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APPENDIX

Table 1. Effect of Various Concentrations of Sodium Hydroxide Solution Used in Liberating Dicyclomine Free Base from Dicyclomine Hydrochloride

Normality of sodium hydroxide	absorbance[a] at 415 nm	
	fifth chloroform extract	sixth chloroform extract
1	0.037 ± 0.005	0.011 ± 0.004
2	0.003 ± 0.001	0.000 ± 0.000
3	0.004 ± 0.002	0.000 ± 0.000
4	0.003 ± 0.002	0.000 ± 0.000
6	0.003 ± 0.002	0.000 ± 0.000

[a] Mean value of three experiments.

Table 2. Effect of pH on the Formation and Extraction of Dicyclomine – Bromcresol Green Complex

pH	Absorbance[a] at 415 nm	% CV
1.0	0.363	2.20
2.0	0.367	1.36
3.0	0.363	1.55
4.0	0.365	1.64
5.0	0.331	1.20
6.0	0.101	0.99
7.0	0.000	0.00
8.0	0.000	0.00
9.0	0.000	0.00

[a] Mean value of four experiments.

Table 3. Effect of Time on Absorbance of Dicyclomine-Bromcresol Green Complex

Time, minutes	Method 1		Method 2	
	Absorbance[a]	% CV	Absorbance[a]	%CV
0	0.393	2.21	0.375	2.53
15	0.393	1.93	0.375	2.53
30	0.391	1.33	0.372	2.55
60	0.390	1.64	0.374	2.29
120	0.389	1.41	0.372	2.58
180	0.387	1.67	0.372	2.28
240	0.388	1.80	0.374	2.29
300	0.389	1.95	0.370	2.48
360	0.390	1.80	0.373	2.22
$\bar{X}$	0.390		0.373	
% CV	0.53		0.44	

[a] Mean value of three experiments.

Table 4. Effect of Temperature on Absorbance of Dicyclomine - Bromcresol Green Complex

Temperature, °C	Method 1		Method 2	
	Absorbance[a]	% CV	Absorbance[a]	% CV
25	0.413	0.42	0.378	1.74
40	0.409	0.56	0.373	1.56
50	0.410	0.84	0.375	1.66
60	0.405	0.74	0.370	1.63
70	0.404	0.39	0.372	1.42
$\bar{X}$	0.408		0.372	
% CV	0.98		0.82	

[a] Mean value of three experiments.

Table 5. Effect of Bromcresol Green Concentration on Absorbance Value of Dicyclomine-Bromcresol Green Complex

Conc^{n}. of BCG, ml x(3×10^{-4}M)	Mole Ratio Dye to Drug	Method 1		Method 2	
		Absorbance[a]	% CV	Absorbance[a]	% CV
0.5	1 : 4	0.099	0.02	0.103	1.94
1.0	2 : 4	0.219	1.37	0.216	1.38
1.5	3 : 4	0.331	0.91	0.325	0.62
2.0	1 : 1	0.444	0.91	0.423	0.47
3.0	3 : 2	0.478	0.42	0.450	0.89
4.0	2 : 1	0.479	0.21	0.448	0.67
6.0	3 : 1	0.480	0.42	0.442	0.45
8.0	4 : 1	0.480	0.63	0.442	0.90

[a] Mean value of four experiments.

BCG = Bromcresol Green

Table 6. Dicyclomine Hydrochloride Absorbance-Concentration Relationship

Method 1			Method 2		
Conc$\frac{n}{\cdot}$, mcg/ml	Absorbance[a]	% CV	Conc$\frac{n}{\cdot}$, mcg/ml	Absorbance[a]	% CV
1.38	0.045	6.67	1.37	0.034	11.76
2.75	0.119	2.52	2.74	0.118	5.93
4.13	0.189	2.65	4.12	0.194	2.57
5.50	0.276	1.81	5.49	0.275	2.18
8.26	0.435	1.15	8.23	0.415	1.93
11.01	0.613	0.82	10.98	0.574	1.05
13.76	0.762	0.52	13.72	0.713	1.26
16.51	0.928	0.75	16.46	0.872	0.69

[a] Mean value of five experiments.

