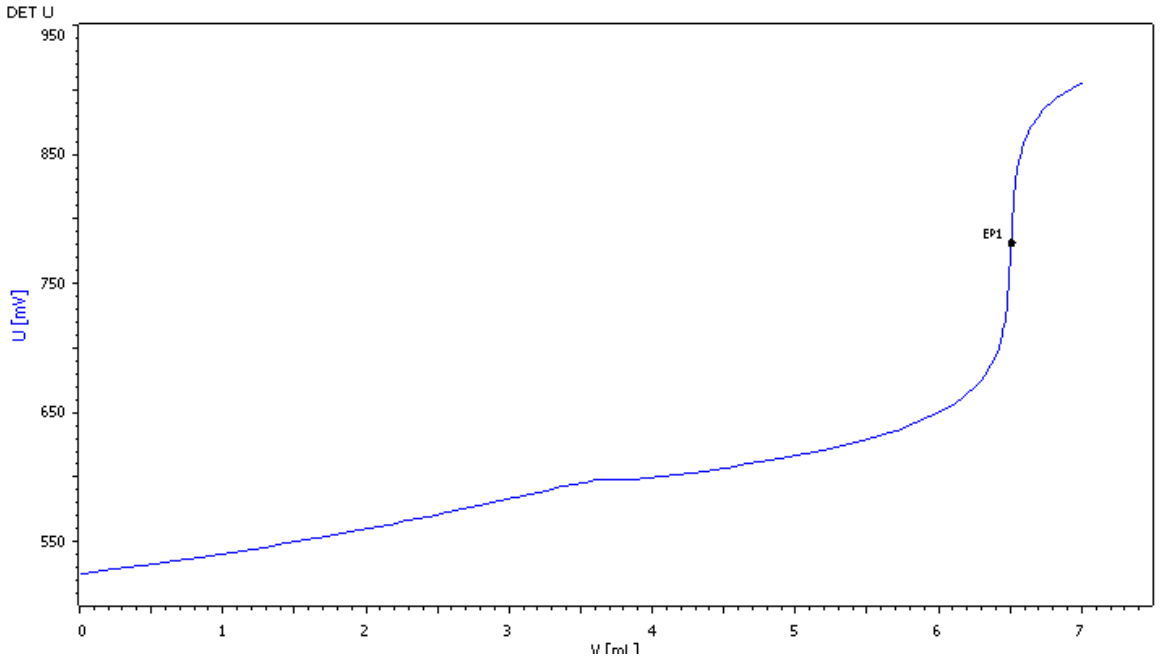
Titration Application Note T-184

Determination of metformin hydrochloride assay according to USP



Metformin is one the most commonly used drugs for diabetes type 2 belonging to the group of biguanides. This Application Note describes the determination of metformin hydrochloride assay according to USP using acetic anhydride as solvent.

Metrohm

Method description

Sample

Pure metformin hydrochloride powder

Sample preparation

No sample preparation is necessary.

Configuration

814 USB Sample Processor (1T/0P)	2.814.0030
843 Pump station (peristaltic)	2.843.0150
Sample rack 22 x 120 mL	6.2041.470
905 Titrando	2.905.0010
800 Dosino, 3x	2.800.0010
Dosing unit 50 mL (Acetic anhydride)	6.3032.250
Dosing unit 10 mL (Formic acid)	6.3032.210
Dosing unit 10 mL (Perchloric acid)	6.3032.210
802 Stirrer	2.802.0020
Propeller for 120 mL beaker	6.1909.050
Titration head 3 x SGJ 14	6.1458.040
Stopper 3 x	6.2730.030
Sample beaker 120 mL	6.1459.300
Solvotrode easyClean, LiCl 2 mol/L in EtOH	6.0229.020

Solutions

Titrant	$c(HClO_4)$ = 0.1 mol/L in glacial acetic acid, should be bought from a supplier
Solvent	Acetic anhydride
	Formic acid

Blank determination

4 mL of formic acid and 50 mL of acetic anhydride are filled into a titration beaker and then titrated with $c(HClO_4)$ = 0.1 mol/L in glacial acetic acid until after the equivalence point. The volume of the equivalence point corresponds to the blank value.

Analysis of samples

50 to 75 mg metformin hydrochloride is weighed into a titration beaker and dissolved in 4 mL formic acid. Afterwards, 50 mL of acetic anhydride is added and after a pause of 30 s the solution is titrated with $c(HClO_4)$ = 0.1 mol/L in glacial acetic acid until after the equivalence point.

Parameters

Mode	DET U
Signal drift	50 mV/min
Pause	30 s
Stirrer	8
Max. waiting time	26 s
Meas. point density	4
Min. increment	10 µL
Stop EP	1
Volume after EP	0.5 mL
EP criterion	50
EP recognition	greatest

Result

Assay % (n=10)	s_{rel} (%)
99.4	0.4

Titration Application Note
Version 1, published in November 2017

Metrohm