polpharma

CERTIFICATE OF ANALYSIS

Product: **TADALAFIL**

Code: **QTDF-0003-000** Batch number: **101011727** Batch size: **33.5 kg**
Manufacturing date: **14.01.2017** Analysis date: **03.02.2017** Retest date: **01.2020**
Manufacturer: **Pharmaceutical Works POLPHARMA S.A., POLAND**
Delivered to: **IT, A.C.E.F SPA**

TEST	TEST METHOD	SPECIFICATION	RESULTS
Appearance	visual examination	white or almost white powder	almost white powder
Solubility	Ph. Eur.	practically insoluble in water, freely soluble in dimethyl sulfoxide, slightly soluble in methylene chloride	conforms
Identification A. IR spectrum B. HPLC	Ph. Eur.	corresponds to reference substance spectrum the principal peak in the chromatogram obtained with the test solution is similar in retention time and size to the principal peak in the chromatogram obtained with reference solution (a)	conforms conforms
Impurities A, B and C (HPLC) impurity A unspecified impurities	Ph. Eur.	not more than 0.15 % not more than 0.10 %	less than 0.05 % less than 0.05 %
Related substances (HPLC) unspecified impurities total	Ph. Eur.	not more than 0.10 % not more than 0.3 %	less than 0.05 % less than 0.05 %
Loss on drying	Ph. Eur.	not more than 0.5 %	0.05 %
Sulfated ash	Ph. Eur.	not more than 0.1 %	0.02 %
Assay calculated on the dried substance (HPLC)	Ph. Eur.	97.5 % to 102.0 %	99.8 %
Content of methylamine (IC) methylamine	POLPHARMA M/2-0149.09	not more than 500 ppm	less than 25 ppm (DL)
Residual solvents [1] ethanol	Ph. Eur.	loss on drying: not more than 0.5 %	0.05 %

[1] – ethanol belongs to 3 Class of solvents acc. Ph. Eur. and is tested by "Loss on drying" test acc.to Ph. Eur.- not more than 0.5 %.

CONCLUSION: This material complies with the requirements of the **Ph. Eur., S/2-0149.12 ed. 02.**

Starogard Gdański, 28.08.2017

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28.08.2017

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