Table 7. Comparison of the Experimental Parameters in Method 1 and Method 2

Experimental Parameter	Method 1	Method 2
1. Color of the Complex	yellow	yellow
2. Wavelength of Maximum Absorption, nm	415	415
3. Color Stability :-		
- Effect of Time	negligible	negligible
- Effect of Temperature	negligible	negligible
4. Dye Concentration Used, mole dye :mole drug	4 : 1	4 : 1
5. Stoichiometric Balance	1 : 1	1 : 1
6. Calibration Curve :-		
- Linear conc^{n} range (mcg/ml)	1.38 - 16.51	1.37 - 16.46
- Slope	0.0600	0.0566
- % CV	0.75 - 6.67	0.69 - 11.76
- reproducibility	good	poor
7. Reagent used	2 N sodium hydroxide was stable.	buffer solution was stable for only two weeks.

Table 8. Percent Labelled Amount of Dicyclomine HCl in Dicyclomine HCl Tablet Using Method 1 and USP Method

sample	Percent Labelled Amount of Dicyclomine HCl	
	Method 1	USP Method
1	98.78	97.62
2	99.79	97.28
3	99.15	97.38
4	98.25	97.81
5	99.07	97.60
6	98.18	97.54
7	98.73	97.80
8	98.16	96.93
9	98.42	97.65
10	98.09	97.53
$\bar{X}$	98.66	97.51
% CV	0.55	0.29

Table 9. Percent Recovery of Dicyclomine HCl in Dicyclomine HCl Tablet by Method 1 and USP Method

Sample	Dicyclomine HCl Added, mg	Method 1		USP Method	
		Dicyclomine HCl Found, mg	% Recovery	Dicyclomine HCl Found, mg	% Recovery
1	1.99	2.01	101.01	2.01	101.01
2	1.99	2.01	101.01	2.01	101.01
3	2.00	2.01	100.50	2.01	100.50
4	2.00	1.98	99.00	2.05	102.50
5	2.00	2.03	101.50	1.98	99.00
$\bar{X}$			100.60		100.80
% CV			0.96		1.24

Table 9. (Continue) Percent Recovery of Dicyclomine HCl in Dicyclomine HCl Tablet by Method 1 and USP Method

Sample	Dicyclomine HCl Added, mg	Method 1		USP Method	
		Dicyclomine HCl Found, mg	% Recovery	Dicyclomine HCl Found, mg	% Recovery
1	2.99	3.04	101.67	3.04	101.67
2	2.99	3.05	102.01	2.99	100.00
3	3.00	3.03	101.00	3.01	100.17
4	3.00	3.05	101.67	3.04	101.33
5	3.00	3.04	101.33	3.00	100.00
$\bar{X}$			101.53		100.63
% CV			0.38		0.79

Table 9. (Continue) Percent Recovery of Dicyclomine HCl in Dicyclomine HCl Tablet by Method 1 and USP Method

Sample	Dicyclomine HCl Added, mg	Method 1		USP Method	
		Dicyclomine HCl Found, mg	% Recovery	Dicyclomine HCl Found, mg	% Recovery
1	3.99	4.03	101.00	4.06	101.75
2	3.99	4.05	101.50	4.00	100.35
3	4.00	4.04	101.10	4.06	101.50
4	4.00	4.03	100.75	4.01	100.35
5	4.00	3.99	99.93	4.01	100.35
$\bar{X}$			100.86		100.86
% CV			0.57		0.69

Table 10. Comparative Analysis of Preparations Containing Dicyclomine HCl

Formulation	Label Content, mg	Method 1		USP Method	
		Amount Found, mg	% Recovery	Amount Found, mg.	% Recovery
Tablet A	10 mg/tablet	9.92	99.20	9.76	97.60
		9.80	98.00	9.73	97.30
		9.91	99.10	9.74	97.40
		9.87	98.70	9.78	97.80
		9.76	97.60	9.76	97.60
$\bar{x}$			98.52		97.54
% CV			0.71		0.19

Table 10. (Continue) Comparative Analysis of Preparations Containing Dicyclomine HCl.

Formulation	Label Content, mg	Method 1		USP Method	
		Amount Found, mg	% Recovery	Amount Found, mg	% Recovery
Tablet B	20 mg/tablet	19.56	97.80	19.57	97.85
		19.69	98.45	19.47	97.35
		19.49	97.48	19.50	97.50
		19.71	98.56	19.38	96.90
		19.53	97.69	19.45	97.25
$\bar{X}$			97.99		97.37
% CV			0.49		0.36

Table 10. (Continue) Comparative Analysis of Preparations Containing Dicyclomine HCl

