teva | api

KalChem INTERNATIONAL Compounding Chemicals You Can Trust

PRODUCT SPECIFICATIONS AND CERTIFICATE OF ANALYSIS

Product Name: PERGOLIDE MESYLATE

Control No.: 70222000721 **Order No.:**

Client Packing Order:

Customer Name: LGM PHARMA, LLC

Quantity: 0.750 KG **Quality Market:** USA

Manufacturing Site: TEVA Czech Industries s.r.o. **Original Analysis Date:** April 2021

Manufacturing Date: November 2020 **Re Test date:** November 2025

Packaging and storage: Preserve in tight, light-resistant containers at temperature up to 25 °C.

TESTS AND METHODS	SPECIFICATIONS	RESULTS*
	SV-702220-02, rev.3 TESTS	
Description *Visual*	White to off-white powder.	Complies
Identity (IR) *USP < 197K>*	IR spectrum of the tested substance exhibits maxima at the same wavelengths as the spectrum of the reference standard obtained under the same conditions.	Complies
Identity (HPLC) *AM\RD\LC022*	The retention time of the principle peak in chromatogram of tested sample corresponds to the retention time of the peak in chromatogram of the reference standard.	Complies
Chromatographic purity *USP, AM\RD\LC023*		
Pergolide sulfoxide	NMT 0.10 %	0.03%
Methylpergolide	NMT 0.10 %	Less than 0.01%
Cyanpergolide	NMT 0.10 %	Less than 0.01%
Norpergolide	NMT 0.10 %	Less than 0.01%
Other impurities individually	NMT 0.10 %	Less than 0.01%
Total impurities	NMT 0.50 %	0.03%
Assay (HPLC) *USP, AM-RD-LC021*	98.0 to 102.0 % calculated on dried substances	101.3%

TEVA Czech Industries s.r.o.

Ostravská 305/29, Komárov, 74770 Opava, Czech Republic TEL. +420 553 641 111 FAX. +420 553 644 118

teva | api

PRODUCT SPECIFICATIONS AND CERTIFICATE OF ANALYSIS

Product Name: PERGOLIDE MESYLATE

Control No.: 70222000721 **Order No.:** .

Client Packing Order:

Customer Name: LGM PHARMA, LLC

Quantity: 0.750 KG **Quality Market:** USA

Manufacturing Site: TEVA Czech Industries s.r.o. **Original Analysis Date:** April 2021

Manufacturing Date: November 2020 **Re Test date:** November 2025

Packaging and storage: Preserve in tight, light-resistant containers at temperature up to 25 °C.

TESTS AND METHODS	SPECIFICATIONS	RESULTS*
Loss on drying *USP <731S>, AM-RD-OT033*	NMT 0.5 %	0.1%
Specific optical rotation *USP <781S>, AM-RD-OT041*	-23 to -17° calculated on dried substance	-18°
Residue on ignition *USP <281>*	NMT 0.1 %	Less than 0.1%
Residual solvents *USP < 467>, AM-AQC-GC1017* Ethanol Methanol Dichloromethane	 NMT 3000 ppm NMT 200 ppm NMT 200 ppm	 345ppm Less than 50ppm Less than 30ppm
Particle size *AM\QC\OT002* Mean 90%	 NMT 100 um NMT 150 um	 18um 51um
Bulk density *AM\RD\OT019*	NLT 0.25 g/ml	0.54g/ml

teva | api

PRODUCT SPECIFICATIONS AND CERTIFICATE OF ANALYSIS

Product Name: PERGOLIDE MESYLATE

Control No.: 70222000721

Order No.:

Client Packing Order:

Customer Name: LGM PHARMA, LLC

Quantity: 0.750 KG

Quality Market: USA

Manufacturing Site: TEVA Czech Industries s.r.o.

Original Analysis Date: April 2021

Manufacturing Date: November 2020

Re Test date: November 2025

Packaging and storage: Preserve in tight, light-resistant containers at temperature up to 25 °C.

Remarks:

1. Conforms to the requirements of the SV-702220-02, rev.3 Specifications.
2. Conforms to the current USP monograph.
3. The following residual solvents Class 1, as defined in the ICH Q3C, benzene, carbon tetrachloride, 1,2-Dichloroethane, 1,1-Dichloroethene and 1,1,1- Trichloroethane are not present in the Active Pharmaceutical ingredient.
4. The product meets the requirements for residual solvents USP <467>, EP 5.4 and ICH guide Q3C.
5. The product has been produced and controlled in compliance with GMP rules and valid documentation. Tested parameters comply with the approved specification.

Quality Control Manager: Jiri Hendrych	**Signature**:** PP\ Marketa Szebestova 9 December 2021 12:14:02
	Print Date: 9 December 2021
	Approval: Martina Handlova

(*) Upon completion of the 'Results' column this document becomes a certificate of analysis **End of C O A**

(**) This document was signed electronically and this is the manifestation of the electronic signature.

TEVA Czech Industries s.r.o.

Ostravská 305/29, Komárov, 74770 Opava, Czech Republic TEL. +420 553 641 111 FAX. +420 553 644 118