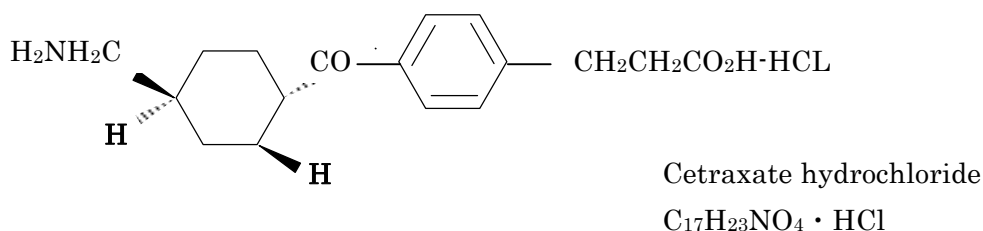


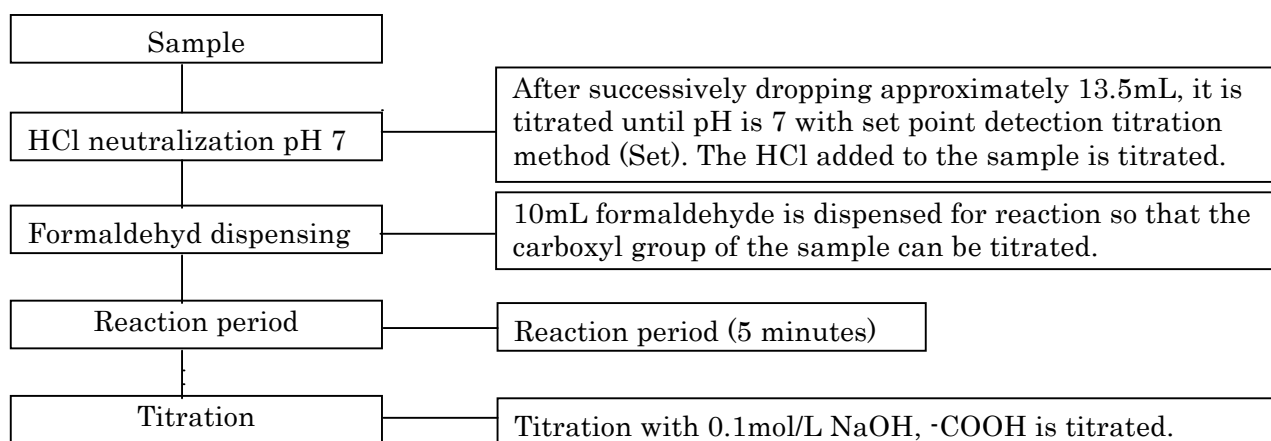
AQUACOUNTER Application Sheet	COM series	DATA No. B6	1st edition
Pharmaceuticals	Measurement of cetraxate hydrochloride purity		

1. Measurement outline

The method for quantifying cetraxate hydrochloride which is used as antineoplastic drug is stipulated in Japanese Pharmacopoeia (13th revision). This section introduces the results of measuring cetraxate hydrochloride purity according to Japanese Pharmacopoeia. In this measurement method, the sample is first added and dissolved in 100mL purified water to be then added with 0.1mol/L sodium hydroxide solution until pH reaches 7, and then titration is conducted on the hydrochloric acid added. Then 10mL formaldehyde solution is added for slow potentiometric titration with 0.1mol/L sodium hydroxide titrant. 1mol of cetraxate hydrochloride reacts quantitatively with 1mol of sodium hydroxide.



[Reaction between cetraxate hydrochloride and formaldehyde]



2. Reagents and Electrodes

(1) Reagents	Titrant	0.1mol/L sodium hydroxide titrant
	Loading buffer	10mL 36 – 38% formaldehyde solution
(2) Electrodes	Indicator electrode	*Glass electrode GE-101B
	Reference electrode	*Reference electrode RE-201
*Standard accessories		

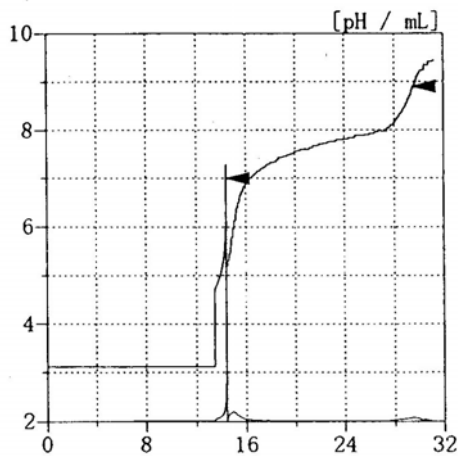
3. Measurement conditions example (for COM-1600S + Buret B-2000 × 1 units)

Master File No.1					
Condition file : 1 + 2 + 3					
Parameters for Condition file 1 (For pH adjustment until pH7)		Parameters for Condition file 2 (For addition of formaldehyde)		Parameters for Condition file 3 (For the measurements)	
Method	SET	Method	DISP	Method	AUTO
Amp No.	1	Amp No.	1	Amp No.	1
Buret No.	1	Buret No.	2	Buret No.	1
Meas Unit	pH	S-Timer	0 sec.	Meas Unit	pH
S-Timer	0 sec.	Disp. Vol.	10 mL	S-Timer	300 sec.
CP	13.50 mL			CP	0 mL
Direction	UP			Direction	N/A
T-Timer	200 sec			T-Timer	0 sec
DP	0.20 mL			DP	0.5 mL
End pH	7.00 pH			End Sens	500
Over mL	0 mL			Over mL	2.00 mL
Max. Vol.	20			Max. Vol.	20
Mode No.	21			Mode No.	22
Unit	mL			Unit	%
Formula	D			Formula	$34.183 \times (D-B) \times F / (S \times 10)$
Blank	BLANK result value			Blank	BLANK result value
Molarity	0.1			Molarity	0.1
Factor	Titer of the titrant			Factor	Titer of the titrant
K	0			K	0

	Mode No.21 (Titration until pH7)	Mode No.22 (Titration of sample)
Pre Int	0 sec	0 sec
Del K	1	2
Del Sens	0 mV	0 mV
Int Time	20 sec	30 sec
Int Sens	3 mV	3 mV
Brt Speed	20	2
Pulse	8	80

4. Measurement example

Sample measurement results



Sample measurement results

Sample No.	Sample volume (g)	Titration value (mL)	Concentration (%)
1	0.142	2.860	0.232
2	0.142	2.857	0.231
3	0.163	3.281	0.231
Avg.			0.231 %
Std. Dev.			0.001 %
C.V.			0.475 %

5. Outline

In conducting this measurement, it is important that the following points be noted:

- (1) It is important that titration of the hydrochloric acid added shall be conducted slowly by adding 13.5mL slowly and successively in advance (burette speed 20) and then stirring for approximately 200 seconds.
- (2) Approximately 5 minutes are required as the reaction time between the sample and formaldehyde.
- (3) Better results can be obtained when the sample is titrated relatively slowly. If the waiting period (Int Time) is set shorter than 30 seconds, the content tended to be larger than 100%.

Key words

Medical product, cetraxate hydrochloride, formaldehyde, Japanese Pharmacopoeia

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