Formulation	Label Content, mg	Method 1		USP Method	
		Amount Found, mg	% Recovery	Amount Found, mg	% Recovery
Capsule C	10 mg/capsule	10.11	101.10	9.91	99.10
		10.09	100.90	9.90	99.00
		10.03	100.30	9.85	98.50
		10.02	100.20	10.02	100.20
		9.98	99.80	9.89	98.90
$\bar{X}$			100.46		99.14
% CV			0.53		0.63

Table 10. (Continue) Comparative Analysis of Preparations Containing Dicyclomine HCl

Formulation	Label Content, mg	Method 1		USP Method	
		Amount Found, mg	% Recovery	Amount Found, mg	% Recovery
Syrup D	5 mg/5 ml	5.07	101.40	4.95	99.00
		4.96	99.20	4.88	97.60
		4.87	97.40	4.95	99.00
		4.91	98.20	4.88	98.60
		4.97	99.40	4.86	99.30
$\bar{X}$			99.12		98.70
% CV			1.52		0.67

Table 10. (Continue) Comparative Analysis of Preparations Containing Dicyclomine HCl

Formulation	Label Content, mg	Method 1		USP Method	
		Amount Found, mg	% Recovery	Amount Found, mg	% Recovery
Syrup E	10 mg/ 5 ml	10.12	101.20	9.89	98.90
		9.98	99.80	9.95	99.50
		10.05	100.50	10.06	100.60
		9.92	99.20	10.12	101.20
		10.18	101.80	9.99	99.90
$\bar{X}$			100.50		100.02
% CV			1.04		0.90

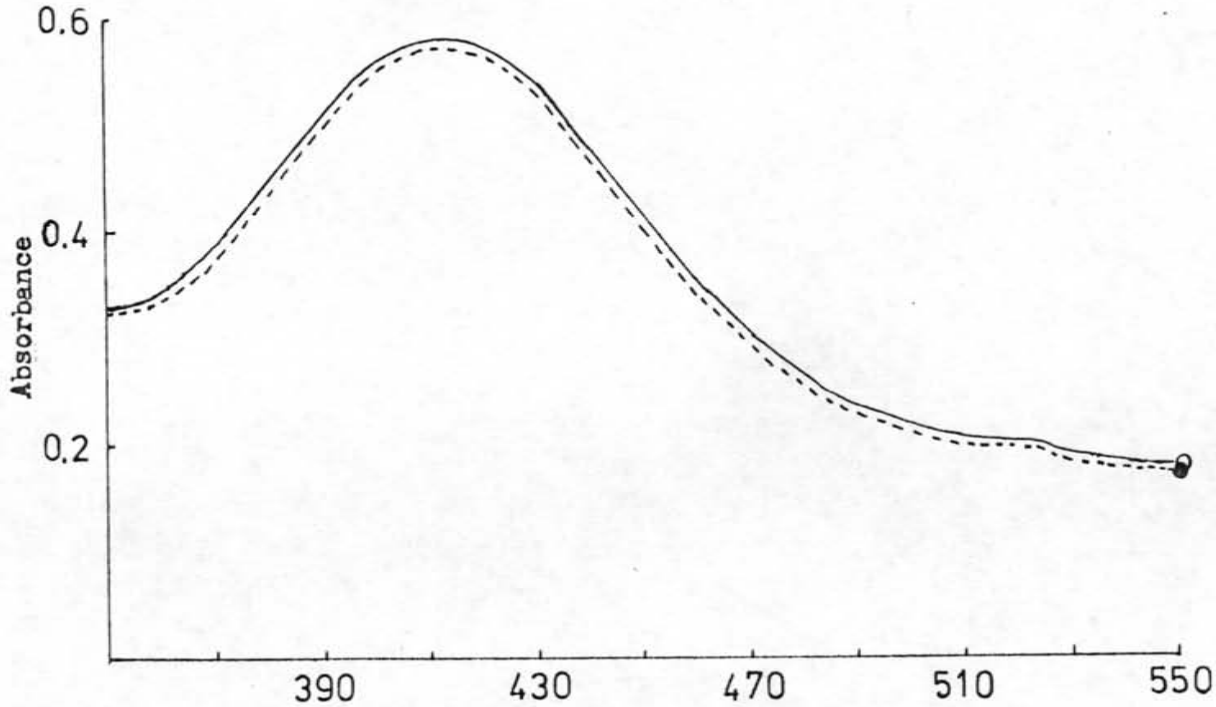

Figure 1. Absorption spectra of dicyclomine-brocresol green complex.

Key : o , method 1 ; ● , method 2.

