Sheet No.
GT200-ME010

Purity Analysis of Theophylline

Method : Neutralization titration
Apparatus : Automatic Titrator GT-200
Electrode: Double junction reference electrode - glass electrode
Reference electrode inner solution: 1 mol/L potassium chloride solution
Reference electrode outer solution: 1 mol/L potassium nitrate solution
Titration mode : INF, Detection; pH
Related standard : Japanese Pharmacopoeia Theophylline, Purity test, Quantification method

*This sheet is provided as information. It is not to guarantee the analysis values. Please use under the ideal conditions considering external factors including the analysis environment and properties of the sample.

Outline

Standards of theophylline are stipulated by the Japanese Pharmacopoeia, which specifies 99.0% or greater of theophylline to be contained when quantifying a dried product.
Theophylline is a substance contained in tea leaves, and is used for painkiller, energy drinks and other products.

Reagents

[Titrant]
■0.1 mol/L sodium hydroxide solution (for volumetric analysis)
[Reagents]
■0.1 mol/L silver nitrate solution (for volumetric analysis)

Analytical Procedure

[Blank test]
(1) Place 100 ml of pure water into a 200-ml beaker using a measuring cylinder.
(2) Accurately measure 20 ml of 0.1 mol/L silver nitrate solution and add into the beaker.
(3) Titrate using 0.1 mol/L sodium hydroxide solution.
[Purity test of theophylline]
(1) Accurately weigh 0.25 g of theophylline in a 200-ml beaker.
(2) Add 100 ml of pure water into the beaker using a measuring cylinder.
(3) Stir until the sample is completely dissolved, and titrate using 0.1 mol/L sodium hydroxide solution.

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[Equation]
Purity(%)=(A1-BL) × M × E × f × FW / S × R/10 (using fixed equation)

A1 : Titer of 0.1 mol/L sodium hydroxide solution to the inflection point (ml)
BL : Titer of 0.1 mol/L sodium hydroxide solution in blank test (ml)
M : Molarity of 0.1 mol/L sodium hydroxide solution
E : Equivalent number of 0.1 mol/L sodium hydroxide solution (1)
FW : Formula weight of theophylline (180.16)
S : Sample amount (g)
R : Dilution rate (1)

Other Requirements

■Ensure to dry theophylline before use.
■Ensure to always use newly prepared silver nitrate solution and sodium hydroxide solution.
■Handle measurement reagents with care after reading through and understanding their labels and safety data sheets.
■Wear personal protective equipment such as protective goggles and gloves when handling the reagents.

Measurement Results

	Sample amount (g)	Titer (ml)	Measurement value (%)
1	0.2558	14.3066	100.4
2	0.2543	14.1944	100.2
3	0.2585	14.4503	100.4

Number of data	(n)	3
Average	(x)	100.3
Standard deviation	(SD)	0.1066
Relative standard deviation	(RSD%)	0.1062

Blank 0.0620 ml

*Measurement values are rounded according to the General Notices of the Japanese Pharmacopoeia.

Purity of theophylline (commercial special grade reagent) was measured using GT-200. Average over 3 measurements was 100.3%. Relative standard deviation (RSD%) was 0.11%, exhibiting measurement with relatively high reproducibility.

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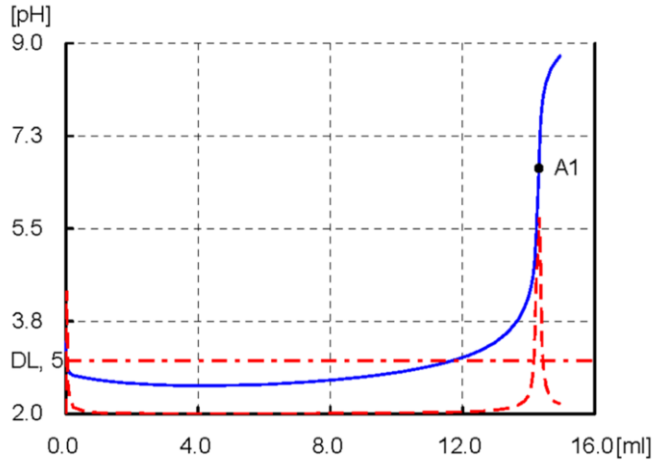
ID No.: 5 GT No.1 User: GT-200

Measurement date: 2013/02/15 13:21
Sample name : Theophylline
Measurement type : Sample Titr
Sample size (S) : 0 [g]



C1: 100.43 [%]

A1: 14.3066 [ml] 6.64 [pH]

Pi	: 3.366	[pH]			
Start	: 0	[ml]	3.366	[pH]	
End	: 14.944	[ml]	8.767	[pH]	Time: 4’ 59”

Run File No.: 0 Quick Mode
Titration File No.: 20 Purity analysis of theophylline (medicine)

Mode	: INF		End1 End1 Width: 7 [pH] ± 3 [pH]
Detect	: pH		
BRT No.	: 1		
Reagent	: 20		
WTint	: 0	[sec]	
Vup	: 400	[µl]	
Vlow	: 20	[µl]	
dE	: 0.1	[pH]	
dT	: 3	[sec]	
DL	: 5	[pH/ml]	
DetCnt	: 10		
Vmax	: 20	[ml]	
Vover	: 0.5	[ml]	C1: (A1-BL)*M*E*f*FW/S*R/10 [%]

Reag	: 0.1M-NaOH	E	: 1	M	: 0.1 [Mol/l]
f	: 1.001	BL	: 0.062 [ml]		
FW	: 180.16	R	: 1		

Buret Injection Speed: 500 [ul/sec]