

Product Information

YMC
EUROPE GMBH

YMC-Triart C18
UHPLC/HPLC
90% Savings

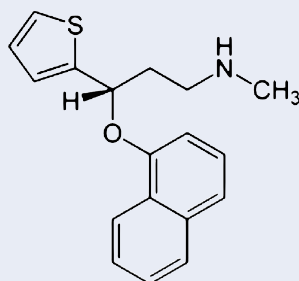
HPLC/UHPLC analysis of Duloxetine and degradation products

Author: DE
Date: 03.01.2014

Duloxetine is a psychoactive drug belonging to the group of selective serotonin-noradrenalin reuptake inhibitors (SSNRI).

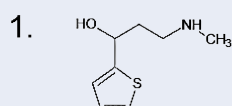
Duloxetine is marketed by Eli Lilly in several preparations, mainly as Cymbalta® or Xeristar® for treatment of depression, generalised anxiety disorders and painful diabetic neuropathy. Other preparations are Ariclam® against painful diabetic neuropathy, hence diseases of the peripheral nervous system and Yentreve® for treating stress urinary incontinence in women.

The chiral Duloxetine (S-enantiomer) is only used as the hydrochloride in pharmaceutical preparations.



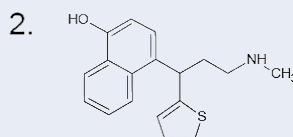
Duloxetine

Several degradation products can be formed by acidic or oxidative degradation processes: the amino alcohol, the para and ortho-isomer as well as α -naphthol.



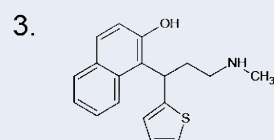
Amino alcohol

(3-Methylamino-1-thiophen-2-yl-propan-1-ol)



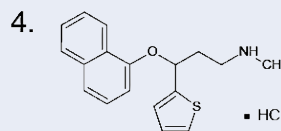
Para isomer

(4-(3-Methylamino-1-thiophen-2-yl-propyl)-naphthalen-1-ol))

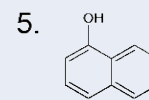


Ortho isomer

(2-(3-Methylamino-1-thiophen-2-yl-propyl)-naphthalen-1-ol)



Duloxetine hydrochloride



α -Naphthol

YMC developed HPLC- and UHPLC-methods using YMC-Triart C18 to separate and analyse Duloxetine HCl and its degradation products. These methods demonstrate the easy transfer of HPLC parameters to UHPLC because of the full scalability of YMC-Triart.

Analysis time can be reduced from 36 min to 3 min when changing from HPLC to UHPCL with appropriate optimisation. This corresponds to time and solvent savings of more than 90%.

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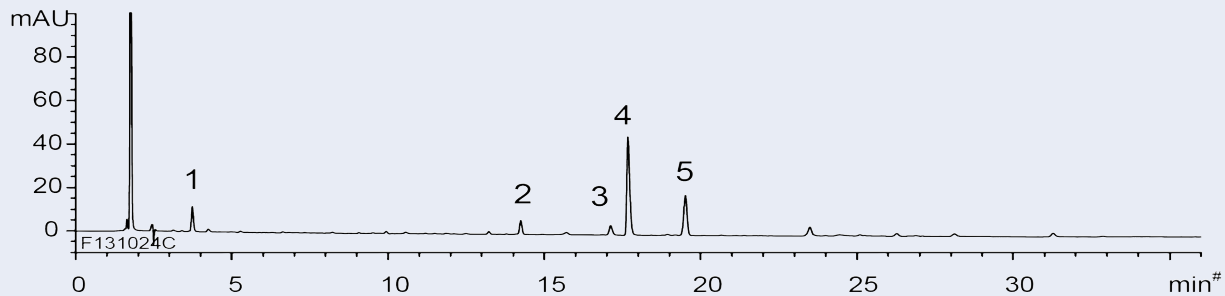


YMC-Triart C18
UHPLC/HPLC
90% Savings

HPLC/UHPLC analysis of Duloxetine and degradation products

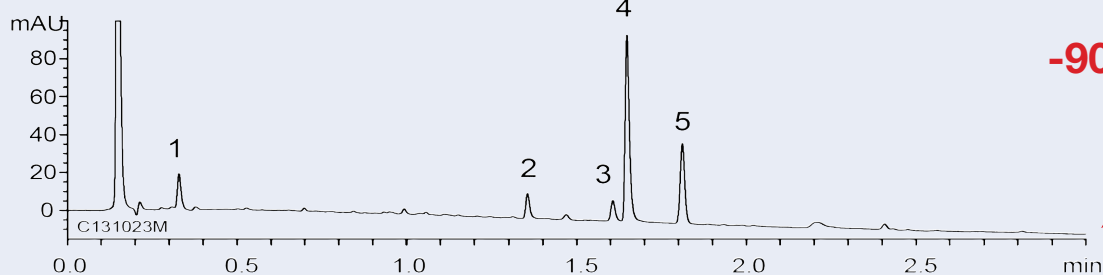
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HPLC method



Column: YMC-Triart C18 (5 μ m, 12 nm) 150 x 3.0 mm ID
Flow rate: 0,425 ml/min
Gradient: 0 min: 10% B; 36 min: 90% B
Injection: 6 μ l

UHPLC method



Column: YMC-Triart C18 (1,9 μ m, 12 nm) 50 x 2.0 mm
Flow rate: 0,8 ml/min
Gradient: 0 min: 10% B; 3 min: 90% B
Injection: 1 μ l

Parameter für die HPLC / UHPLC-Methode

Eluent A: ammoniumacetate (10 mM)
Eluent B: acetonitrile
Temperature: 30°C
Detection: UV at 230 nm
Sample: oxidative degradation products of Duloxetine hydrochloride*
*sample preparation according to Arvara et al. [1]

It was possible to develop both HPLC and UHPLC methods using YMC-Triart C18 for separating Duloxetine and its oxidative degradation products. Due to the full scalability of YMC-Triart, an easy method transfer from HPLC to UHPLC conditions was possible. By using the optimised UHPLC method more than 90% saving in terms of time and solvent can be achieved compared to the HPLC method.

[1] Veera Reddy, Avara et al., Der Pharma Chemica, 2012, 4 (4): 1735-41.