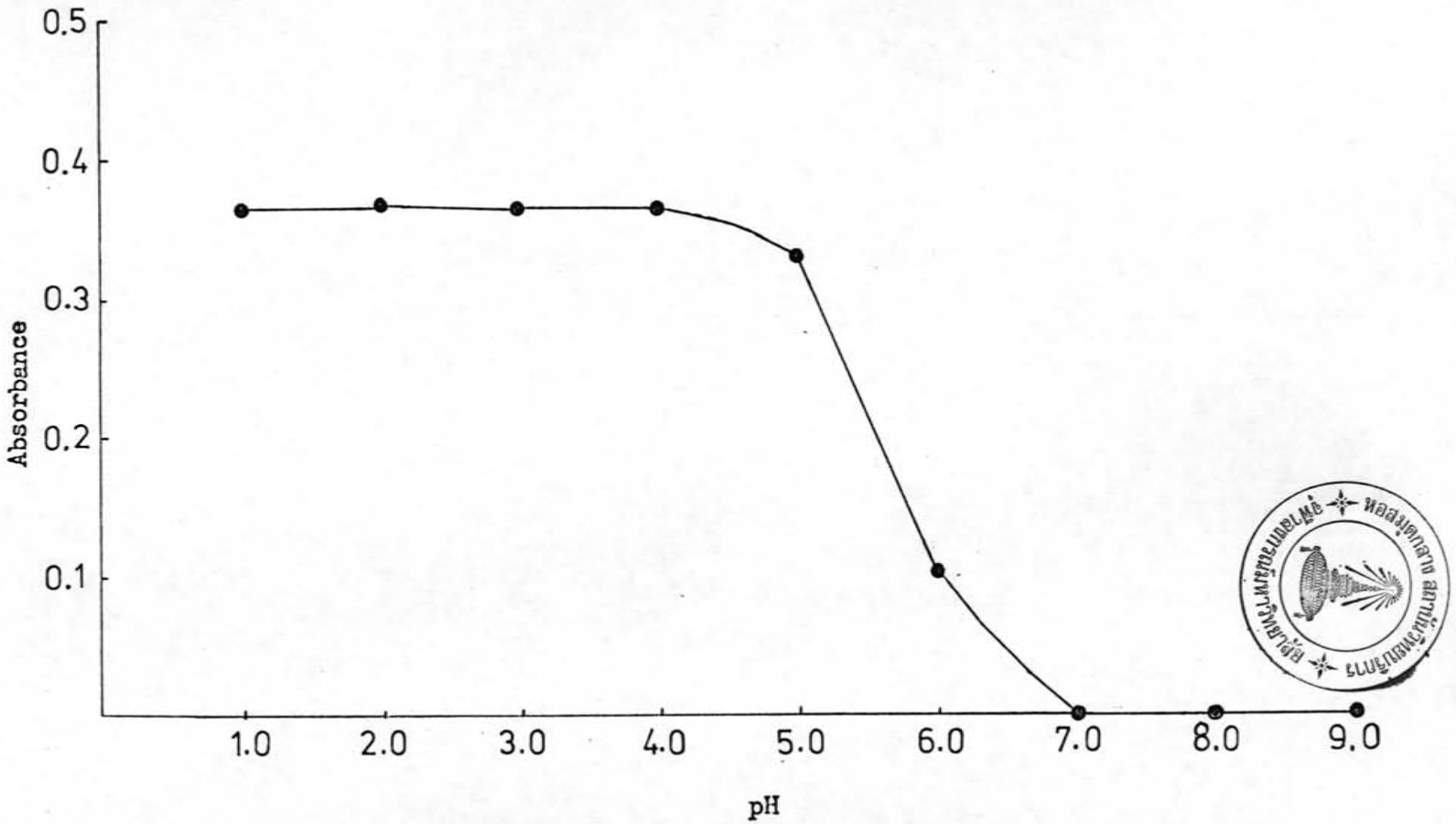

Figure 2. Effect of pH on formation and extraction of dicyclomine-bromcresol green complex.

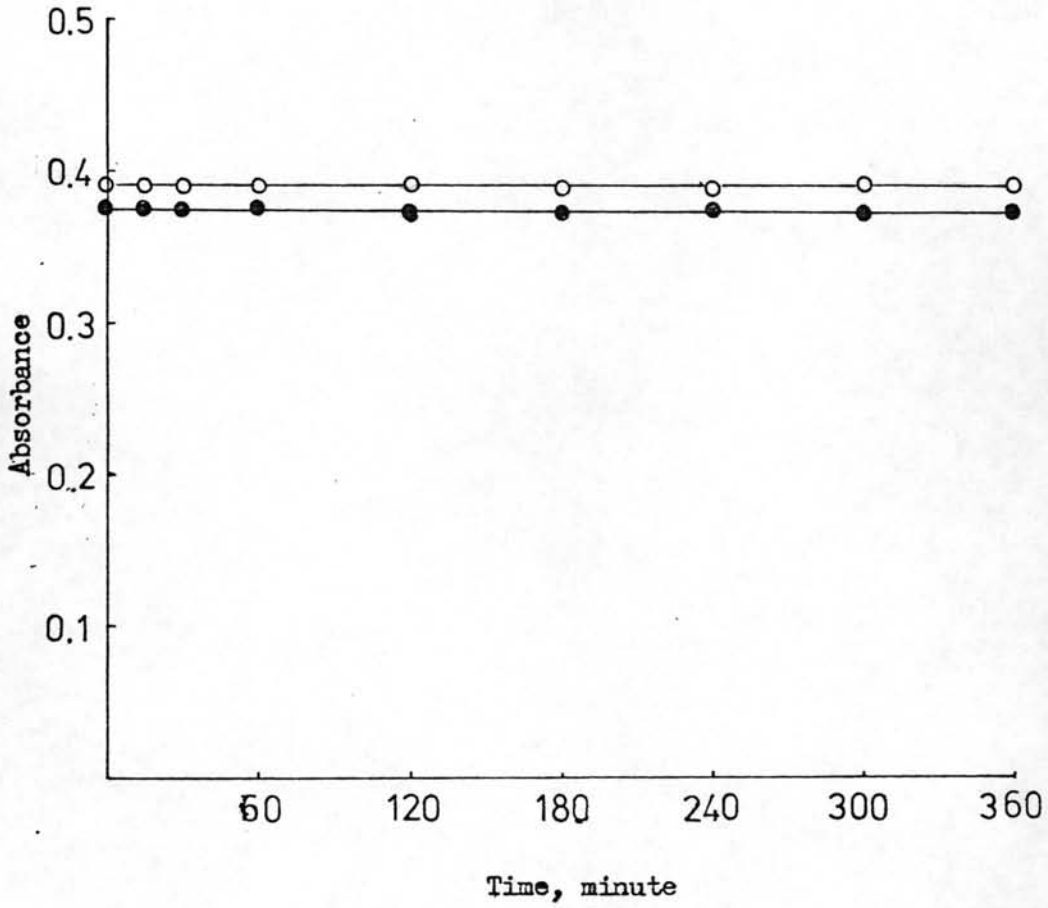

Figure 3. Effect of time on absorbance of dicyclomine-bromoresol green complex
Key : ○ , method 1; ● , method 2.

