

**PRODUCT  
SPECIFICATIONS  
AND  
CERTIFICATE OF ANALYSIS**

Page 1 of 3

**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*
<b>SV-702220-02, rev.3 TESTS</b>		
<b>Description</b> <i>Visual</i>	White to off-white powder.	Complies
<b>Identity (IR)</b>  <i>USP &lt;197K&gt;</i>	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
<b>Identity (HPLC)</b>  <i>AMRD/LC022</i>	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
<b>Chromatographic purity</b> <i>USP, AMRD/LC023</i> Pergolide sulfoxide Methylpergolide Cyanpergolide Norpergolide Other impurities individually Total impurities	NMT 0.10 % NMT 0.10 % NMT 0.10 % NMT 0.10 % NMT 0.10 % NMT 0.10 % NMT 0.50 %	0.03% Less than 0.01% Less than 0.01% Less than 0.01% Less than 0.01% 0.03%
<b>Assay (HPLC)</b> <i>USP, AM-RD-LC021</i>	98.0 to 102.0 % calculated on dried substances	101.3%

TEVA Czech Industries s.r.o.

**PRODUCT  
SPECIFICATIONS  
AND  
CERTIFICATE OF ANALYSIS**

Page 2 of 3

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

TEVA Czech Industries s.r.o.

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

**PRODUCT  
SPECIFICATIONS  
AND  
CERTIFICATE OF ANALYSIS**

Page 3 of 3

<b>Product Name:</b> PERGOLIDE MESYLATE		<b>Order No.:</b> .
<b>Control No.:</b> 70222000721		<b>Client Packing Order:</b>
<b>Customer Name:</b> LGM PHARMA, LLC		
<b>Quantity:</b> 0.750 KG		<b>Quality Market:</b> USA
<b>Manufacturing Site:</b> TEVA Czech Industries s.r.o.	<b>Original Analysis Date:</b>	April 2021
<b>Manufacturing Date:</b> November 2020		<b>Re Test date:</b> November 2025
<b>Packaging and storage:</b> 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