polpharma

CERTIFICATE OF ANALYSIS

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

Code: **QCRT-0005-200** Batch number: **601091427** Batch size: **25 kg**
Manufacturing date: **21.07.2014** Analysis date: **29.09.2014** Retest date: **07.2017**
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	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 %	0.90 %
Sulfated ash	Ph. Eur. 2.4.14	not more than 0.1 %	0.02 %
Assay calculated on the anhydrous substance (HPLC)	Ph. Eur. 2.2.29	98.0 % to 102.0 %	99.8 %
Nickel	POLPHARMA M/2-0048.20	not more than 2.5 ppm	less than 2.5 ppm
Residual solvents - 2-propanol	POLPHARMA M/2-0048.17	not more than 3000 ppm	746 ppm

* - non – routine test

CONCLUSION: This material complies with the requirements of the **Ph. Eur., S/2-0048.22 ed. 03.**

Starogard Gdański, 30.09.2014

Certification Team Coordinator
API Plant
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30.09.2014

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