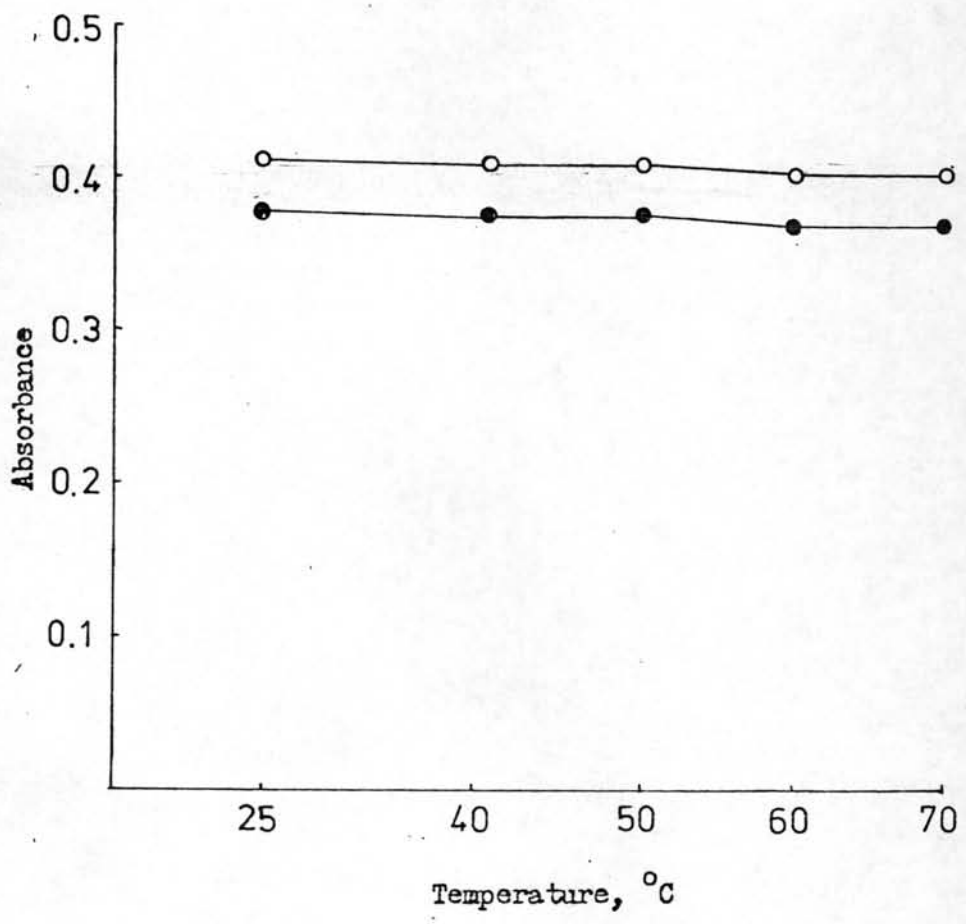

Figure 4. Effect of temperature on stability of dicyclomine-bromcresol green complex. Key : ○ , method 1; ● , method 2.

