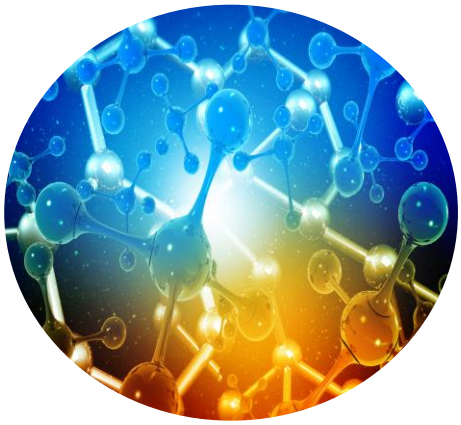


USP Vardenafil Hydrochloride Assay and Organic Impurities on Gemini® 5 µm C18 and Gemini 5 µm NX-C18

Zeshan Aqeel and Phil Koerner
Phenomenex, Inc., 411 Madrid Ave., Torrance, CA 90501 USA

Overview

Vardenafil hydrochloride is a phosphodiesterase-5 enzyme (PDE-5) inhibitor used to treat erectile dysfunction and it is closely related in function to sildenafil citrate (Viagra®) and tadalafil (Cialis®). Vardenafil hydrochloride is the generic version of the brand name drug Levitra®. This application note for the LC-UV assay and organic impurities for Vardenafil hydrochloride drug substance is based on the official USP monograph which calls for an L1 (C18) 5 µm, 250 x 3.0 mm column under gradient conditions for both assay and organic impurities. The mobile phase, standard solution, and system suitability solution for the assay and organic impurities were prepared in accordance with the USP monograph, using the USP Vardenafil hydrochloride reference standard (catalog no. 1711010) and Vardenafil hydrochloride system suitability reference standard (containing 99% Vardenafil hydrochloride and 1% 7-Methylvardenafil, catalog no. 1711029). All solutions containing Vardenafil were protected from light.

We show the results achieved using two different organo-silica columns, Gemini C18 and Gemini NX-C18, which both contain C18 bonded phase with TMS endcapping. Both columns met the system suitability requirements for the assay and organic impurities (**Table 1**) as outlined in the USP monograph for Vardenafil hydrochloride.

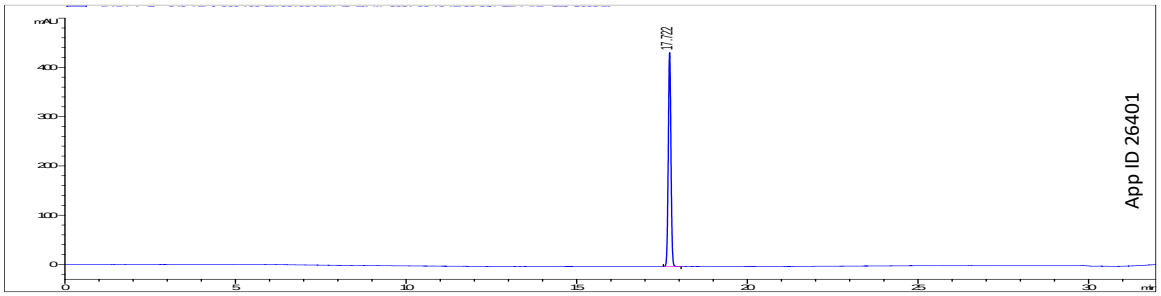
LC-UV Conditions

Column: Gemini 5 µm C18 (00G-4435-Y0)
Gemini 5 µm NX-C18 (00G-4454-Y0)
Dimension: 250 x 3.0 mm
Mobile Phase: A = Phosphate buffer (1.3 g of monobasic potassium phosphate and 0.7 g of dibasic sodium phosphate dihydrate in 1 L of water)
B = Acetonitrile

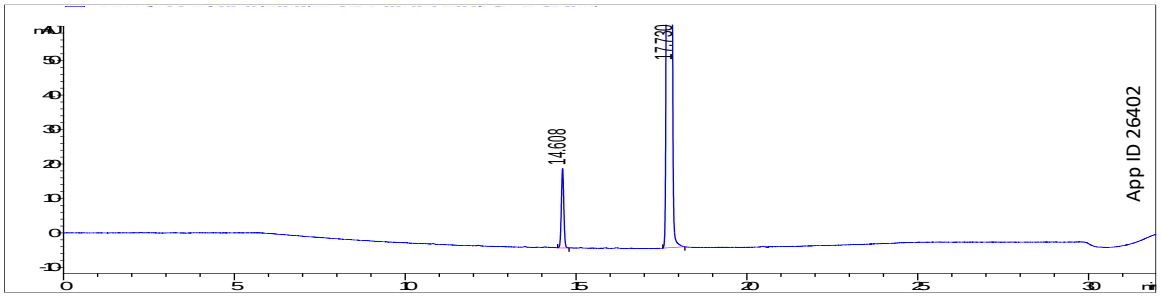
Gradient	Time (min)	% B
	0	20
	2	20
	22	75
	27	75

Flow Rate: 0.5 mL/min
Temperature: 45 °C
Detector: UV @ 242 nm
Injection: 10 µL
System: Agilent® 1260 (binary)
Sample: As indicated in chromatogram

Gemini® 5 µm C18 250 x 3.0 mm (00G-4435-Y0)

