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Development of tablet formulations containing genistein solid dispersion optimized using Box-Behnken design for enhanced solubility

Suranate Phanapithakkun[1,2], Gorawit Yusakul[1,3], Chanakan Sitthisak[1], Thipapun Plyduang[1,2]
[1]School of Pharmacy, Walailak University, Nakhon Si Thammarat, Thailand.
[2]Drug and Cosmetics Excellence Center, Walailak University, Nakhon Si Thammarat, Thailand.
[3]Functional Materials and Nanotechnology Center of Excellence, Walailak University, Nakhon Si Thammarat, Thailand.

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SUPPLEMENTARY MATERIALS

1. The HPLC chromatograms

The HPLC chromatograms are shown in Figure S1. Chromatogram A represents the genistein reference standard, chromatogram B represents the genistein solid dispersion, chromatogram C and D represent the genistein solid dispersion tablets F1 and F2, respectively. The retention time of genistein was about 5.8 – 5.9 minutes.

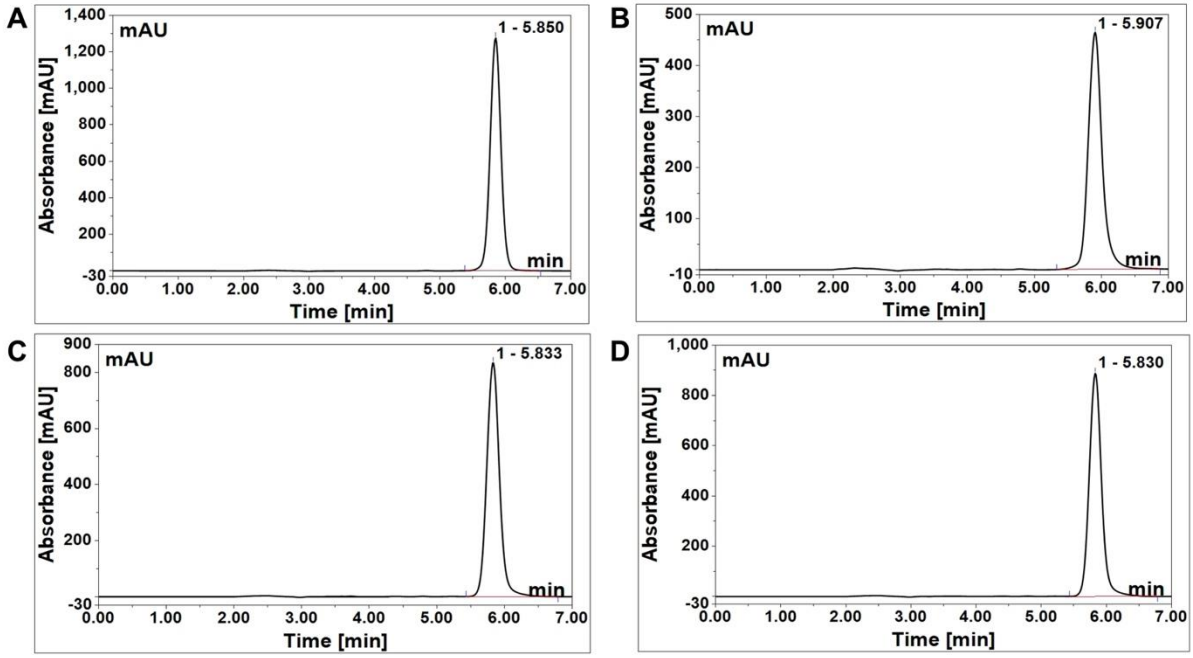

Figure S1. HPLC chromatograms: (A) reference standard at 100 µg/mL, (B) genistein solid dispersion, (C and D) genistein solid dispersion tablets F1 and F2, respectively

2. Calibration curve of genistein

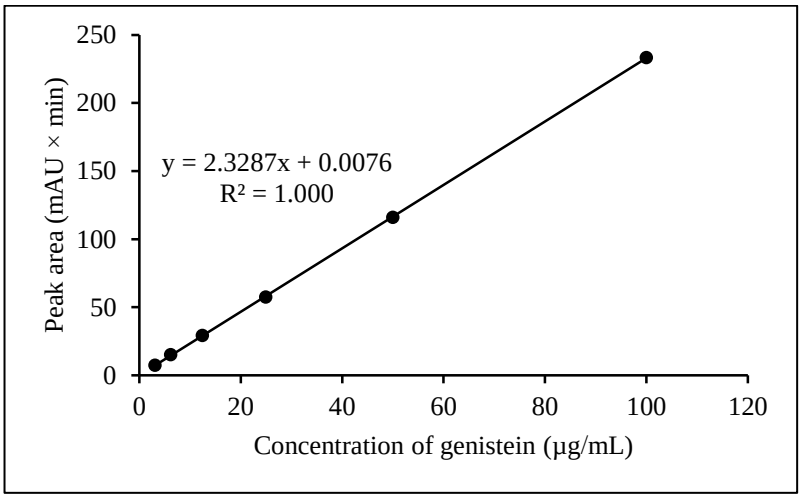

Figure S2. Standard calibration curve of genistein ranging from 3.13 to 100 µg/ml

