

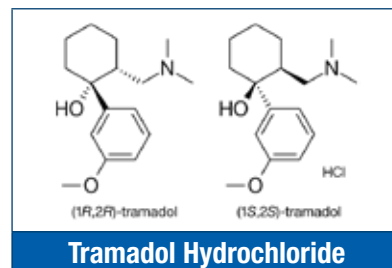
APPLICATIONS

Tramadol Hydrochloride and Related Substances

Ph. Eur. monograph 1681

Overview

The Ph. Eur. Monograph 1681 outlines the separation of Tramadol from impurities. This method was studied and recommendations have been made to conform with the Ph. Eur. Monograph 1681 requirements.



Ph. Eur. Monograph 1681 Details

Test Solution	Dissolve 0.15 g of Tramadol Hydrochloride CRS* in the mobile phase and dilute to 100 mL with the mobile phase.
Reference Solution (b)	Dissolve 5 mg of Tramadol Impurity A CRS* in 4.0 mL of the test solution and dilute to 100 mL with the mobile phase.

Column

Size	250 x 4.0 mm
Stationary Phase	End-capped base-deactivated octylsilyl silica gel for chromatography R (5 µm)
Temperature	25 °C
Mobile Phase	295 volumes of acetonitrile R and 705 volumes of a mixture of 0.2 mL of trifluoroacetic acid R and 100 mL of water R
Flow Rate	1.0 mL/min
Detection	Spectrophotometer @ 270 nm
Injection	20 µL
Run Time	4 times the retention time of Tramadol

Relative Retention with Reference to Tramadol (about 5 min)**

Impurity A	about 0.85 min
-------------------	----------------

System Suitability

Reference Solution (b)	Minimum resolution of 2.0 between peaks due to Impurity A and Tramadol
-------------------------------	--

* Tramadol Hydrochloride CRS (Y0000155) and Tramadol Impurity A CRS (Y0000156) were purchased from European Directorate for the Quality of Medicines & HealthCare (EDQM) – Council of Europe; Postal address: 7 Allée Kastner CS 30026F - 67081 STRASBOURG (France).

** Retention times, relative retentions, and retardation factors are provided for information only and are not mandatory, no deviation allowance is defined.

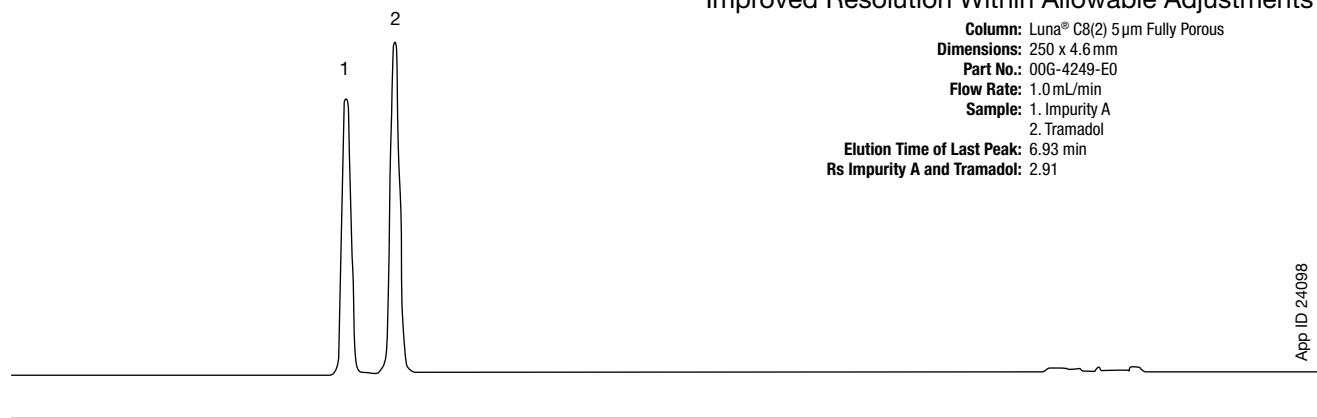
Method 1

Improved Resolution Within Allowable Adjustments

Column: Luna[®] C8(2) 5 µm Fully Porous
Dimensions: 250 x 4.6 mm
Part No.: 00G-4249-E0
Flow Rate: 1.0 mL/min

Sample: 1. Impurity A
 2. Tramadol

Elution Time of Last Peak: 6.93 min
Rs Impurity A and Tramadol: 2.91



App ID 24098



APPLICATIONS

Adjustments for Meeting System Suitability (European Pharmacopoeia 9.0, Chapter 2.2.46. Chromatographic separation techniques)

