Batch Release Certificate № 2414

Client:	Macarthys Laboratories ltd UK		
Importing Country:	United Kingdom		
Client product name:	Xaggitin XL 36 mg		
Product name:	Methylphenidate Prolonged-release tablet 36 mg		
Manuf. Batch Number:	2000046984		
Client Batch Number:	120140		
Dosage form:	☒ **Tablets** ☐ **Capsules**		
Name of API supplier:	JOHNSON MATTHEY INC.		
Batch Number of API/CEP Rev.:	D100004521 / R0-CEP 2017-119-Rev 02		
Manufacturing date:	05/2022	**Expiry date:**	05/2024
Package size:	1 bottle x 30	**Package Type:**	☐ **Blister** ☒ **Bottle**
Quantity released:	16 440 packs	**MA/NDA/ANDA:**	PL 01883/0361
Bulk production site:	Balkanpharma-Dupnitsa AD 3, Samokovsko Shosse Str. Dupnitsa 2600, Bulgaria **MIA:** BG/MIA-0299		
Packaging site:	Balkanpharma-Dupnitsa AD 3, Samokovsko Shosse Str. Dupnitsa 2600, Bulgaria **MIA:** BG/MIA-0299		
Testing site:	Balkanpharma-Dupnitsa AD 3, Samokovsko Shosse Str. Dupnitsa 2600, Bulgaria **MIA:** BG/MIA-0299		
Release site:	Balkanpharma-Dupnitsa AD 3, Samokovsko Shosse Str. Dupnitsa 2600, Bulgaria **MIA:** BG/MIA-0299		
Results of analysis:	**CoA** № 292792		
Comments:	**Storage:** This medicinal product does not require any special storage conditions.		

Digitally signed by Chitic Vlad
Date: 2023.04.21 12:15:18 EEST
Reason: MoldSign Signature
Location: Moldova

1. I hereby confirm that the above mentioned batch has been released to the market by Balkanpharma Dupnitsa AD.
2. I hereby declare that the above information is authentic and accurate. This batch has been manufactured, including packaging and quality control at the above mention site, in full compliance with the GMP requirements of the local Regulatory Authority and with the specification in the Marketing Authorisation of the importing country.
3. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP and Technical Agreement.
4. Were there any significant deviations from the manufacturing process stated in the Technical Agreement concerning product quality or release:
   ☒ No ☐ Yes (see copy of deviation report)

Date: 29/06/2022

V. Galeva-Karakoleva

Signature: _____

QP

QUALITY CONTROL DEPARTMENT
DUPNITSA, BULGARIA
CERTIFICATE OF ANALYSIS AND COMPLIANCE

PRODUCT:	**Methylphenidate 36 mg Prolonged-Release Tablets**		
LIST #:	**3331650**	**INTERNAL LOT #:**	**2000046984**
METHOD:	**SDIR006560/2**	**EXPIRATION DATE:**	**N/A**
MANUFACTURING DATE:	**15-May-2022**		
SPECIFICATION #:	**SDIR006560/2**	**LIMS LOT NUMBER:**	**292792**
ANALYTICAL RELEASE DATE:	**22-Jun-2022**	**PACKAGING SIZE:**	**N/A**

TEST	LIMITS	RESULTS
Външен вид/ Tablet description		
Външен вид/ Tablet description	Бели, филмирани, двойноизпъкнали табл етки с капсулна форма. Маркировка ' 2394', напечатана с черно мастило от един ата страна / White film coated, capsule-shaped, biconvex tablet. Marking '2394' printed in black ink on one side	Conforms
Идентичност/ Identification: IR		
IR	Спектърът на пробата трябва да съответс тва на този на стандарта / The spectrum of the sample should correspond to that of the standard	Conforms
Равномерност на дозови единици/ Uniformity of dosage units (Content Uniformity)		
Равномерност на дозови единици/ Uniformity of dosage units- AV	Да отговаря на Ph. Eur. 2.9.40, AV <=15.0 / Complies with Ph. Eur. 2.9.40, AV <=15.0	5.7
Stage passed		1

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TEST	LIMITS	RESULTS
Средна маса/ Average tablet mass		
Средна маса/ Average tablet mass	345.8 mg ± 5 % (328.5 mg - 363.1 mg)	344.9 mg
Съдържание на вода/ Water content		
Съдържание на вода/ Water content	Не повече от 6 % / NMT 6 %	4 %
Съдържание на Methylphenidate в една таблетка/ Assay (HPLC)		
1. Assay in percentage	95 % - 105 % от обявеното съдържание / 95 % - 105 % of the stated amount	97 %
2. Assay in milligram	34.2 mg - 37.8 mg	34.9 mg

