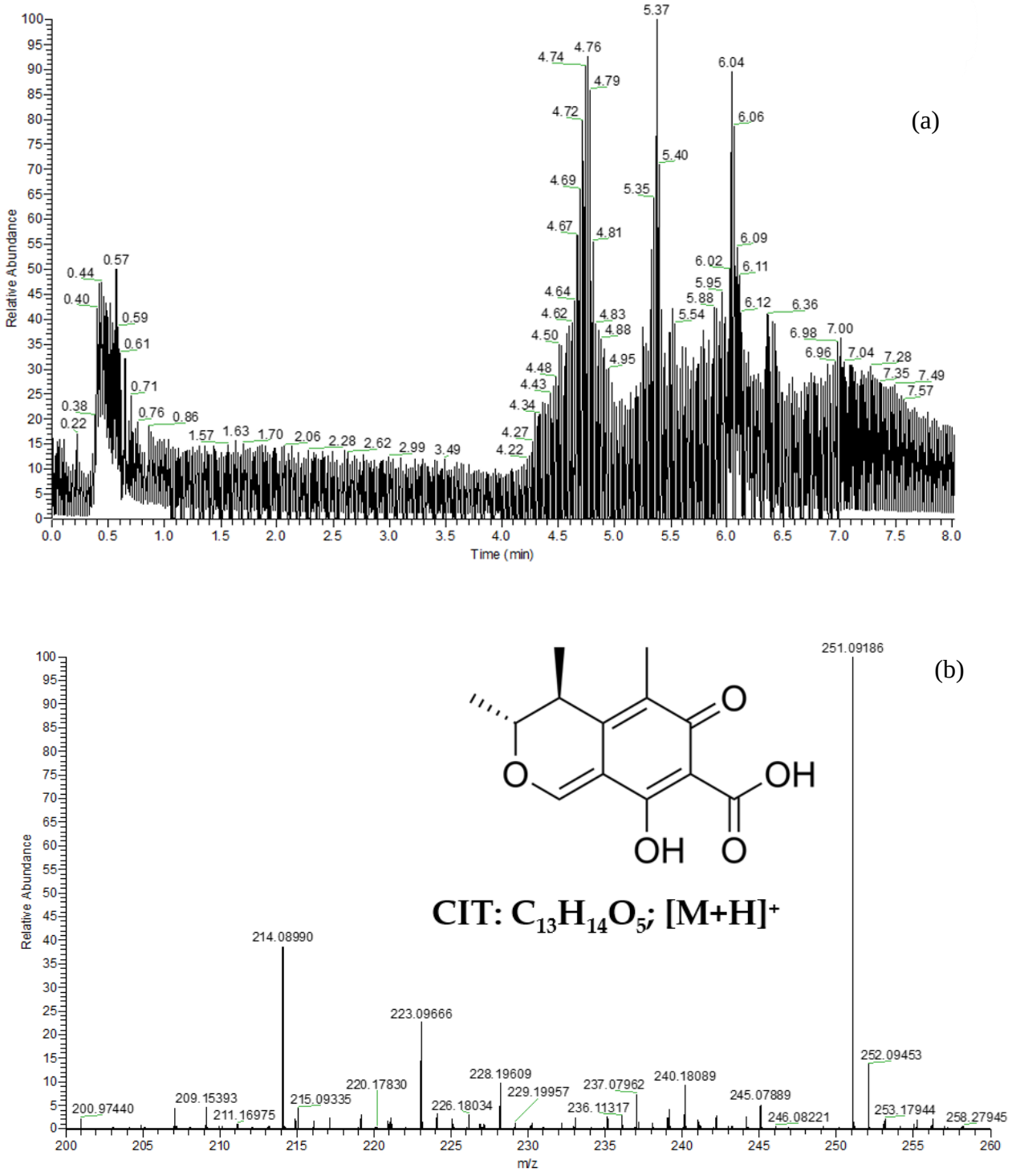

Figure S1. Extracted ion chromatogram (a) and mass spectra (b) of citrinin