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Batch Certificate for Finished Medicinal Product No. 1821/2024	
Name: Cilosvitae Comprimidos	**Destination country:** Chile
Batch number: 13160520	**Batch size:** 11 760
Strength (Dose): 50 mg	**Pharmaceutical form:** tablets
Package size: 28	**Package type:** blister foil PVC/PVDC/AL, carton box
Manufacture date: 05 2023	**Expiry date:** 04 2027
Marketing Authorization number: F-25419	
Index: GCLAP0420101	
Name and address of manufacturers:	
A. Manufacturer of product in bulk: Adamed Pharma S.A. Headquarters: Pieńków , ul. M. Adamkiewicza 6A, 05-152 Czosnów Manufacturing site: ul. Marszałka Józefa Piłsudskiego 5, 95-200 Pabianice	B. Manufacturer of finished product: Adamed Pharma S.A. Headquarters: Pieńków , ul. M. Adamkiewicza 6A, 05-152 Czosnów Manufacturing site: ul. Marszałka Józefa Piłsudskiego 5, 95-200 Pabianice
C. Manufacturer responsible for batch testing: Adamed Pharma S.A. Headquarters: Pieńków , ul. M. Adamkiewicza 6A, 05-152 Czosnów Manufacturing site: ul. Marszałka Józefa Piłsudskiego 5, 95-200 Pabianice	D.Manufacturer responsible for certification of product batch: Adamed Pharma S.A. Headquarters: Pieńków , ul. M. Adamkiewicza 6A, 05-152 Czosnów Manufacturing site: ul. Marszałka Józefa Piłsudskiego 5, 95-200 Pabianice
Number of Manufacturing Authorization:	
A. 204/0039/15	B. 204/0039/15
C. 204/0039/15	D. 204/0039/15
Certificate of GMP:	
A. ISF.405.7.2024.IP.1 WTC/0039_01_01/11	B. ISF.405.7.2024.IP.1 WTC/0039_01_01/11
B. ISF.405.7.2024.IP.1 WTC/0039_01_01/11	D. ISF.405.7.2024.IP.1 WTC/0039_01_01/11
Comments: leaflet- PULAPE005094-02, carton box- PKJAPE005092-02; dev. no. 148/2023	
Size of retention sample: 48	

☐ *I confirm that all folding box have been labeled in accordance with the serialization requirements*
☐ *I confirm that all folding box vs carton box have been labeled in accordance with the aggregation requirements*
☒ *batch is not subject to serialization*

Certification: *I hereby certify that , transport conditions have been verified, all the manufacturing stages of finished medicinal product have been carried out in full compliance with the GMP requirements and with the requirements of permit(s) and documentation concerning Marketing Authorization(s) of finished medicinal product of the destination country/countries.*

Osoba Wykwalifikowana
Qualified Person
Kamila Trajalska

2024 -04- 16

Date: ..... Signature, name and surname of the QP: .....

Adamed Pharma S.A.
Pieńków, ul. M. Adamkiewicza 6A, 05-152 Czosnów
tel.: +48 22 732 77 00, fax: +48 22 732 77 00
e-mail: adamed@adamed.com.pl
www.adamed.com.pl

Rejestracja: Krajowy Rejestr Sądowy, prowadzony przez Sąd Rejonowy dla m.st. Warszawy, XIV Wydział Gospodarczy Krajowego Rejestru Sądowego, pod nr. KRS 0000116926, NIP 731-17-51-025; Kapitał zakładowy: 718 430 000 PLN, wpłacony w całości.

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CERTIFICATE OF ANALYSIS No. 1178 /24

Product name: **Cilosvitae comprimidos, 50 mg tablett, 28 tablets**

Batch No. of finished product: 13160520		Destination country: **Chile**
Batch No. of product in bulk: 12819446	No. of the Analytical Report for product in bulk: ---	
Manufacturing date: 05 2023	Expiry date:04 2027	

I. Results for physico – chemical and microbiological tests

No.	Tests:	Limits:	Results:
1.	**2.**	**3.**	**4.**
1.	Description	White or off-white, flat-faced, round tablets, debossed on one side "50"	conforms
2.	Tablet diameter	6.8 – 7.2 mm	7.1 mm
3.	Average mass of one tablet	110.0 mg ± 7.5% (101.8 – 118.3 mg)	110.3 mg
4.	Uniformity of dosage units - mass variation	according to the requirements	conforms
5. 5.1. 5.2.	Identification: IR High-performance liquid chromatography method HPLC	 according to the requirements according to the requirements	 conforms conforms
6.	Chromatographic purity: - impurity A - impurity B - impurity C - any other individual impurity - total of impurities	 not more than 0.1% not more than 0.1% not more than 0.1% not more than 0.1% not more than 0.5%	 <0.05% <0.05% <0.05% <0.05% <0.05%
7. 7.1. 7.2.	Dissolution test and disintegration time testing Dissolution Disintegration time	 Not less than 75% (Q) of the labelled amount is dissolved in 45 minutes Not more than 7 minutes	 mean: 96% (91 - 98)% 02'15"
8.	Assay of the active substance	50.0 mg ± 5% (47.5 – 52.5 mg)	47.9 mg
9.	Microbiological purity: - total aerobic microbial count in 1 g - total moulds and yeast in 1 g - *Escherichia coli* in 1 g	 not more than 10^3 not more than 10^2 absent	 <10 <10 absent

The test was performed according to: Quality Specification **SQ-WG/2036 edition 1**
Date of the end: 12.04.2024

The Certificate of Analysis was prepared by: M.Żurek-Zarzycka Checked by: Date: 2024 -04- 12

Declaration: I certify that analysis of finished product was performed in accordance with the current, approved analytical documentation registered in the Registration Dossier. The tests were carried out in accordance with the procedures and GMP requirements.

Opinion: product meets the requirements of Quality Specification **SQ-WG/2036 edition 1**

Date: 2024 -04- 12

Signature: Lider Zespołu Ewelina Sapińska