Richard Bittner AG
Ossiacherstr. 7
9560 Feldkirchen | Austria

OMEGA BITTNER

QUALITY CERTIFICATE Nr. Ukr 2326060A-36/23

Name of the product :	**REMENS®**
Importing country :	Ukraine
Marketing authorization number:	UA /10052/01/01
Validity Term:	Unlimited
Strength/Potency:	**1 tablet contains:** Cimicifuga D1 17,9 mg, Sanguinaria D6 37,2 mg, Jaborandi D6 37,2 mg, Sepia D12 37,2 mg, Lachesis D12 37,2 mg
Dosage form:	**Tablets**
Package size and type	36 tablets in blisters, 12 tablets per blister, 3 blisters per pckg.
Batch number:	*2326060A*
Size of Batch:	2.142 packages
Date of manufacturer:	07/2023
Expiry date:	07/2028
Name, address and authorization number of all manufacturing sites and quality control sites	Richard Bittner AG Ossiacherstrasse 7, A-9560 Feldkirchen, Austria No: INS-480748-101435909-17828458
Certificate of GMP of all sites listed above	No: INS-480748-101435909-17828456

Results of Analysis

Parameters	Specifications	Results
Organoleptic Results		
Appearance	round, flat white or white with the yellowish tint tablets, with possible sprinkles and one-break-mark	ok
Physical Results		
Diameter	8.9 - 9.2 mm	9.1 mm
Height	2.7 - 3.3 mm	3.1 mm
Average mass	237.5 - 262.5 mg	250.2 mg
Uniformity of mass	average mass ± 5 %	conforms
Subdivision of tablets	Must comply with Ph. Eur. monograph on tablets	conforms
Resistance to crushing	NLT 30 N	50 N
Grateness	≤ 1.0 %	0.1 %
Disintegration	< 15 min	2 min
Loss on drying	< 5.0 %	1.3 %
Identity		
Thin layer-Chromatography	Zones must correspond to zones of the mother tincture	ok
Microbiological Purity		
TAMC	$< 10^3$ / g	15 / g
TYMC	$< 10^2$ / g	20 / g
E. coli	absence / 1 g	negative / g

Comments: Storage conditions: Store in the original carton at the temperature not above 30°C. Keep out of reach of children.

Certification statement: I hereby certify that the above information is authentic and accurate. This batch of product has been manufactured, including packaging/labeling and quality control at the above mentioned site(s) in full compliance with the GMP requirements of the local Regulatory Authority and with the specifications in the Marketing Authorization of the importing country or product specification file for Investigational Medicinal Products. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP

Name and position/title of person authorising the batch release: Dipl.-Ing. Thomas Wallner
Qualified Person

Date of the signature: 31.08.2023

Control laboratory, Richard Bittner AG, Feldkirchen, Austria

Вх. ак. N1421
від 14.03.2024