Method Parameter	Allowed Adjustments (isocratic elution)	Method 1
Mobile Phase pH	± 0.2 units	As specified
Concentration of Salts in Buffer	± 10 %	As specified in Monograph 1681 Details Table
Composition of the Mobile Phase	± 30 % of the minor solvent component relative or 2 % absolute, whichever is the larger. No other component is altered by more than 10 % absolute.	As specified in Monograph 1681 Details Table
Wavelength of Detector	No deviations permitted	270 nm (as specified)
Injection Volume	May be decreased, provided detection and repeatability of the peak(s) to be determined are satisfactory.	20 µL (as specified)
Column Temperature	± 10 °C	Ambient (as specified)
Stationary Phase	No change of the identity of the substituent permitted (e.g. no replacement of C8 by C18)	Octylsilyl silica gel for chromatography (as specified)
Column Length	± 70 %	250 mm (as specified)
Column Internal Diameter	± 25 %	4.6 mm (+15 %)
Particle Size	-50 %	5 µm (as specified)
Flow Rate	± 50 %	1.0 ml/min (as specified)

Luna[®] Ordering Information

5 µm Microbore and Minibore Columns (mm)								SecurityGuard [™] Cartridges (mm)	
Phases	50 x 1.0	150 x 1.0	250 x 1.0	30 x 2.0	50 x 2.0	150 x 2.0	250 x 2.0	4 x 2.0*	
C8(2)	—	00F-4249-A0	—	00A-4249-B0	00B-4249-B0	00F-4249-B0	00G-4249-B0	/10pk AJ0-4289 for ID: 2.0-3.0 mm	

5 µm MidBore and Analytical Columns (mm)								SecurityGuard [™] Cartridges (mm)	
Phases	30 x 3.0	50 x 3.0	150 x 3.0	250 x 3.0	30 x 4.6	50 x 4.6	75 x 4.6	4 x 2.0*	4 x 3.0*
C8(2)	00A-4249-Y0	00B-4249-Y0	00F-4249-Y0	00G-4249-Y0	00A-4249-E0	00B-4249-E0	00C-4249-E0	/10pk AJ0-4289	/10pk AJ0-4290 for ID: 2.0-3.0 mm 3.2-8.0 mm

5 µm Analytical and Semi-Prep Columns (mm)					SecurityGuard [™] Cartridges (mm)	
Phases	100 x 4.6	150 x 4.6	250 x 4.6	250 x 10	4 x 3.0*	10 x 10 [‡]
C8(2)	00D-4249-E0	00F-4249-E0	00G-4249-E0	00G-4249-N0	/10pk AJ0-4290 for ID: 3.2-8.0 mm	/3pk AJ0-7222 9-16 mm

*SecurityGuard[™] Analytical Cartridges require holder, Part No.: KJ0-4282
[‡]SemiPrep SecurityGuard Cartridges require holder, Part No.: AJ0-9281

APPLICATIONS

Australia

t: +61 (0)2-9428-6444
f: +61 (0)2-9428-6445
auiinfo@phenomenex.com

Austria

t: +43 (0)1-319-1301
f: +43 (0)1-319-1300
anfrage@phenomenex.com

Belgium

t: +32 (0)2 503 4015 (French)
t: +32 (0)2 511 8666 (Dutch)
f: +31 (0)30-2383749
beinfo@phenomenex.com

Canada

t: +1 (800) 543-3681
f: +1 (310) 328-7768
info@phenomenex.com

China

t: +86 400-606-8099
f: +86 (0)22 2532-1033
phen@agela.com

Denmark

t: +45 4824 8048
f: +45 4810 6265
nordicinfo@phenomenex.com

Finland

t: +358 (0)9 4789 0063
f: +45 4810 6265
nordicinfo@phenomenex.com

France

t: +33 (0)1 30 09 21 10
f: +33 (0)1 30 09 21 11
franceinfo@phenomenex.com

Germany

t: +49 (0)6021-58830-0
f: +49 (0)6021-58830-11
anfrage@phenomenex.com

India

t: +91 (0)40-3012 2400
f: +91 (0)40-3012 2411
indiainfo@phenomenex.com

Ireland

t: +353 (0)1 247 5405
f: +44 1625-501796
eireinfo@phenomenex.com

Italy

t: +39 051 6327511
f: +39 051 6327555
italiainfo@phenomenex.com

Luxembourg

t: +31 (0)30-2418700
f: +31 (0)30-2383749
nlinfo@phenomenex.com

Mexico

t: 01-800-844-5226
f: 001-310-328-7768
tecnicomx@phenomenex.com

The Netherlands

t: +31 (0)30-2418700
f: +31 (0)30-2383749
nlinfo@phenomenex.com

New Zealand

t: +64 (0)9-4780951
f: +64 (0)9-4780952
nzinfo@phenomenex.com

Norway

t: +47 810 02 005
f: +45 4810 6265
nordicinfo@phenomenex.com

Puerto Rico

t: +1 (800) 541-HPLC
f: +1 (310) 328-7768
info@phenomenex.com

Spain

t: +34 91-413-8613
f: +34 91-413-2290
espinfo@phenomenex.com

Sweden

t: +46 (0)8 611 6950
f: +45 4810 6265
nordicinfo@phenomenex.com

United Kingdom

t: +44 (0)1625-501367
f: +44 (0)1625-501796
ukinfo@phenomenex.com

USA

t: +1 (310) 212-0555
f: +1 (310) 328-7768
info@phenomenex.com

All other countries Corporate Office USA

t: +1 (310) 212-0555
f: +1 (310) 328-7768
info@phenomenex.com

