polpharma

CERTIFICATE OF ANALYSIS

Product: **SILDENAFIL CITRATE milled Ph.Eur.**

Code: **QCRT-0005-200** Batch number: **602061327** Batch size: **23 kg**
Manufacturing date: **01.06.2013** Analysis date: **09.07.2013** Retest date: **05.2016**
Manufacturer: **Pharmaceutical Works POLPHARMA S.A., POLAND**
Delivered to: **IT, A.C.E.F. SPA**

TEST	TEST METHOD	SPECIFICATION	RESULTS
Appearance	visual examination/ Ph. Eur. 5.11 *	white or almost white, slightly hygroscopic *, crystalline powder	almost white, slightly hygroscopic , crystalline powder
Solubility	Ph.Eur. 1.4	slightly soluble in water and in methanol, practically insoluble in hexane	conforms
Identification IR spectrum	Ph.Eur. 2.2.24.	comparison with reference substance spectrum of sildenafil citrate CRS	conforms
Impurity E (TLC)	Ph.Eur. 2.2.27.	not more than 0.1 %	conforms
Related substances (HPLC) - impurity A - unspecified impurity - sum of unspecified impurities - total impurities	Ph.Eur. 2.2.29.	 not more than 0.3 % not more than 0.10 % not more than 0.3 % not more than 0.5 %	 less than 0.05 % less than 0.05 % less than 0.05 % less than 0.05 %
Heavy metals	Ph.Eur. 2.4.8 method C	not more than 20 ppm	less than 20 ppm
Water	Ph.Eur. 2.5.12	not more than 2.5 %	1.1 %
Sulfated ash	Ph.Eur. 2.4.14	not more than 0.1 %	0.05 %
Assay calculated on the anhydrous substance (HPLC)	Ph. Eur. 2.2.29	98.0 % to 102.0 %	100.8 %
Residual solvents - methanol - ethanol - 2-propanol - dichloromethane - ethyl acetate - toluene - N,N-dimethylacetamide - acetone - benzene	POLPHARMA M/2-0048.17	 not more than 300 ppm not more than 500 ppm not more than 3000 ppm not more than 60 ppm not more than 500 ppm not more than 100 ppm not more than 300 ppm not more than 100 ppm not more than 2 ppm	 6 ppm < 60 ppm (QL) less than 14 ppm (DL) 783 ppm less than 1 ppm (DL) less than 7 ppm (DL) less than 1 ppm (DL) 36 ppm < 60 ppm (QL) 4 ppm < 5 ppm (QL) less than 0.1 ppm (DL)

* - non – routine test

Starogard Gdański, 22.07.2013

Certification Team Coordinator
Fine Chemicals BU
Orlikowska
Beata Orlikowska

Pharmaceutical Works POLPHARMA SA
Pelplińska 19
83-200 Starogard Gdański
Poland

District Court in Gdańsk, VII Economic Department
National Court Register 0000127044
NIP 592-02-02-822
Initial capital 100 207 830 PLN (fully paid in)

phone +48 58/ 563 16 00
fax +48 58/ 562 23 53
e-mail: sekretariat@polpharma.com
http://www.polpharma.pl

polpharma

CERTIFICATE OF ANALYSIS

Product: **SILDENAFIL CITRATE milled Ph.Eur.**

Code: **QCRT-0005-200** Batch number: **602061327** Batch size: **23 kg**
Manufacturing date: **01.06.2013** Analysis date: **09.07.2013** Retest date: **05.2016**
Manufacturer: **Pharmaceutical Works POLPHARMA S.A., POLAND**
Delivered to: **IT, A.C.E.F. SPA**

TEST	TEST METHOD	SPECIFICATION	RESULTS
Residual solvents - triethylamine	POLPHARMA M/2-0048.15	not more than 320 ppm	less than 25 ppm (DL)
Particle size D(v, 0.1) D(v, 0.5) D(v, 0.9)	POLPHARMA S/6-0351	for information	 2.4 µm 8.6 µm 30 µm
Microbiological purity * -total aerobic microbial count (TAMC) -total combined yeasts/moulds count (TYMC)	Ph. Eur. 2.6.12	 not more than 10^3 cfu/g not more than 10^2 cfu/g	 less than 10 cfu/g less than 10 cfu/g

* - non – routine test

CONCLUSION: This material complies with the requirements of the **Ph.Eur., S/2-0048.15 ed. 02.**

Starogard Gdański, 22.07.2013

Certification Team Coordinator
Fine Chemicals BU

Beata Orlikowska

Pharmaceutical Works POLPHARMA SA
Pelplińska 19
83-200 Starogard Gdański
Poland

District Court in Gdańsk, VII Economic Department
National Court Register 0000127044
NIP 592-02-02-822
Initial capital 100 207 830 PLN (fully paid in)

phone +48 58/ 563 16 00
fax +48 58/ 562 23 53
e-mail: sekretariat@polpharma.com
http://www.polpharma.pl