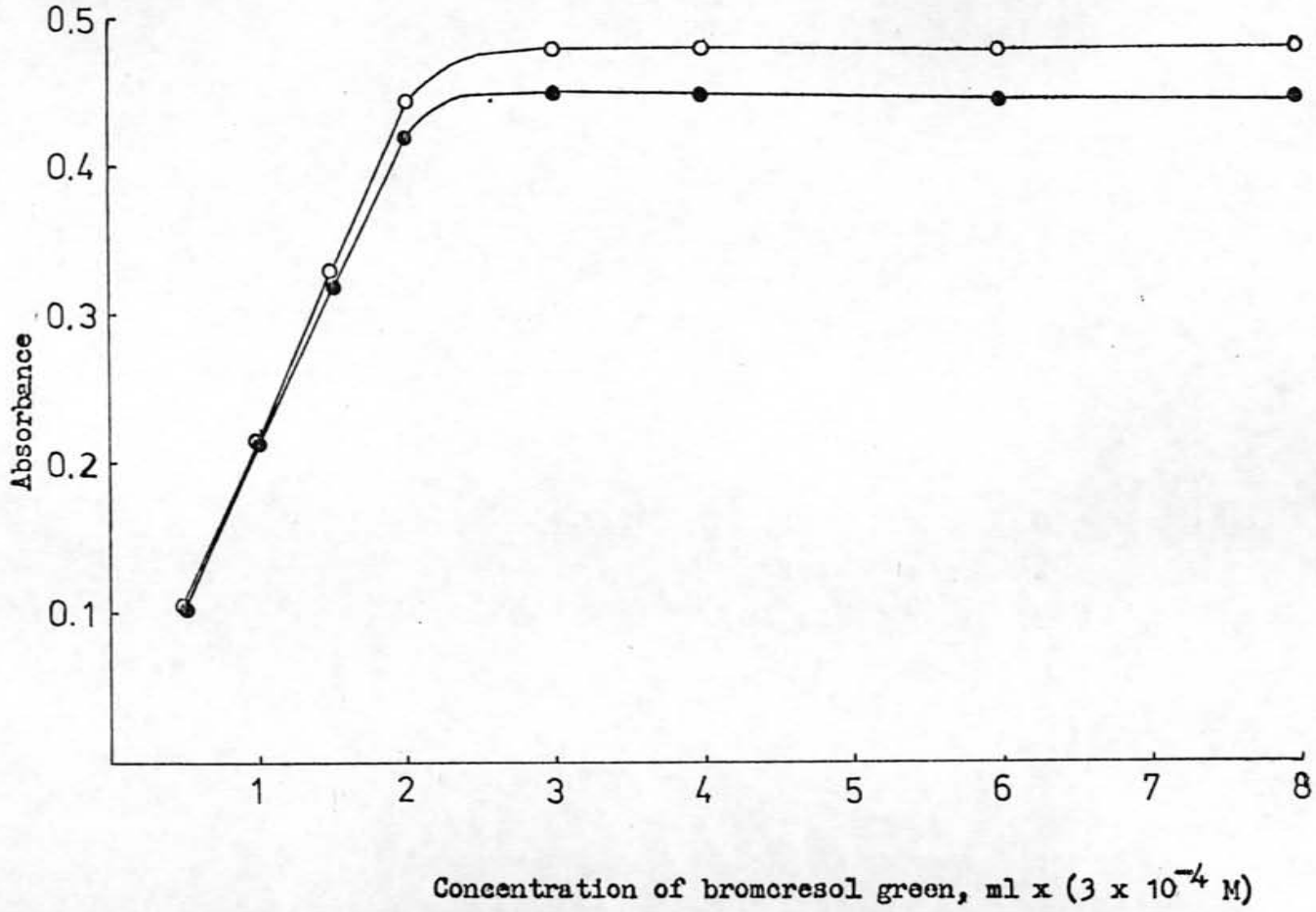

Figure 5. Effect of bromcresol green concentration on color formation of dicyclomine-bromcresol green complex.

Key : ○ , method 1; ● , method 2.

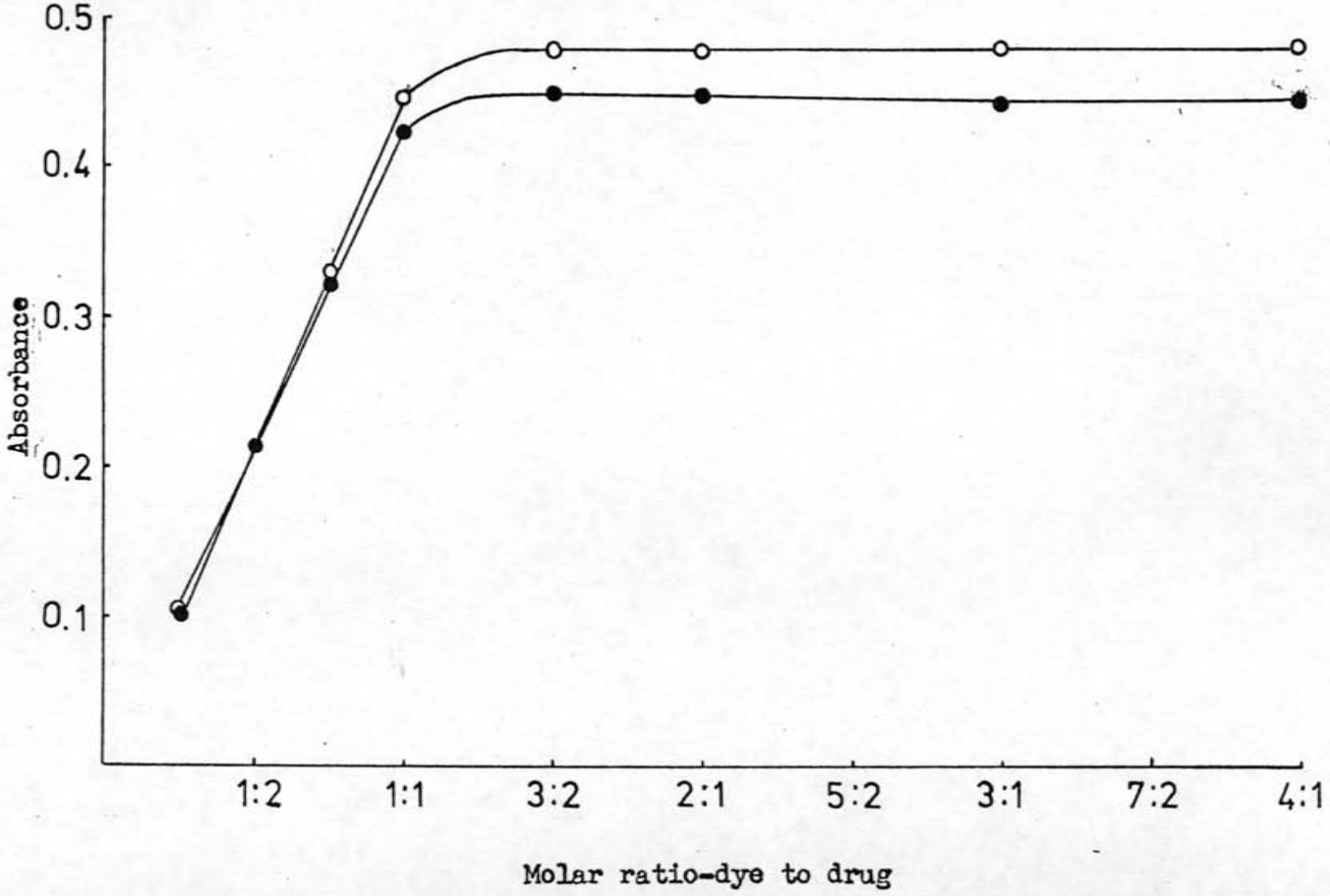

Figure 6. Mole ratio curve obtained from dicyclomine-bromcresol green complex. Key : o , method 1, ● , method 2.

