polpharma

CERTIFICATE OF ANALYSIS

Product: **SILDENAFIL CITRATE**

Code: **QCRT-00W4-000** Batch number: **101031828** Batch size: **45 kg**
Manufacturing date: **08.03.2018** Analysis date: **16.04.2018** Retest date: **03.2021**
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 [1)]	white or almost white, slightly hygroscopic [1)], 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 - impurity D - unspecified impurity - total impurities	Ph. Eur. 2.2.29.	not more than 0.15 % not more than 0.15 % not more than 0.10 % not more than 0.5 %	less than 0.05 % less than 0.05 % RRT 0.6: 0.05 % 0.05 %
Water	Ph. Eur. 2.5.12	not more than 2.5 %	0.44 %
Sulfated ash	Ph. Eur. 2.4.14	not more than 0.1 %	0.03 %
Assay calculated on the anhydrous substance (HPLC)	Ph. Eur. 2.2.29	98.0 % to 102.0 %	100.3 %
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	1005 ppm

[1)] – non-routine test

CONCLUSION: This material complies with the requirements of the **Ph. Eur., S/2-0048.22 ed. 06.**

Starogard Gdański, 08.05.2018

Certification Team Coordinator
API Plant
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08.05.2018

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