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TEST	LIMITS	RESULTS
Сродни вещества/ Related substances (HPLC)		
1. Примес A/ Impurity A ((2RS)-phenyl[(2RS)-piperidin-2-yl]acetic acid)	Не повече от 0.5 % / NMT 0.5 %	0.03 (0.031) %
2. Примес B/ Impurity B (Methyl (2RS)-phenyl [(2SR)-piperidin-2-yl] acetate)	Не повече от 0.5 % / NMT 0.5 %	Not detected %
3. Единичен неидентифициран примес/ Each unspecified impurity	Не повече от 0.2 % / NMT 0.2 %	Not detected %
4. Общо примеси/ Total Impurities	Не повече от 1.0 % / NMT 1.0 %	0.03 (0.031) %

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TEST	LIMITS	RESULTS
Степен на разтваряне (Кошнички, 100 rpm)/ Dissolution (Basket, 100 rpm) (HPLC)		
1. Ацетатен буфер pH 4.5 за 2 часа/ Acetate buffer pH 4.5 for 2 hours: 0.5 hour- Min	19 - 29 %	26 %
2. Ацетатен буфер pH 4.5 за 2 часа/ Acetate buffer pH 4.5 for 2 hours: 0.5 hour- Max	19 - 29 %	29 %
3. Ацетатен буфер pH 4.5 за 2 часа/ Acetate buffer pH 4.5 for 2 hours: 0.5 hour- Avg	19 - 29 %	28 %
4. Stage passed (0.5 hour)		1
1. Натриев фосфат буфер pH 6.6/ Sodium phosphate buffer pH 6.6: 3 часа/ 3 hours- Min	33 - 53 %	46 %
2. Натриев фосфат буфер pH 6.6/ Sodium phosphate buffer pH 6.6: 3 часа/ 3 hours- Max	33 - 53 %	52 %
3. Натриев фосфат буфер pH 6.6/ Sodium phosphate buffer pH 6.6: 3 часа/ 3 hours- Avg	33 - 53 %	50 %
4. Stage passed (3 hours)		1
1. Натриев фосфат буфер pH 6.6/ Sodium phosphate buffer pH 6.6: 10 часа/ 10 hours- Min	Не по-малко от 85 % / NLT 85 %	98 %
2. Натриев фосфат буфер pH 6.6/ Sodium phosphate buffer pH 6.6: 10 часа/ 10 hours- Max	Не по-малко от 85 % / NLT 85 %	102 %

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TEST	LIMITS	RESULTS
3. Натриев фосфат буфер pH 6.6/ Sodium phosphate buffer pH 6.6: 10 часа/ 10 hours-Avg	Не по-малко от 85 % / NLT 85 %	100 %
4. Stage passed (10 hours)		1
Остатъчни разтворители/ Residual solvents		
1. Isopropyl Alcohol	Не повече от 5000 ppm / NMT 5000 ppm	1583 ppm
2. Acetone	Не повече от 5000 ppm / NMT 5000 ppm	<400(103) ppm
Микробиологично качество/ Microbiological quality (Да отговаря на/ Complies with Ph.Eur.5.1.4)- Пер иодично изпитване/ Not routinely performed		
1. Общ брой аеробни микроорганизми/ Total aerobic microbial count (TAMC)	Не повече от/ NMT 10^3 CFU/g	Test Not Required
2. Общ брой дрожди и плесени/ Total yeasts and mould count (TYMC)	Не повече от/ NMT 10^2 CFU/g	Test Not Required
3. Escherichia coli	Отсъствие в 1g/ Absent in 1g	Test Not Required
	Периодично изпитване/ Not routinely performed. Извършва се на първите три произв одствени партиди и след това най-малко веднъж годишно / Tested on the first three production scale batches and then at least annually	

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References:

Reviewed By: Aneliya Yordanova **Date: 22-Jun-2022**

Approved By: Magdalina Angelova **Date Released: 23-Jun-2022**

Balkanpharma-Dupnitsa AD, Dupnitsa 2600, Bulgaria, 3 Samokovsko Shosse Str., T +359 (701) 58 477, E-mail: dupoperations@teva.bg, www.teva.bg

This is to certify that this material was produced in compliance with the principles of cGMP.

Serialization Data Release

GTIN: 05060078672030

Lot Number: 120140

Message from ATTP: Lot is released, Outbound EPCIS is triggered and EOB file is generated.

Next Release