3. The analytical recovery of the HPLC method

The accuracy of the method was assessed using the standard addition technique. Three concentrations of genistein were added to the sample and analyzed in triplicate. The total amount of genistein was determined using the calibration plot, and the percentage recovery was calculated using the following equation.

$$\text{Recovery (\%)} = \frac{\text{Experimentally measured concentration}}{\text{Theoretical concentration spiked}} \times 100$$

Table S1. The analytical recovery of the HPLC method

Analytes	**Theoretical concentration spiked (µg/mL)**	**Measured concentration (µg/mL)**	**Mean recovery (%) ± SD**
Genistein	32	33.05	102.66 ± 0.61
		32.66	
		32.84	

40	40.82	101.73 ± 0.59
	40.84	
	40.42	
48	48.19	100.22 ± 0.60
	48.34	
	47.78	

4. The precision performance of the HPLC method

The precision of a measurement technique refers to the degree of agreement among individual tests when the method is applied repeatedly to analyze multiple replicates on different occasions. Repeatability (intraday precision) was assessed by analyzing three concentrations and three replicates of each concentration of genistein within the same day. Intermediate precision (inter-day precision) was evaluated by analyzing three concentrations and three replicates of each concentration of genistein on three separate days. The overall precision of the method was expressed as the relative standard deviation (%RSD).

Table S2. The precision performance of the HPLC method

Spike conc. (ug/mL)	Mean	Standard deviation	%RSD
Repeatability			
32	70.84	0.20	0.28
40	78.69	0.23	0.29
48	86.10	0.28	0.32
Intermediate precision			
32	70.88	0.18	0.25
40	78.81	0.20	0.25
48	86.08	0.22	0.26

5. Table S3. BBD experimental parameters

Factors	Symbol	Unit	Level		
			Low (−1)	**Medium (0)**	**High (+1)**
Independent variables					
Quantity of PEG 4000	X_1	%(w/w)	1	4.5	8
Quantity of P 407	X_2	%(w/w)	0.25	2.625	5
Quantity of XPVP	X_3	%(w/w)	0.25	1.625	3
Dependent variable					
Solubility of genistein	Y_1	µg/mL			

6. Response surface methodology (RSM) optimization response

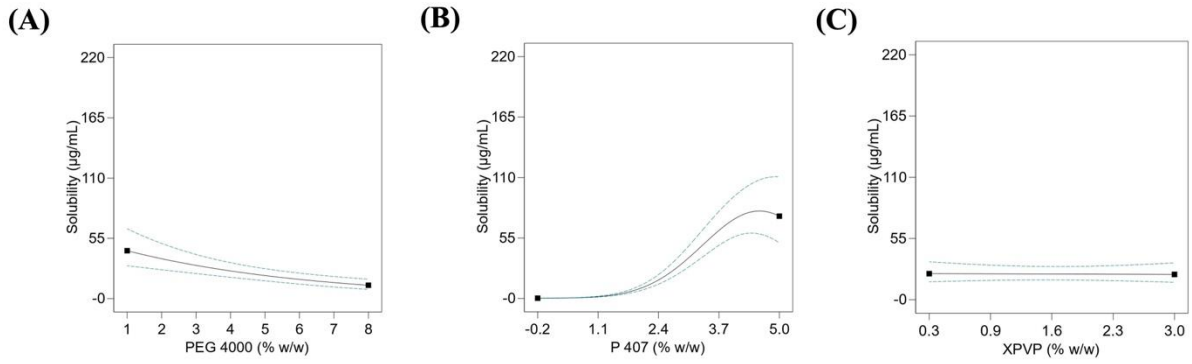

Figure S3. One-factor graph; effect of each parameter including (A) amount of PEG 4000 (B) amount of P 407 and (C) amount of XPVP on the genistein solubility (µg/mL)

7. Table S4. The genistein content in each SD formulation

Formulations	Genistein content (%)	
	Mean	**SD**
1	98.61	0.48
2	98.09	0.87
3	99.08	0.75
4	98.63	0.63
5	98.31	0.71
6	98.53	0.29
7	98.70	0.63
8	99.13	0.19
9	99.13	0.23
10	99.39	0.21
11	99.84	0.95
12	99.82	0.53
13	99.04	0.94
14	100.89	0.36
15	98.47	0.84
16	98.14	0.20
17	100.84	0.27
Optimized	99.99	1.09

The data shown are means ± SD of 3 replicates.