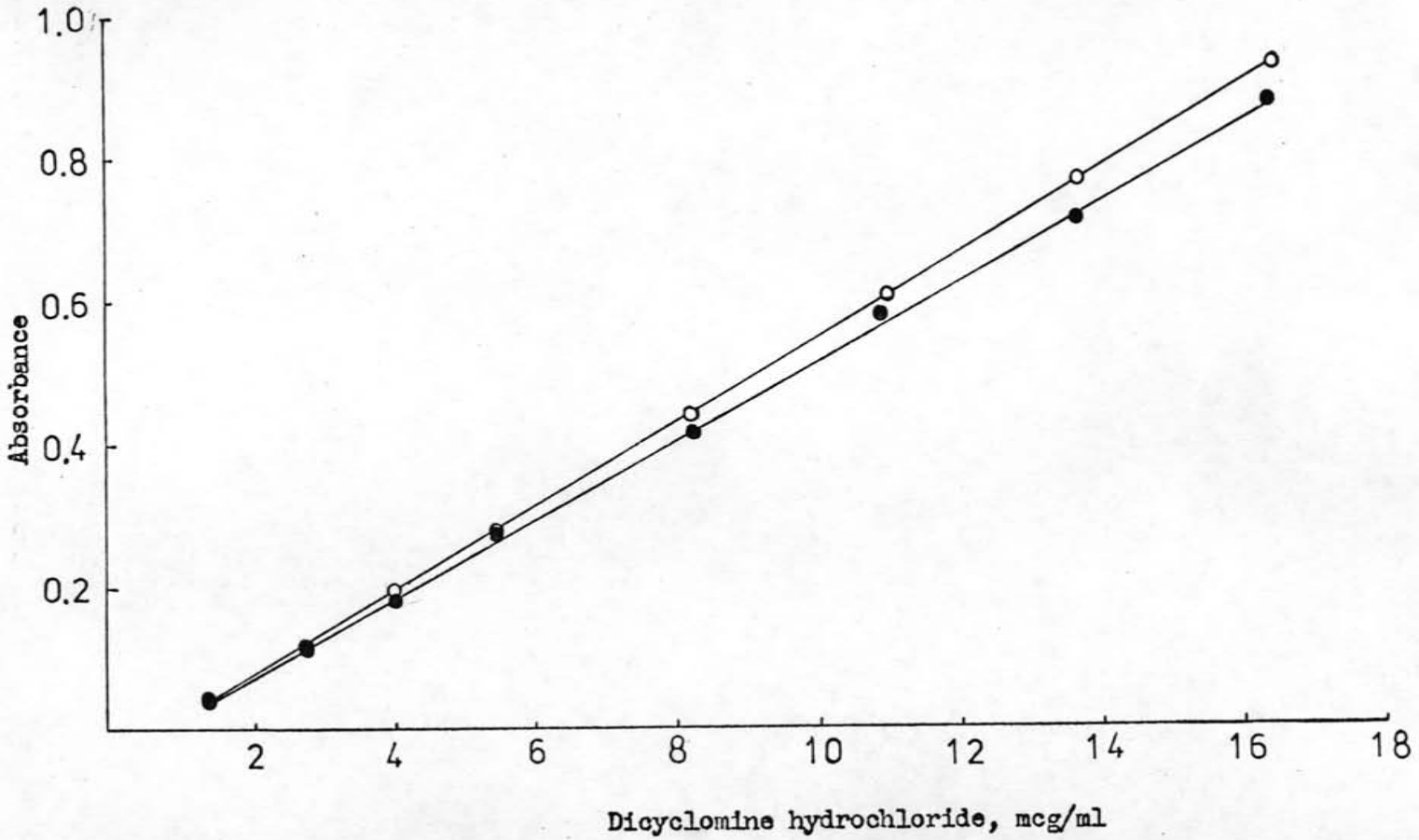

Figure 7. Calibration curve of dicyclomine hydrochloride with bromcresol green. Key : o , method 1; ● , method 2.

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