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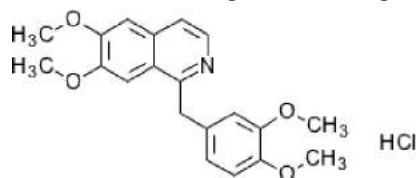
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HIRANUMA APPLICATION DATA		Automatic Titrator	Data No.	B19	Apr. 19,2018
Drugs and Medicines	Purity determination for papaverine hydrochloride by perchloric acid titration				

1. Abstract

Determination for papaverine hydrochloride is defined in Japanese Pharmacopoeia. Papaverine hydrochloride is used for improvement of vasodilatation and symptoms on gastritis, disease of biliary tract (gallbladder) system, acute arterial embolus, acute pulmonary embolism, peripheral circulatory failure, and inadequate coronary circulation.

The purity determination of papaverine hydrochloride using potentiometric titration with perchloric acid titrant is introduced in this report. Sample is dissolved by heating with acetic anhydride / glacial acetic acid mixture and cooled to room temperature. After that, the titration is performed, 1 mol papaverine hydrochloride reacts with 1 mol perchloric acid quantitatively.



Papaverine hydrochloride ($C_{20}H_{21}NO_4 \cdot HCl$, FW:375.85)

2. Configuration of instruments and Reagents

(1) Configuration of instruments

Main unit	: Hiranuma Automatic Titrator COM Series
Electrodes	: Glass electrode GE-101B
	: Reference electrode RE-201Z
	Inner solution has to be changed to saturated sodium perchlorate in glacial acetic acid.

(2) Reagents

Titration solvent	: Mixture of glacial acetic acid and acetic anhydride (3:7, v/v)
Inner solution	: Saturated sodium perchlorate in glacial acetic acid

3. Measurement procedure

- (1) Take about 0.5 g of sample into 200 mL beaker and weigh accurately to 0.1 mg digits.
 - (2) Add 100 mL of titration solvent and dissolve sample by heating and stirring. After that, cool it down to room temperature.
 - (3) Immerse the electrode and titrate by 0.1 mol/L Perchloric acid – acetic acid standard solution.
- Additionally, perform the blank test with the same procedure of sample measurement.

4. Measurement conditions and results

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Cndt No.	1	ConstantNo.	1		Mode No.	17
Method	Auto	Size	0 g		Pre Int	0 sec
Buret No.	1	Blank	0 mL		Del K	0
Amp No.	1	Molarity	0.1 mol/L		Del Sens	0 mV
D. Unit	mV	Factor	1.002		Int Time	5 sec
S-Timer	10 sec	K	0		Int Sens	3 mV
C.P. mL	0 mL	L	0		Brst Speed	2
T Timer	0 sec				Pulse	16
D.P. mL	0 mL	Unit	mL			
End Sens	300	Formula	D			
Over mL	0.2 mL	Digits	3			
Max.Vol.	1 mL	Auto In Pram.	Non			