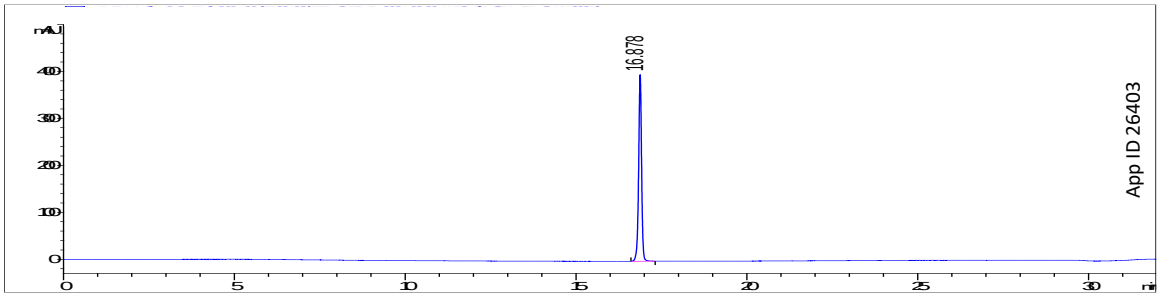


Standard Solution:
0.15 mg/mL of USP Vardenafil Hydrochloride RS

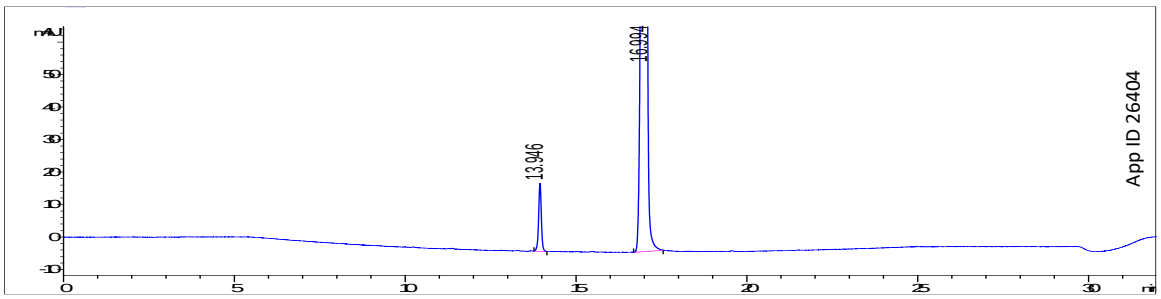


System Suitability Solution:
0.5 mg/mL of USP Vardenafil System Suitability RS
1. 7-Methyl Vardenafil
2. Vardenafil

Gemini 5 µm NX-C18 250 x 3.0 mm (00G-4454-Y0)



Standard Solution:
0.15 mg/mL of USP Vardenafil Hydrochloride RS



System Suitability Solution:
0.5 mg/mL of USP Vardenafil System Suitability RS
1. 7-Methyl Vardenafil
2. Vardenafil

Table 1. Summary of Results for Vardenafil Hydrochloride Assay and Organic Impurities

			System Suitability Solution*	Standard Solution (Assay)	
Column	**Analyte**	**Retention Time, min**	**Resolution (NLT 5.0)**	**% RSD (n = 6) (NMT 0.85 %)**	**Tailing Factor (0.8 – 1.5)**
Gemini® 5 µm C18	7-Methyl Vardenafil	14.608		---	---
	Vardenafil	17.730	22.8	0.074	1.02
Gemini 5 µm NX-C18	7-Methyl Vardenafil	13.946		---	---
	Vardenafil	16.994	21.2	0.079	0.94

*System Suitability Solution and resolution requirement is the same for both assay and organic impurities

Need a different column size or sample preparation format?

No problem! We have a majority of our available dimensions up on www.phenomenex.com, but if you can't find what you need right away, our super helpful Technical Specialists can guide you to the solution via our online chat portal www.phenomenex.com/LiveChat.

Australia
t: +61 (0)2-9428-6444
auinfo@phenomenex.com

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

Belgium
t: +32 (0)2 503 4015 (French)
t: +32 (0)2 511 8666 (Dutch)
beinfo@phenomenex.com

Canada
t: +1 (800) 543-3681
info@phenomenex.com

China
t: +86 400-606-8099
cninfo@phenomenex.com

Czech Republic
t: +420 272 017 077
cz-info@phenomenex.com

Denmark
t: +45 4824 8048
nordicinfo@phenomenex.com

Finland
t: +358 (0)9 4789 0063
nordicinfo@phenomenex.com

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

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

Hong Kong
t: +852 6012 8162
hkinfo@phenomenex.com

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

Ireland
t: +353 (0)1 247 5405
eireinfo@phenomenex.com

Italy
t: +39 051 6327511
italiainfo@phenomenex.com

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

Mexico
t: 01-800-844-5226
tecnicomx@phenomenex.com

The Netherlands
t: +31 (0)30-2418700
nlinfo@phenomenex.com

New Zealand
t: +64 (0)9-4780951
nzinfo@phenomenex.com

Norway
t: +47 810 02 005
nordicinfo@phenomenex.com

Poland
t: +48 22 104 21 72
pl-info@phenomenex.com

Portugal
t: +351 221 450 488
ptinfo@phenomenex.com

Singapore
t: +65 800-852-3944
sginfo@phenomenex.com

Slovakia
t: +420 272 017 077
sk-info@phenomenex.com

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

Sweden
t: +46 (0)8 611 6950
nordicinfo@phenomenex.com

Switzerland
t: +41 (0)61 692 20 20
swissinfo@phenomenex.com

Taiwan
t: +886 (0) 0801-49-1246
twinfo@phenomenex.com

Thailand
t: +66 (0) 2 566 0287
thaiinfo@phenomenex.com

United Kingdom
t: +44 (0)1625-501367
ukinfo@phenomenex.com

USA
t: +1 (310) 212-0555
info@phenomenex.com

All other countries/regions
Corporate Office USA
t: +1 (310) 212-0555
info@phenomenex.com

www.phenomenex.com
Phenomenex products are available worldwide. For the distributor in your country/region, contact Phenomenex USA, International Department at international@phenomenex.com