

The drugs olanzapine, clozapine, quetiapine, risperidone, and paliperidone (= 9-OH-risperidone) belong to the class of the so called "atypical" neuroleptics and are used for the treatment of schizophrenia. Co-medication, smoking, caffeine and food are factors that extensively influence their metabolism and thus lead to a high intra- and interindividual variability of drug concentrations in blood. In order to avoid severe side effects by overdosing and to ensure an optimal therapeutic effect, therapeutic drug monitoring (TDM) is required. The RECIPE Complete Kit represents a fully automated, robust on-line SPE technique, that allows for a direct sample injection into the HPLC system.

Psychoactive Drugs

Atypical Neuroleptics in Plasma / Serum – on-line Analysis

Test Data

Linearity: Olz / D-Olz: 5 / 10 - 1000 µg/l
Clz / D-Clz: 6 / 5 - 5000 µg/l
Qtp: 10 - 2000 µg/l
Plp, Rsp: 1 - 200 µg/l

Recovery: 100 %

LOD: 2 µg/l (Olz, Clz, D-Clz), 4 µg/l (D-Olz, Qtp), 0.4 µg/l (Plp, Rsp)

LLOQ: 5 µg/l (Olz), 6 µg/l (Clz), 10 µg/l (D-Olz, Qtp), 4 µg/l (D-Clz), 1 µg/l (Plp, Rsp)

Intraassay precision: 0.2 - 2 %

Interassay precision: 1 - 6 %

HPLC Parameters

A: Determination of Olz, D-Olz, Clz, D-Clz, Qtp

B: Determination of Plp, Rsp

Isocratic pump 1 (SPE-buffer): flow rates: 0.5 / 1.0 ml/min

Isocratic pump 2 (mobile phase): flow rate: **A:** 1.3 ml/min
B: 1.0 ml/min

Switching valve: 6-port/3-channel (order no. FK1102)

Injection volume: **A:** 250 µl, **B:** 750 µl

Injection interval: **A:** 22 min, **B:** 20 min

UV-detector: **A:** 254 nm, **B:** 280 nm

HPLC-thermostat: 30 °C

Sample Pretreatment

Addition of IS:

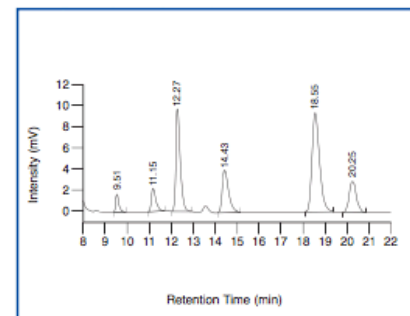
A: Add 20 µl Internal Standard IS/ml sample
B: Add 10 µl Internal Standard IS/ml sample

↓ centrifuge

on-line Analysis:

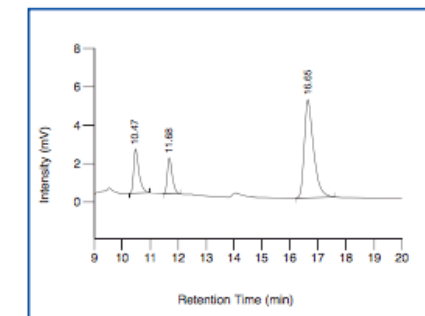
A: Inject 250 µl
B: Inject 750 µl

Chromatogram of the plasma calibrator, order no. 40013 (+ 20 µl Internal Standard IS per ml sample, order no. 40012)



Desmethylolanzapine (D-Olz): 9.51 min, Olanzapine (Olz): 11.15 min, Desmethylclozapine (D-Clz): 12.27 min, Internal Standard IS: 14.43 min, Clozapine (Clz): 18.55 min, Quetiapine (Qtp): 20.25 min

Chromatogram of the plasma calibrator, order no. 40113 (+ 10 µl Internal Standard IS per ml sample, order no. 40012)



Paliperidone (Plp): 10.47 min, Risperidone (Rsp): 11.68 min, Internal Standard IS: 16.65 min

Ordering Information

Order No.	Description	Quantity
40000	ClinRep® Complete Kit for Atypical Neuroleptics in Plasma / Serum for 100 assays	1 pce.
Kit Components (order no. 40000):		
40009	SPE-Buffer	2 x 40009 (2 x 1000 ml)
40010	Mobile Phase	2 x 40010 (2 x 2000 ml)
40013	Plasma Calibrator, lyophil. Manual	5 x 3 ml 1 pce.
	Quick Reference	1 pce.
Optional Components:		
40012	Internal Standard IS	2 ml
40014	Test Solution, lyophil.	5 x 2 ml
40113	Plasma Calibrator, lyophil., for Risperidone and Paliperidone	5 x 5 ml
40114	Test Solution, for Risperidone and Paliperidone	15 ml
Start Accessories:		
40030	Analytical Column with test chromatogram	1 pce.
40031	SPE-Column	1 pce.
40032	Guard Column Holder incl. 1 Guard Column	1 pce.
40033	Guard Column	5 pcs.
FK7400	Inline-Filter (stainless steel sieve, free of dead volume)	1 pce.
Refill Service:		
40034	SPE-Column, refill (original column needs to be returned)	1 pce.
Accessories:		
FK1102	Switching valve, Sykam (6-port/3-channel) incl. electr. drive, PEEK	1 pce.
FK7340	Sealings and sieves	4 pcs. each
ClinChek® Controls:		
40080	Plasma Control, lyophil., Level I	10 x 3 ml
40081	Plasma Control, lyophil., Level II	10 x 3 ml
40082	Plasma Control, lyophil., Level I, II	2 x 5 x 3 ml
40180	Plasma Control, lyophil., for Risperidone and Paliperidone, Level I	10 x 5 ml
40181	Plasma Control, lyophil., for Risperidone and Paliperidone, Level II	10 x 5 ml
40182	Plasma Control, lyophil., for Risperidone and Paliperidone, Level I, II	2 x 5 x 5 ml

→ Fully automated method

→ on-line sample preparation

→ 100 % recovery