Measurement of sample

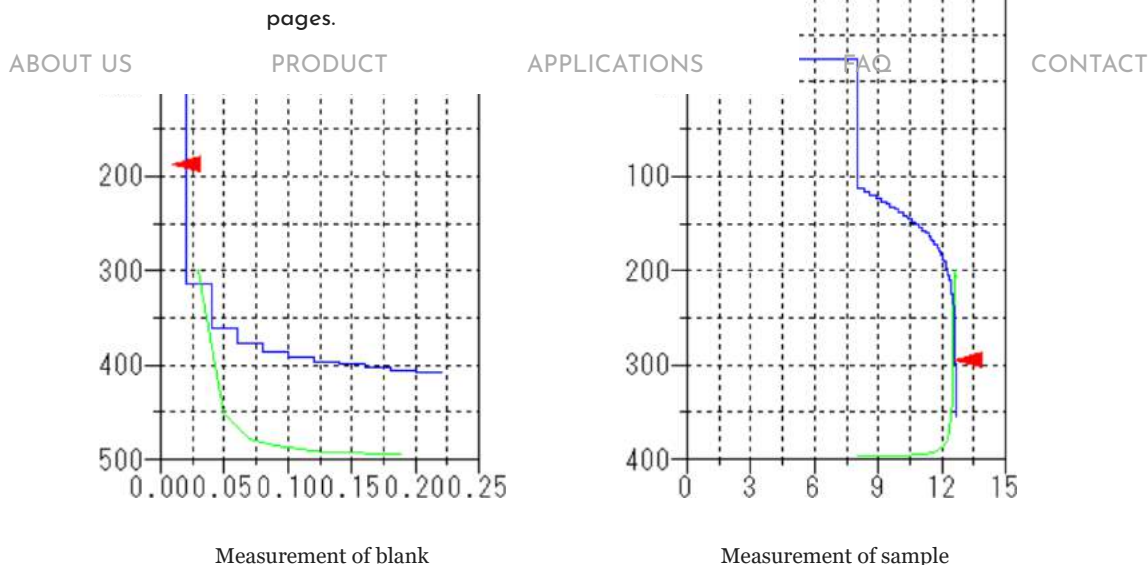
Cndt No.	1	ConstantNo.	1	Mode No.	8
Method	Auto	Size	0 g	Pre Int	0 sec
Buret No.	1	Blank	0.10 mL	Del K	0
Amp No.	1	Molarity	0.1 mol/L	Del Sens	0 mV
D. Unit	mV	Factor	1.002	Int Time	5 sec
S-Timer	10 sec	K	375.85	Int Sens	3 mV
C.P. mL	8 mL	L	0	Brst Speed	2
T Timer	30 sec			Pulse	40
D.P. mL	0 mL	Unit	%		
End Sens	300	Formula	$(D-B)*K*F*M/(S*10)$		
Over mL	0.00 mL	Digits	4		
Max.Vol.	20 mL	Auto In Pram.	Non		

Measurement results

Measurement of blank		
Number of Measurement	Size (g)	Titration volume (mL)
1	—	0.010
2	—	0.010
Avg. (Blank)		0.010 mL

Measurement of sample			
Number of Measurement	Size (g)	Titration volume (mL)	Purity (%)
1	0.4593	12.216	100.0830
2	0.4815	12.761	99.7310
3	0.4746	12.595	99.8637
Statistic calculation		Avg.	99.89 %
		SD	0.18 %
		RSD	0.18 %

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Examples of measurement curves

5. Note

(1) Temperature correction of perchloric acid standard solution

This measurement determines the purity of the sample. Therefore, please pay attention for accurate weighing, measurement of factor or blank. Especially, the factor determination of perchloric acid – acetic acid standard solution should be regularly performed with potassium hydrogen phthalate. Acetic acid used as a solvent for the titrant has a relatively large thermal expansion coefficient. For example, a temperature change of 1 °C on this titrant causes a volume change of 0.1 %. Factor titration and sample measurement should be performed at the same room temperature as much as possible for accurate measurement.

When the temperature of the sample measurement is different from that of factor titration, assign the following correction formula for titrant factor to the concentration calculation of sample.

$$F = \frac{F_0}{1 + \alpha(t - t_0)}$$

F : Corrected factor at sample titration

F₀ : Factor at titrant factor determination

α : Thermal expansion coefficient of titrant

(Acetic acid = 1.07×10⁻³)

t : Temperature at sample titration

t₀ : Temperature at titrant factor determination

(2) Preparation of inner solution for reference electrode

The inner solution of the reference electrode RE-201Z is filled with saturated KCl aqueous solution when purchased. This inner solution have to be replaced to saturated sodium perchlorate in acetic acid solution for this measurement. Replacement procedure is described below.

- Prepare the saturated solution of sodium perchlorate in acetic acid with reagent grade of these.
- Discharge inner solution from reference electrode RE-201Z and wash inside it with water and then acetic acid.
- Fill the prepared inner solution into reference electrode from the supply port.
- Leave the electrode for one day before use.

Keywords: Drug, Papaverine hydrochloride, Japanese pharmacopoeia, Perchloric acid titration, Non-aqueous titration, Saturated sodium perchloric acid – acetic acid solution

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