

Simec AG

Areal Bleiche West Postfach 413 CH - 4800 Zofingen Telefon +41 62 752 83 08 Fax +41 62 752 83 09 E-Mail: info@simec.ch www.simec.ch

Test report

Number C 42299

Object of analysis:

Pharmacom Anastrazolos

Customer:

Frank Dawson

Samples: 1

Batch:

NJK766

Receipt: 22.03.2016

Subject:

Anastrozole: Assay, Identification

Method(s):

HPLC

ample / Analysis:	Method	Status	Result	Specification	complies
Anastrozole:					
dentification Content	HPLC HPLC	N N	complies 0.98 mg/tablet	complies 1 mg/tablet	yes -

Method-status:

G = GMP A = accreditated V = generally validated P = validated on product N = not validated

E = external lab

Remarks:

The sample(s) mentioned above have been analysed as they have been sent to us by the client. We have not controlled external processes like manufacturing, labelling, sampling, shipping, storage. These results are for information only and do not compensate for correct quality control by the manufacturer/distributor. Generally, pharmaceutical products have to be produced and distributed under full GMP/GDP regime, including GMP-compliant analyses with validated

methods.

Signatures:

controlled & released:

completed: 31.05.2016

The enclosed results refer exclusively to the object of examination described above. The measuring accuracy is available on request. Only handwritten signatures are valid. Without written permission, it is not allowed to publish single parts of this report.

page 1 of 1

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Report steroid analysis

HPLC:

Nr.5

Analysendatum:

27.05.2016 19:02:29

Druckdatum:

Injektvolumen:

30.05.2016

20

08:38:36

Vial:

C42299 A

Operator: Chrom.-Beding.

Probenidentifikation:

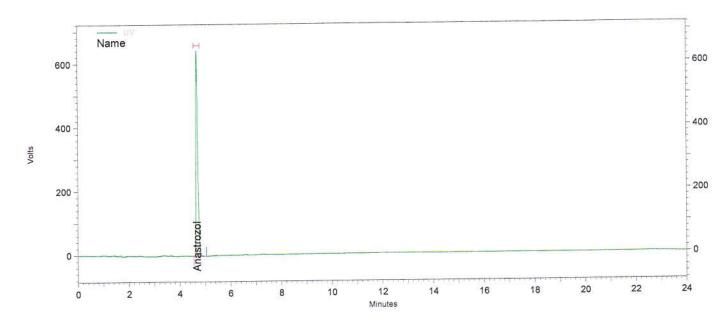
admin siehe Dosie

Temperatur: Säule

RT Nr. 56

Detektion:

UV 215nm



Channel A

UV Results

Name	Time	Area	Amount	Area Percer
Anastrozol	4,680	12750204	0,000	100,00
Totals		12750204	0,000	100,00

Daten File:

C:\EZChrom Elite\Enterprise\Projects\Simec\Data\2016\Mai

2016\27,05,16\C42299+C42807\004_C42299 A-Rep1.dat

Methode:

Report steroid analysis

HPLC:

Nr.5

Analysendatum:

27.05.2016 19:28:03

Druckdatum:

30.05.2016

08:38:40

Vial:

3

Injektvolumen:

20

Probenidentifikation:

C42299 A admin

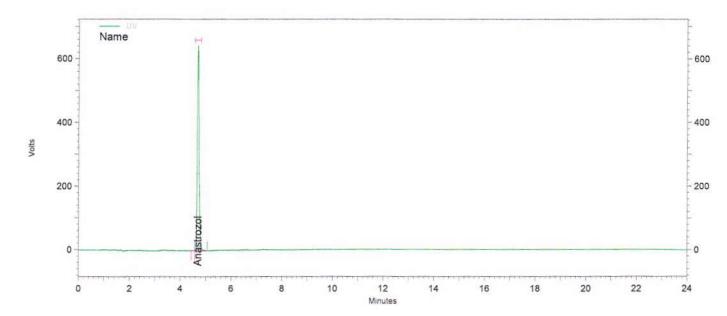
Operator: Chrom.-Beding.

siehe Dosie

Temperatur:

RT

Säule Detektion: Nr. 56 UV 215nm



Channel A

UV Results

Name	Time	Area	Amount	Area Percer
	4,477	2520	0,000	0,02
Anastrozol	4,690	12756743	0,000	99,98
Totals				
		12759263	0,000	100,00

C:\EZChrom Elite\Enterprise\Projects\Simec\Data\2016\Mai

2016\27,05,16\C42299+C42807\004_C42299 A-Rep2.dat

Methode:

Report steroid analysis

HPLC:

Nr.5

Analysendatum:

27.05.2016 19:53:23

Druckdatum:

30.05.2016

08:38:44

Vial:

3

Injektvolumen:

20

Probenidentifikation:

Probenidentifikation

admin

Operator: Chrom.-Beding.

siehe Dosie

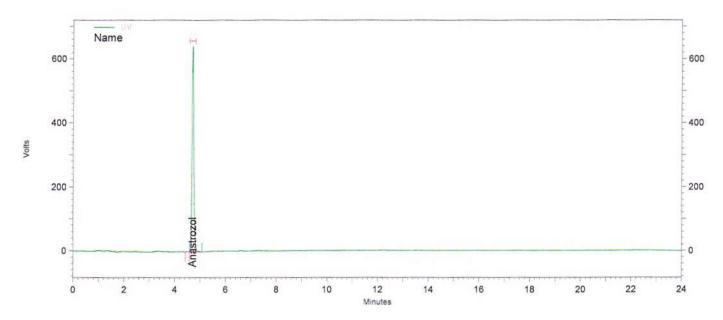
C42299 A

Temperatur:

RT Nr. 56

Säule Detektion:

UV 215nm



Channel A

UV Results

Name	Time	Area	Amount	Area Percer
	4,480	4790	0,000	0,03
Anastrozol	4,697	12704653	0,000	99,96
Totals		12700442	0.000	100.00
		12709443	0,000	100,00

Daten File:

C:\EZChrom Elite\Enterprise\Projects\Simec\Data\2016\Mai

2016\27,05,16\C42299+C42807\004_C42299 A-Rep3.dat

Methode:

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Report steroid analysis

HPLC:

Nr.5

Analysendatum:

27.05.2016 20:18:50

Druckdatum:

30.05.2016

08:38:48

Vial:

Injektvolumen:

20

Probenidentifikation:

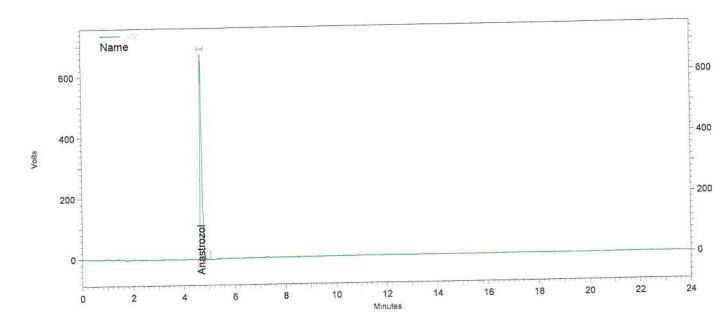
Operator:

C42299 B admin siehe Dosie

Chrom.-Beding. Temperatur:

RT

Säule Detektion: Nr. 56 UV 215nm



Channel A

UV Results

Time	Area	Amount	Area Percer
4,683	13387720	0,000	100,00
	13387720	0,000	100,00
		4,683 13387720	4,683 13387720 0,000

Daten File:

C:\EZChrom Elite\Enterprise\Projects\Simec\Data\2016\Mai

2016\27,05,16\C42299+C42807\005_C42299 B-Rep1.dat

Methode:

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Report steroid analysis

HPLC:

Nr.5

Analysendatum:

27.05.2016 20:44:17

Druckdatum:

Injektvolumen:

30.05.2016

20

08:38:52

Vial:

Probenidentifikation: Operator:

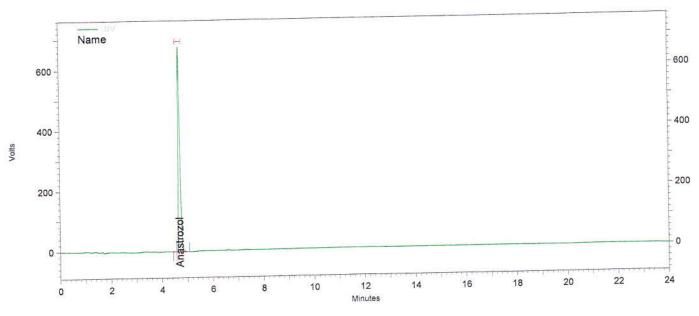
C42299 B admin

Chrom.-Beding.

siehe Dosie

Säule





Channel A

UV Results

UV Results	Time	Area	Amount	Area Percer
Name Anastrozol	4,477 4,693	2316 13446832	0,000 0,000	0,01 99,98
Totals		13449148	0,000	100,00

Daten File:

C:\EZChrom Elite\Enterprise\Projects\Simec\Data\2016\Mai

2016\27,05,16\C42299+C42807\005_C42299 B-Rep2.dat

Methode:

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Report steroid analysis

HPLC:

Nr.5

Analysendatum:

27.05.2016 21:09:39

Druckdatum:

Injektvolumen:

30.05.2016

20

08:38:56

Vial:

C42299 B

Operator:

admin siehe Dosie

Chrom.-Beding. Temperatur:

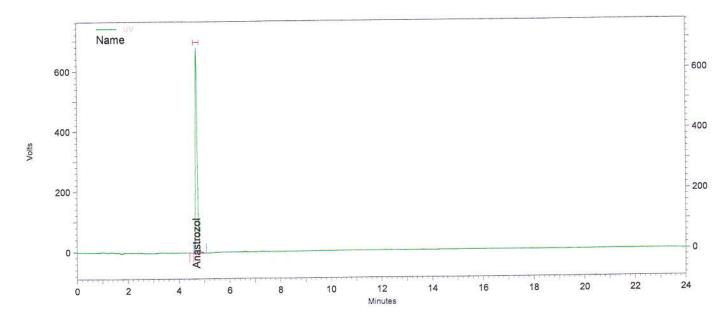
RT

Nr. 56

Säule Detektion:

Probenidentifikation:

UV 215nm



Channel A

11/1	Resu	1+0
1 V	KESII	115

UV Results Name	Time	Area	Amount	Area Percer
Anastrozol	4,480 4,690	5116 13478250	0,000 0,000	0,03 99,96
Totals		13483366	0,000	100,00

Daten File:

C:\EZChrom Elite\Enterprise\Projects\Simec\Data\2016\Mai

2016\27,05,16\C42299+C42807\005_C42299 B-Rep3.dat

Methode: