

SUPPLEMENT 1

Name of the medicinal product

KanJang Andrographis® with fixed combination of Andrographis paniculata herb extract and Eleutherococcus senticosus root extract.

Pharmaceutical form

Capsules

Indication for use

Herbal Medicinal Product for the “*reduction in the severity and duration of symptoms of uncomplicated respiratory tract infections (common cold)*”.

Dosage

The recommended daily dose is 2 capsules 3 times per day for adults.

Quantitative Composition

Substance	Quantity per one capsule, mg
<i>Active ingredients</i>	
Herba Andrographidis standardised extract containing 66-110 mg of native dry extract (DER 4,5-8,0 :1, extraction agent - ethanol* 70 %, V/V) corresponding to 10 mg of the sum of andrographolides (andrographolide and deoxydidehydro-andrographolide) and 45-67% of maltodextrin**(adjuvant for adjustment)	250
<i>Radix Eleutherococci</i> root extract, containing 11.4 mg of native dry extract (DER 17-30:1, extraction agent – ethanol 70%, V/V) , corresponding to 194-342 mg of herbal substance (<i>Radix Eleutherococci</i> , standardized for the content of eleutherosides B and E (0.4 mg/capsule) and 50% of maltodextrine** (adjuvant for adjustment)	22,8
<i>Inactive ingredients</i>	
Microcrystalline cellulose	70
Magnesium stearate	7.2
Vegetable capsule	75
Total weight	425 ± 21

Product: **Kan Jang Andrographis**
 Product category: Herbal medicinal product
 Dosage form: capsules
Daily dose: 6 capsules size 1
 Batch number: 50145
 Batch size: 5000 capsules

Composition

Ingredients	Ratio	Ratio ^{native} extract	1 capsule contains		
			herbal substance , mg	native extract, mg	dry extract, mg
<i>Andrographis paniculata</i> herb, dry extract batch nr: 1521114	3.9:1	6.7:1	1003.47	195.7 10mg andrographolides	249,0
<i>Eleutherococcus</i> <i>senticosus</i> , radix dry extract, batch nr:1521077	9,00:1	18.00:1	205.00	11,4	22,8
Microcrystalline cellulose, batch nr. 1960752					85,0
Magnesium stearate, batch nr. 1960738					7,2
Total					364,00
Capsules of plant origin size 1, colour: clear, weight – 76 mg					
Hypromellose – 100%, water content – 6%					
Filled capsules weight			440,00mg±33mg		

Product: **Placebo**
 Product category: Herbal medicinal product
 Dosage form: capsules
Daily dose: 6 capsules size 1
 Batch number: 50137-1
 Batch size: 4000 capsules

Composition

Ingredients	1 capsule contains, mg
Lactose monohydrate, batch nr. U2EX 417	205
Decaffeinated coffe, batch nr. U2EX 424	151
Magnesium stearate	8
Total	364
Capsules of plant origin size 1, colour: clear, weight – 76 mg	
Hypromellose – 100%, water content – 6%	
Filled capsules weight	440 mg±33 mg

Certificate of analysis

Capsule: Ken Jong Andrographis Batch no: 50.145

Doc.no:
ANJC.

Extr. Andr. succ 1521114

Bulk batch no:

Internal spec. no:

Extr. Eleuth succ 1521077

SP.FV-

Extr.

Parameter of analysis	Method	Reference	Result
Appearance	Occular	SP.FV-	
Smell	O.L	SP.FV-	
Total ash	Ph.Eur.Curr.Ed		6%
Ash, insoluble in HCl	Ph.Eur.Curr.Ed		1%
Loss on drying	Ph.Eur.Curr.Ed		3%
Identity (TLC)	<u>SM-010</u>	<u>ref</u>	<u>ref</u>
HPLC			
Eleuth B	<u>SM-066</u>		<u>0,084 mg/del</u>
Eleuth E	<u>SM-066</u>		<u>0,119 mg/del</u>
Σ Eleutherosides			<u>0,203 mg/del</u>
Andrographolide			<u>8,15 mg/del</u>
DDD-andr.			<u>1,50 mg/del</u>
Σ Andr + DDD-andr			<u>9,65 mg/del</u>
Neoandr.			<u>3,44 mg/del</u>
Weight including capsule	Ph.Eur.Curr.Ed	<u>440 ± 33 mg</u>	<u>418 ± 3 mg</u>
Weight without capsule	-	<u>364 ± 27 mg</u>	<u>342 ± 3 mg</u>
Diameter	-		<u>6,9 ± 0,1 mm</u>
Length	-		<u>19,3 ± 0,1 mm</u>
Disintegration	Ph.Eur.Curr.Ed (SM-032)	≤ 30 min	<u>< 30 min</u>
		Reference	Released
Microbial contamination	Ph.Eur.Curr.Ed	Ph.Eur.Cat B	

Date of analysis: 111028

Date of release: 2011/1/5

Analyst, sign: no/JY

QP-responsible:

Comments:

Manufacturing date:

Expiry date (two years):

Kan Jang Andrographis capsules

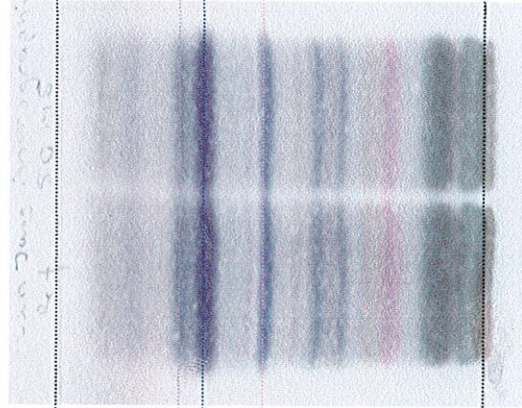
HPTLC

50 145

Method: SM-010

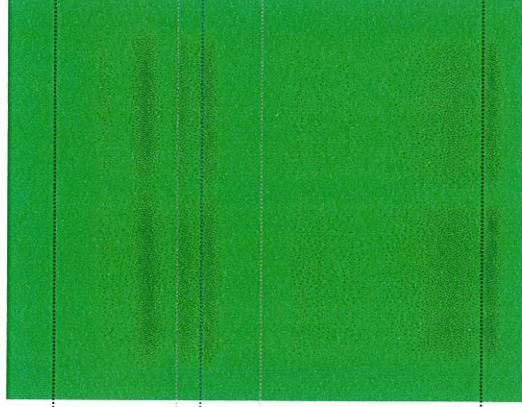
VIS

Ref 3400036
Test 50145

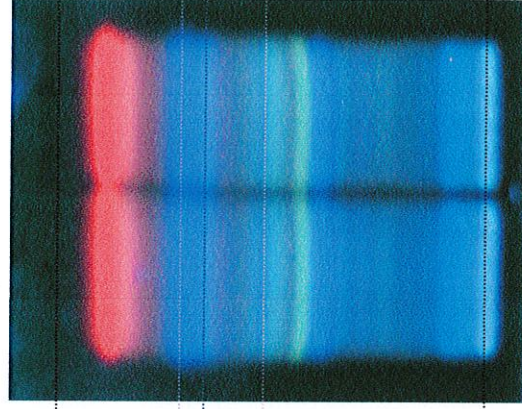


DDD-and
Rf: 0,71
Andr
Rf: 0,66
Neo-and
Rf: 0,51

254nm



366nm



Front

Start

Absorbent: Silica gel 60 F₂₅₄ precoated HPTLC plates
Solvent system: Ethylacetate : methanol : water (38 : 7 : 4)
Spray reagents: vanillin-sulphuric acid solution

Sign: *Mattias*

Date: 2011-11-02



SampleName KJ kaps 50145

Current Date 2011-10-28
 Software Empower 2 Software Build 2154
 Column no.: Acquity UPLC BEH C18 1.7µm
 01773000715504
 Channel 205 nm, 223 nm, 254 nm
 Run Time 5.00 Minutes

Processing Method Andrographis
 Start Date 2011-10-28 10:09:49 CEST

**Name Andrographolide,
 Deoxy-didehydroandrographolide,
 Neoandrographolide**

Tbl. weight: 342 (418) mg

**Component Results
 Name: Andrographolide**

	SampleName	SampleWeight	RT	Area	Height	Name	Percent_amount
1	KJ kaps 50145	3.12880	1.974	502517	316756	Andrographolide	2.384
2	KJ kaps 50145	3.12880	1.975	502858	317162	Andrographolide	2.385
3	KJ kaps 50145	3.12880	1.975	502143	317438	Andrographolide	2.382
Mean							2.383
Std. Dev.							0.002
% RSD							0.07

**Component Results
 Name: Neoandrographolide**

	SampleName	SampleWeight	RT	Area	Height	Name	Percent_amount
1	KJ kaps 50145	3.12880	2.931	179403	167106	Neoandrographolide	1.009
2	KJ kaps 50145	3.12880	2.932	179028	166937	Neoandrographolide	1.007
3	KJ kaps 50145	3.12880	2.933	178994	166954	Neoandrographolide	1.007
Mean							1.007
Std. Dev.							0.001
% RSD							0.13

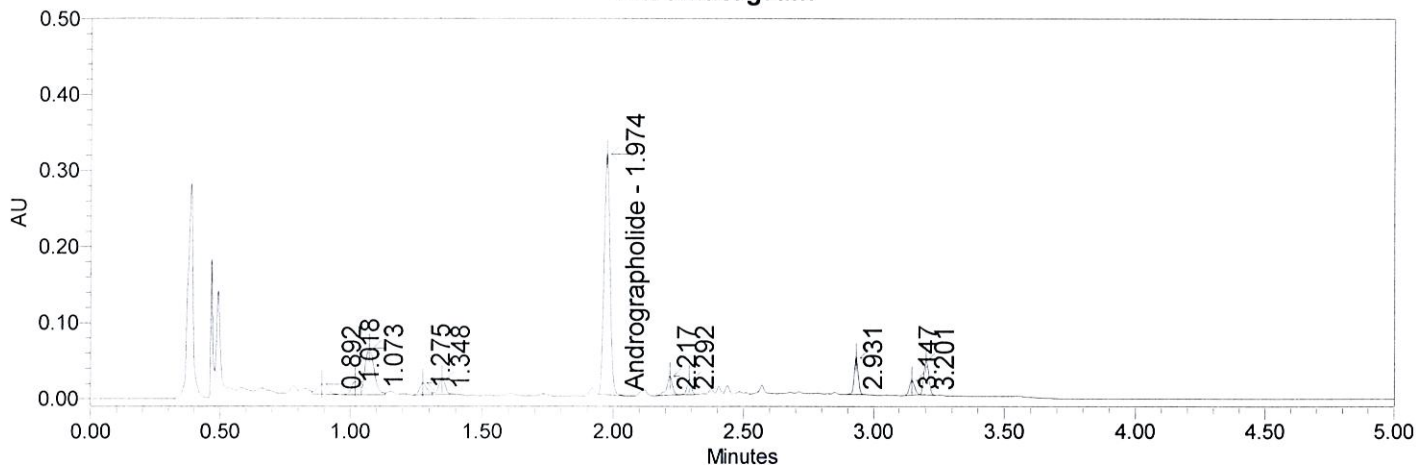
**Component Results
 Name: Deoxy-didehydroandrographolide**

	SampleName	SampleWeight	RT	Area	Height	Name	Percent_amount
1	KJ kaps 50145	3.12880	3.201	73898	54169	Deoxy-didehydroandrographolide	0.439
2	KJ kaps 50145	3.12880	3.202	73800	54106	Deoxy-didehydroandrographolide	0.438
3	KJ kaps 50145	3.12880	3.202	74005	54232	Deoxy-didehydroandrographolide	0.439
Mean							0.439
Std. Dev.							0.001
% RSD							0.14

Results	mg/tbl	calculated	%found
Andrographolide:	8,15 mg/tbl	8,38 mg/tbl	
Neoandrographolide:	3,44 mg/tbl	3,70 mg/tbl	
Deoxy-11,12-didehydroandrographolide:	1,50 mg/tbl	1,59 mg/tbl	
Total :	13,09 mg/tbl	13,67 mg/tbl	96%

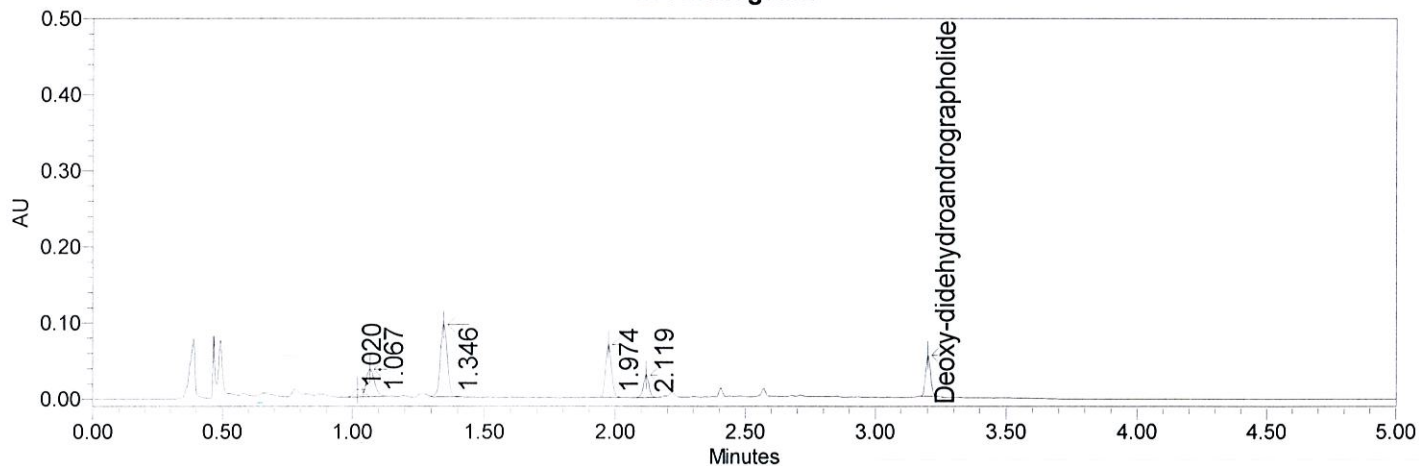
Sign: 

Chromatogram



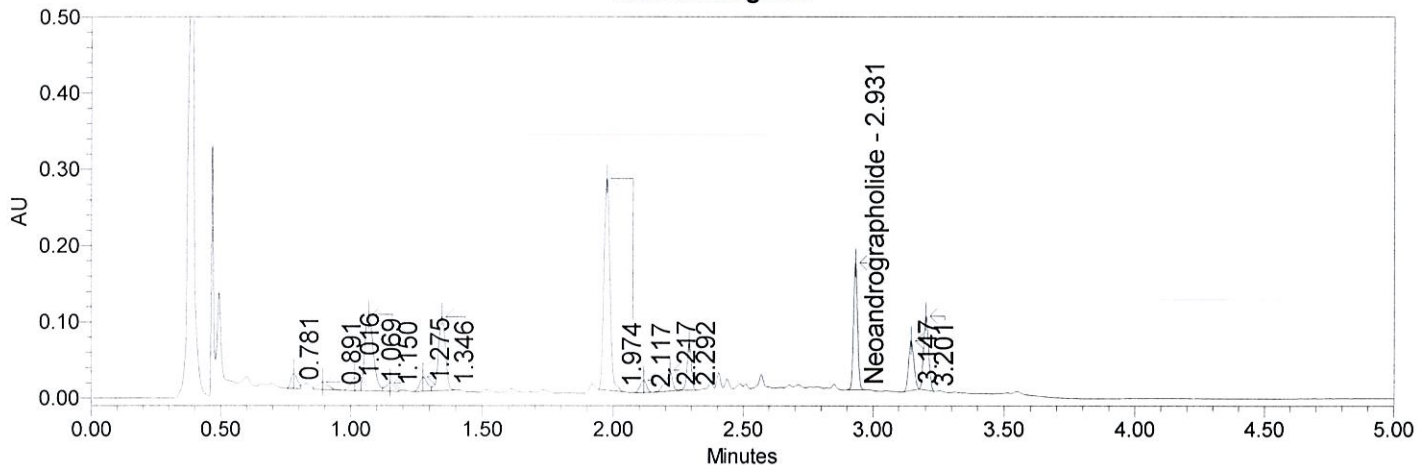
SampleName KJ kaps 50145; Vial 1:A,1; Injection 1; Date Acquired 2011-10-28 10:10:40 CEST; Channel Name 223 nm

Chromatogram



SampleName KJ kaps 50145; Vial 1:A,1; Injection 1; Date Acquired 2011-10-28 10:10:40 CEST; Channel Name 254 nm

Chromatogram



SampleName KJ kaps 50145; Vial 1:A,1; Injection 1; Date Acquired 2011-10-28 10:10:40 CEST; Channel Name 205 nm

Sign: 



SampleName KJ kaps 50145

Software Empower 2 Software Build 215

Column no.: 937031

Current Date 2011-11-01

Eleutherosid B

Run Time 35.00 Minutes

Processing Method Acanthopanax_KJT

Eleutherosid E

Channel PDA_210.0nm, PDA_220.0nm

Start Date 2011-10-31 10:28:24 CET

Tablet_Weight

Tbi. weight: 342(418)mg

System Name HPLC

Name: Eleutherosid B

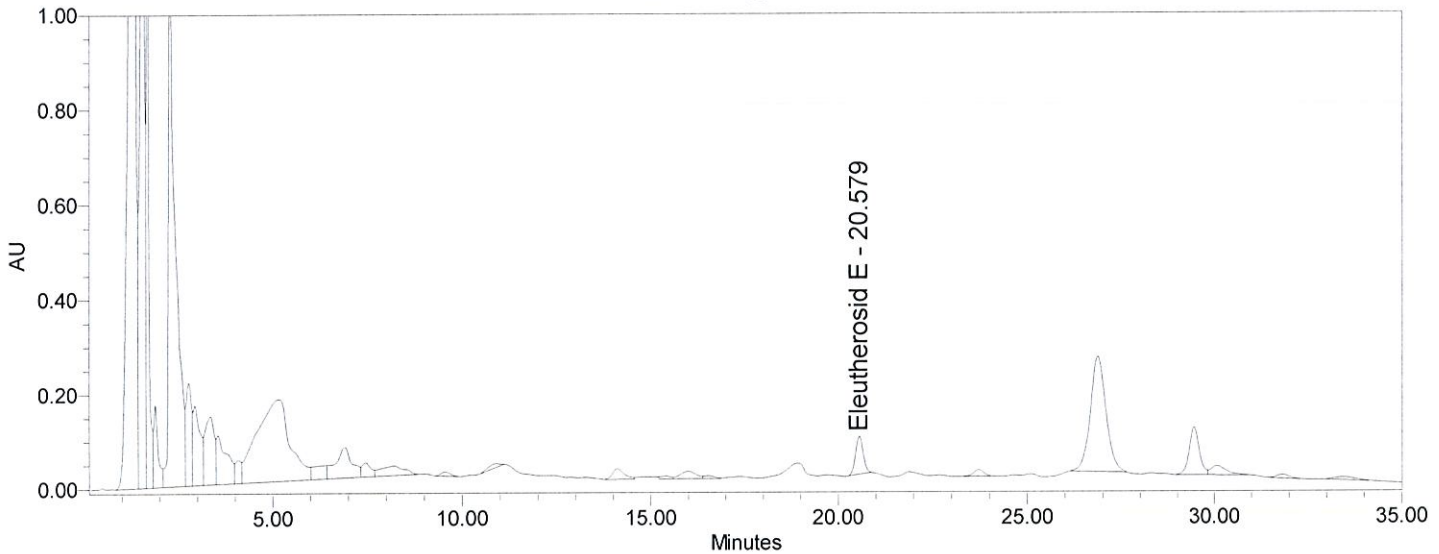
	SampleName	Injection Volume (ul)	SampleWeight	RT	Area	Height	Name	Procent_Amount
1	KJ kaps 50145	20.00	606.00000	6.898	777314	50588	Eleutherosid B	0.0247
2	KJ kaps 50145	20.00	606.00000	7.548	774718	40082	Eleutherosid B	0.0246
3	KJ kaps 50145	20.00	606.00000	7.550	786407	43669	Eleutherosid B	0.0250
Mean								0.0248
Std. Dev.								0.0002
% RSD								0.78

Name: Eleutherosid E

	SampleName	Injection Volume (ul)	SampleWeight	RT	Area	Height	Name	Procent_Amount
1	KJ kaps 50145	20.00	606.00000	20.579	1147289	80158	Eleutherosid E	0.0353
2	KJ kaps 50145	20.00	606.00000	21.273	1144666	74949	Eleutherosid E	0.0353
3	KJ kaps 50145	20.00	606.00000	21.279	1153406	72314	Eleutherosid E	0.0355
Mean								0.0354
Std. Dev.								0.0001
% RSD								0.39

Results	mg/tablet	calculated	% found
Eleutherosid B:	0,085 mg/dtl	0,089	96%
Eleutherosid E:	0,121 mg/dtl	0,114	106%
Eleutherosides:	0,206 mg/dtl	0,203	101%

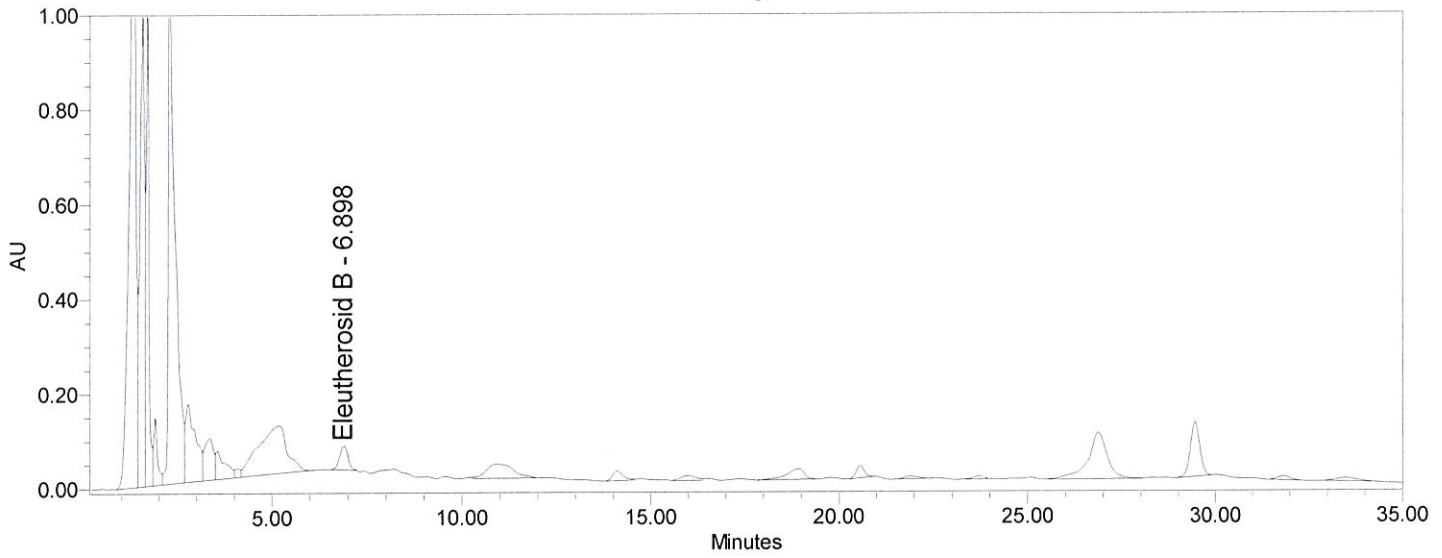
Chromatogram



SampleName KJ kaps 50145; Vial 1; Date Acquired 2011-10-31 12:02:06 CET; Channel Name PDA_210.0nm

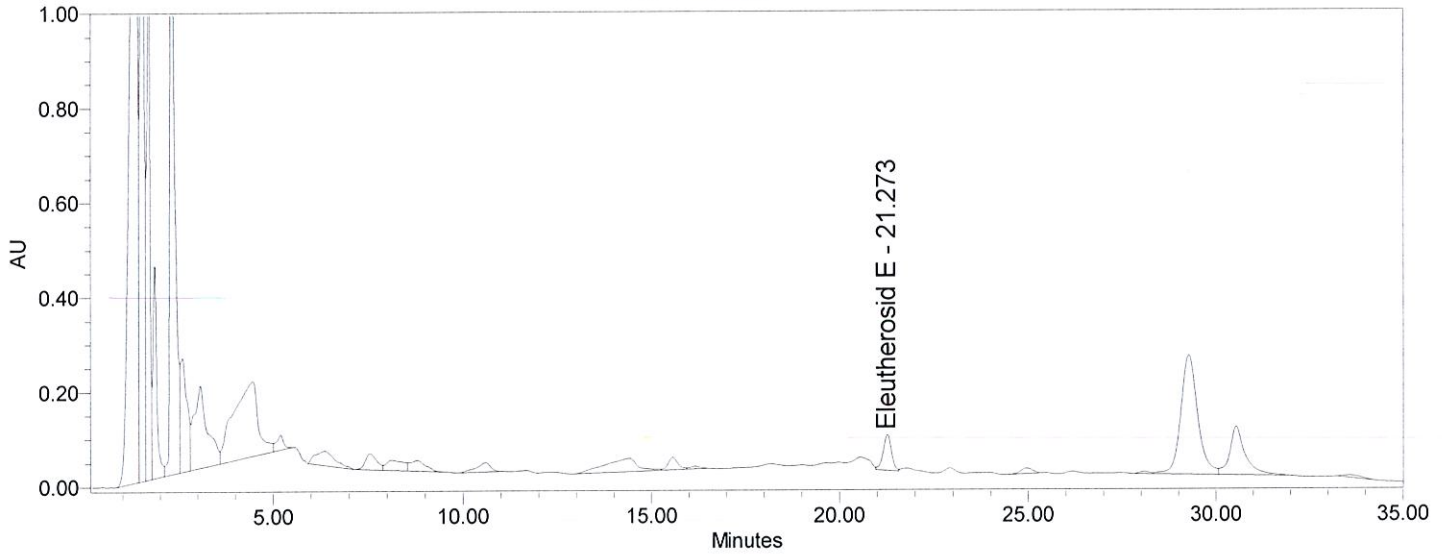
Sig.: 

Chromatogram




SampleName KJ kaps 50145; Vial 1; Date Acquired 2011-10-31 12:02:06 CET; Channel Name PDA_220.0nm

Chromatogram



SampleName KJ kaps 50145; Vial 1; Date Acquired 2011-10-31 19:06:22 CET; Channel Name PDA_210.0nm

Sig.: 



SampleName KJ kaps 50145

Software Empower 2 Software Build 215.

Current Date 2011-11-07

Eleutherosid B

Column no.: 937031

Processing Method Acanthopanax_KJT

Eleutherosid E

Run Time 35.00 Minutes

Start Date 2011-11-01 13:30:57 CET

Channel PDA_210.0nm, PDA_220.0nm

Tablet_Weight *342 (418) mg*

System Name HPLC

Name: Eleutherosid B

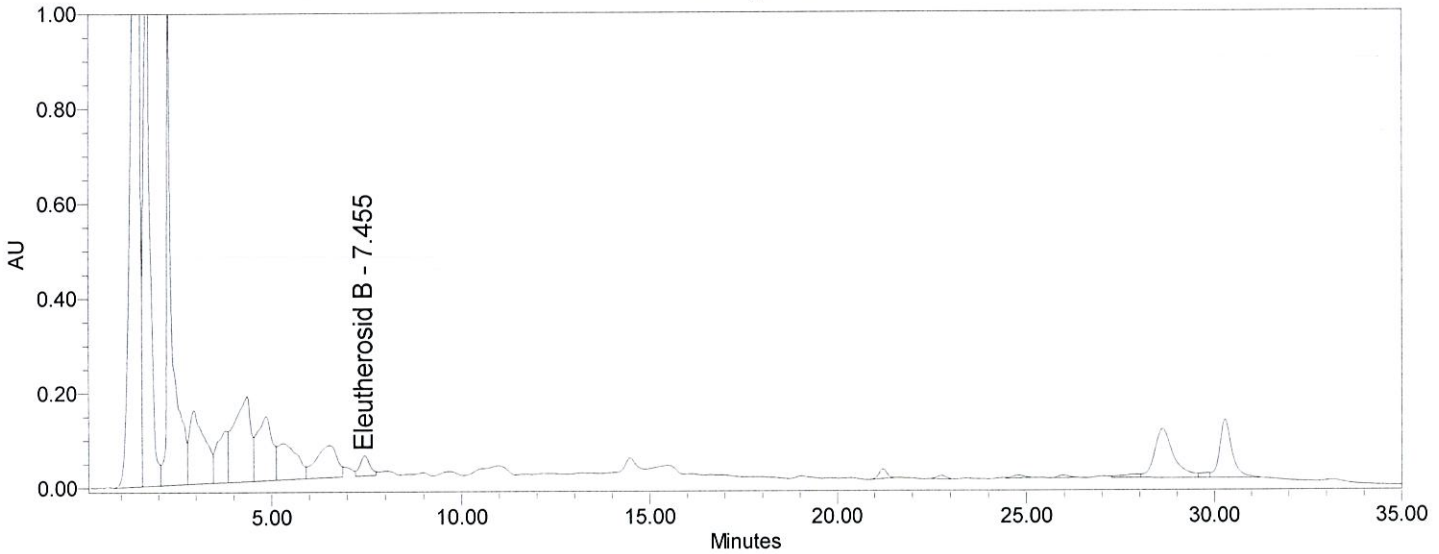
	SampleName	Injection Volume (ul)	SampleWeight	RT	Area	Height	Name	Procent_Amount
1	KJ kaps 50145	20.00	606.00000	7.062	769506	47784	Eleutherosid B	0.0245
2	KJ kaps 50145	20.00	606.00000	7.431	770998	41823	Eleutherosid B	0.0245
3	KJ kaps 50145	20.00	606.00000	7.455	777146	42652	Eleutherosid B	0.0247
Mean								0.0246
Std. Dev.								0.0001
% RSD								0.52

Name: Eleutherosid E

	SampleName	Injection Volume (ul)	SampleWeight	RT	Area	Height	Name	Procent_Amount
1	KJ kaps 50145	20.00	606.00000	21.107	1130714	72690	Eleutherosid E	0.0348
2	KJ kaps 50145	20.00	606.00000	21.207	1126124	73673	Eleutherosid E	0.0347
3	KJ kaps 50145	20.00	606.00000	21.223	1125963	73463	Eleutherosid E	0.0347
Mean								0.0347
Std. Dev.								0.0001
% RSD								0.24

Results	mg/tablet	calculated	% found
Eleutherosid B:	<i>0,084 mg /tbl</i>	<i>0,089</i>	<i>94%</i>
Eleutherosid E:	<i>0,119 mg /tbl</i>	<i>0,114</i>	<i>104%</i>
Eleutherosides:	<i>0,203 mg /tbl</i>	<i>0,203</i>	<i>100%</i>

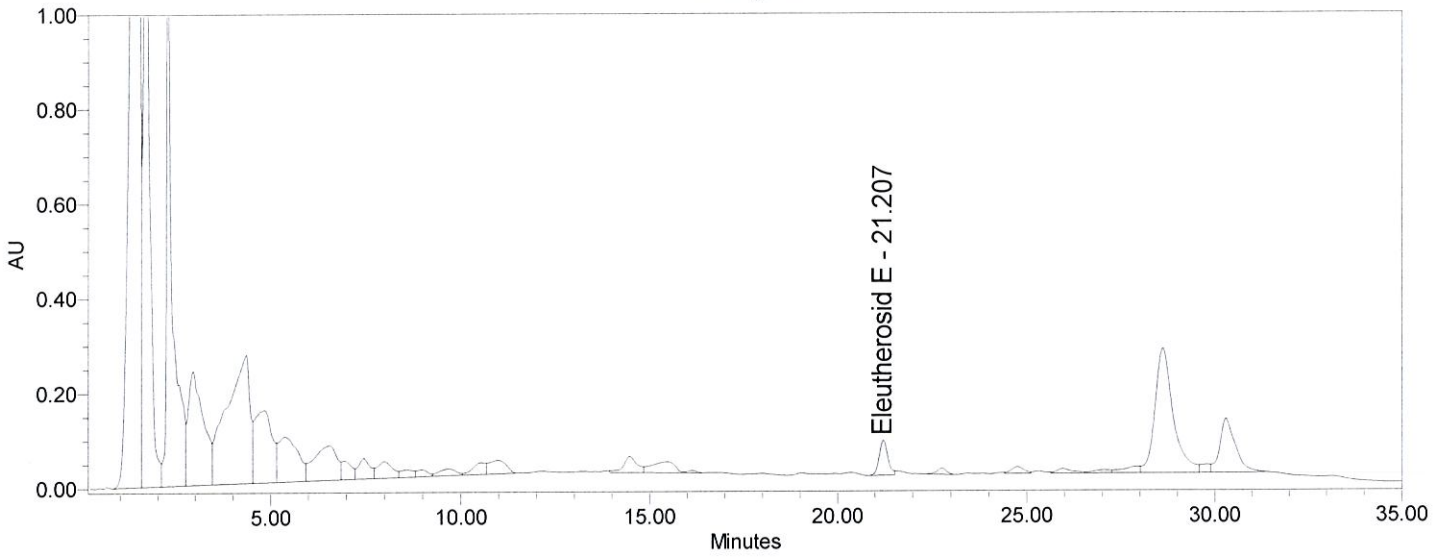
Chromatogram



SampleName KJ kaps 50145; Vial 1; Date Acquired 2011-11-02 17:01:52 CET; Channel Name PDA_220.0nm

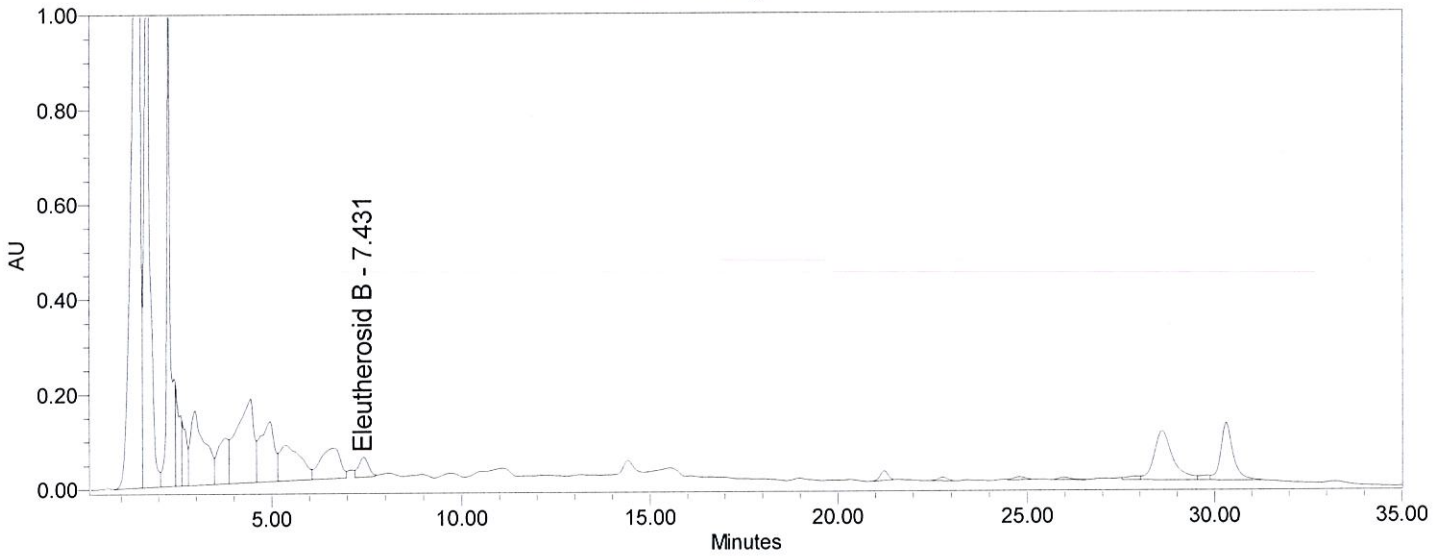
Sig.: *[Signature]*

Chromatogram




SampleName KJ kaps 50145; Vial 1; Date Acquired 2011-11-02 17:01:52 CET; Channel Name PDA_210.0nm

Chromatogram



SampleName KJ kaps 50145; Vial 1; Date Acquired 2011-11-02 15:29:28 CET; Channel Name PDA_220.0nm

Sig.: 

Certificate of analysis

Capsule: Ken Jong Andrographis Batch no: 50.145

Doc.no:
ANJC.

Extr.
Extr.
Extr.

Bulk batch no:

Internal spec. no:
SP.FV-

Parameter of analysis	Method	Reference	Result
Appearance	Occular	SP.FV-	
Smell	O.L	SP.FV-	
Total ash	Ph.Eur.Curr.Ed		5%
Ash, insoluble in HCl	Ph.Eur.Curr.Ed		1%
Loss on drying	Ph.Eur.Curr.Ed		3%
Identity (TLC)	<u>SM-010</u>	<u>=ref</u>	<u>=ref</u>
HPLC			
Eleuth B	<u>SM-066</u>		<u>0,084 mg/dcl</u>
Eleuth E	<u>SM-066</u>		<u>0,119 mg/dcl</u>
Σ Eleutherosides			<u>0,203 mg/dcl</u>
Andrographolide			<u>8,15 mg/dcl</u>
DDD -andr			<u>1,50 mg/dcl</u>
Σ Andr + DDD -andr			<u>9,65 mg/dcl</u>
Neoandr			<u>3,44 mg/dcl</u>
Weight including capsule	Ph.Eur.Curr.Ed	<u>440 ± 33 mg</u>	<u>418 ± 4 mg</u>
Weight without capsule	-	<u>364 ± 27 mg</u>	<u>341 ± 4 mg</u>
Diameter	-		<u>6,9 ± 0,1 mm</u>
Length	-		<u>19,3 ± 0,1 mm</u>
Disintegration	Ph.Eur.Curr.Ed (SM-032)	≤ 30 min	<u>< 30 min</u>
		Reference	Released
Microbial contamination	Ph.Eur.Curr.Ed	Ph.Eur.Cat B	<u>conform</u>

Date of analysis: 111101

Date of release: 20111114

Analyst, sign: no) W

QP-responsible: M

Comments:	Manufacturing date:
	Expiry date (two years):

PhytoLab GmbH & Co.KG Dutendorfer Straße 5-7 91487 Vestenbergsgreuth

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Fax: +49 9163 88-379
annette.reichel@phytolab.de

Date: 9.11.11

Cust.No: 91778



Certificate of analysis

Report-No.: 13292590- 40 001
Cust.-lot: 50145
Sample labelling: Kan Jang capsule
Sample description: 135 capsules
Packing: 9x blister
Receipt of sample: 3.11.11

Test	Unit	Limit	Testresult
Microbiology: Category B, Herbal medicinal products containing, for example, extracts and/ or herbal drugs, with or without excipients, where the method of processing (for example, extraction) or, where appropriate, in the case of herbal drugs, of pre-treatment reduces the levels of organisms to below those stated for this category, according to Ph. Eur. 7.0, 5.1.8, SOP 803911:			Conform
Total aerobic microbial count (TAMC), Ph. Eur. 7.0, 2.6.12, SOP 300007	CFU/g	< = 50,000	50
Moulds (quantitative), Ph. Eur. 7.0, 2.6.12, SOP 300014	CFU/g		< 10
Yeasts (quantitative), Ph. Eur. 7.0, 2.6.12, SOP 300023	CFU/g		10
Total combined yeasts and moulds count (TYMC), Ph. Eur. 7.0, 2.6.12, SOP 300033	CFU/g	< = 500	10
Bile-tolerant gram-negative bacteria (semiquantitative, PN method), Ph. Eur. 7.0, 2.6.31, SOP 300044	CFU/g	< = 100	< 10
Escherichia coli (absence test), Ph. Eur.7.0, 2.6.31, SOP 300058	/g	Absent	Absent
Salmonella (absence test), Ph. Eur. 7.0, 2.6.31, SOP 300122	/25 g	Absent	Absent

Information on the method employed and on method characteristics is available to customers on request. The results apply to the supplied sample. Copying of the document is only permissible without any modification of the document.

Certificate of analysis

Report-No.: 13292590- 40 001
Cust.-lot: 50145
Sample labelling: Kan Jang capsule

Test	Unit	Limit	Testresult
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Vestenbergsreuth, 9.11.11



Dr. Claudia Borst

Kan Jang Andrographis capsules, blister HPTLC 50 145

Method: SM-010

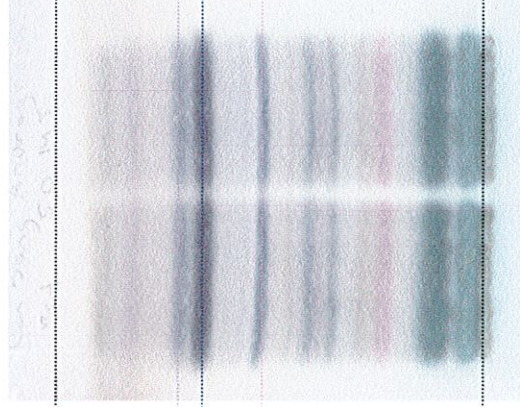
VIS

Ref 3400039
Test 50145

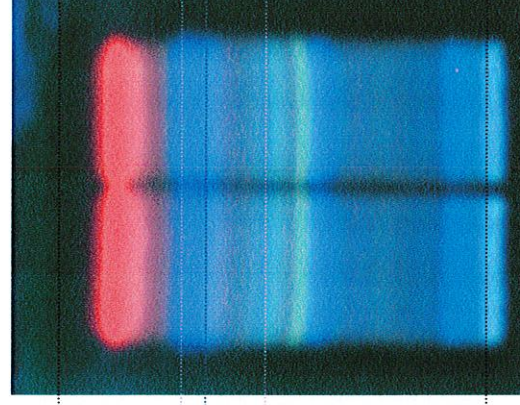
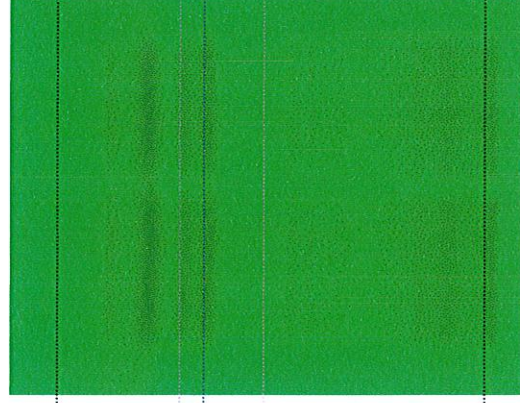
254nm

366nm

Front



DDD-and
R_f: 0,71
Andr
R_f: 0,66
Neo-and
R_f: 0,52



Start

Absorbent: Silica gel 60 F₂₅₄ precoated HPTLC plates
Solvent system: Ethylacetate : methanol : water (38 : 7 : 4)
Spray reagents: vanillin-sulphuric acid solution

Sign: *Maria*

Date: 2011-11-03



PhytoLab GmbH & Co.KG Dutendorfer Straße 5-7 91487 Vestenbergsgreuth

Swedish Herbal Institute
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annette.reichel@phytolab.de

Date: 9.11.11

Cust.No: 91778



Certificate of analysis

Report-No.: 13292590- 40 001
Cust.-lot: 50145
Sample labelling: Kan Jang capsule
Sample description: 135 capsules
Packing: 9x blister
Receipt of sample: 3.11.11

Test	Unit	Limit	Testresult
Microbiology: Category B, Herbal medicinal products containing, for example, extracts and/ or herbal drugs, with or without excipients, where the method of processing (for example, extraction) or, where appropriate, in the case of herbal drugs, of pre-treatment reduces the levels of organisms to below those stated for this category, according to Ph. Eur. 7.0, 5.1.8, SOP 803911:			Conform
Total aerobic microbial count (TAMC), Ph. Eur. 7.0, 2.6.12, SOP 300007	CFU/g	< = 50,000	50
Moulds (quantitative), Ph. Eur. 7.0, 2.6.12, SOP 300014	CFU/g		< 10
Yeasts (quantitative), Ph. Eur. 7.0, 2.6.12, SOP 300023	CFU/g		10
Total combined yeasts and moulds count (TYMC), Ph. Eur. 7.0, 2.6.12, SOP 300033	CFU/g	< = 500	10
Bile-tolerant gram-negative bacteria (semiquantitative, PN method), Ph. Eur. 7.0, 2.6.31, SOP 300044	CFU/g	< = 100	< 10
Escherichia coli (absence test), Ph. Eur.7.0, 2.6.31, SOP 300058	/g	Absent	Absent
Salmonella (absence test), Ph. Eur. 7.0, 2.6.31, SOP 300122	/25 g	Absent	Absent

Information on the method employed and on method characteristics is available to customers on request. The results apply to the supplied sample. Copying of the document is only permissible without any modification of the document.



Certificate of analysis

Report-No.: 13292590- 40 001
Cust.-lot: 50145
Sample labelling: Kan Jang capsule

Test	Unit	Limit	Testresult
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Vestenbergsreuth, 9.11.11

Dr. Claudia Borst

2011.11.15 / BW

Certificate of analysis

Product: **Andrographis pan. extr. siccum**

Batch no: 152114

Internal spec. no

Batch no., previous extract: 1421047

Batch no., drug: 1010247

SP EX-001

Parameter of analysis	Method	Reference	Result
Appearance	Occular	SP.EX-001	= ref
Loss on drying	Ph.Eur.Curr.Ed	≤ 5%	2%
pH in 5% H ₂ O-solution	Ph.Eur.Curr.Ed	5 - 7	6
Identity TLC	SM-010	= ref	= ref
Andrographolide	SM-118	- %	3,38%
14-deoxy-11,12-didehydroandrographolide	SM-118	- %	0,64%
Σ Andrographolides	SM-118	4.2-8.4%	4,02%
Σ Andrographolides in native extract	SM-118	6.0-14.0%	6,93%
Neoandrographolide	SM-118	n.a.	1,49%
Methylparahydroxybenzoate	SM-121	0.2-0.6%	0,35%
Nativ ratio	SM-087	4.5-8.0 : 1	6,7 : 1
Microbiology	Ph.Eur Curr.Ed. 5.1.8	Ph. Eur. Cat B	conform
Ethanol	Ph.Eur.Curr.Ed. 2.4.24	≤ 2%	0,9%

Date of analysis 2011. 10. 21

Date of release 2011 10 31

Analyst signature bu/mo

QP-responsible MF

Comments: Ratio: 3,9 : 1
* Andrographolides are out of limits, but in the nativ extract are in the limits. ✓

Manufacturing date
2011. 10. 18
Expiry date (three years)
2014 - 11



Sample Name:
Andr 1521114

Rapport_extrakt

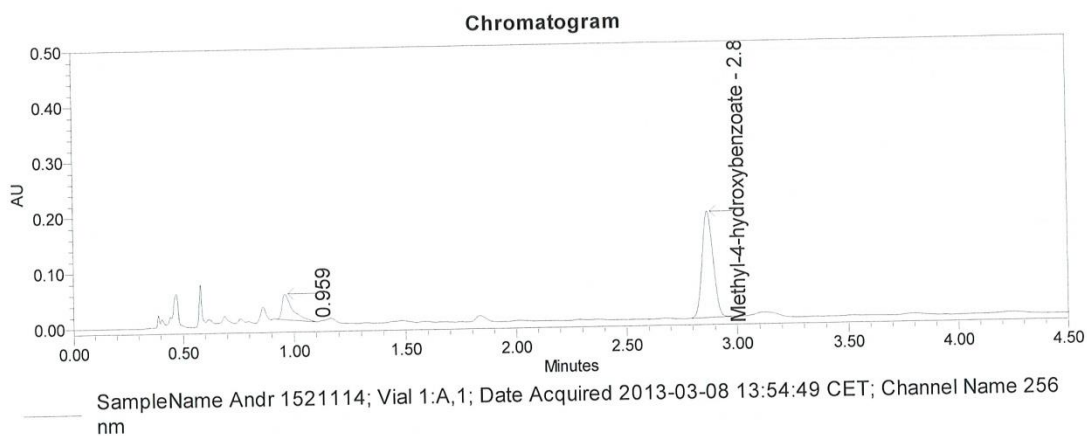
Method: SM-121
Sample Type: Unknown
Vial: 1:A,1
Injection #: 1, 2, 3
Injection Volume: 2.00 ul
Run Time: 4.5 Minutes
Sample Set Name: Andr 114 047

Acquired By: EvaV
Date Acquired: 2013-03-08 13:54:49 CET,
Acq. Method Set: Kons med andr
Date Processed: 2013-03-08 14:09:51 CET,
Processing Method: Kons med andr
Channel Name: 256 nm
Column no.: 01363035115404

Component Results
SampleName: Andr 1521114

	SampleName	Vial	Inj	SampleWeight	Dilution	RT	Area	Height	Name	Percent_amount
1	Andr 1521114	1:A,1	3	7.61000	1.00000	2.867	653670	191651	Methyl-4-hydroxybenzoate	0.3491
2	Andr 1521114	1:A,1	1	7.61000	1.00000	2.868	656709	191503	Methyl-4-hydroxybenzoate	0.3507
3	Andr 1521114	1:A,1	2	7.61000	1.00000	2.873	654695	191117	Methyl-4-hydroxybenzoate	0.3496
Mean						2.87	655025			0.350
Std. Dev.						0.00	1546			0.001
% RSD						0.1	0.2			0.2

Result	%	Calculated	% Found
Methyl-4-hydroxybenzoate:	0,35%	0,365%	96%



Sign.: 

Andrographis siccum
HPTLC
15 21114

Method: SM-010

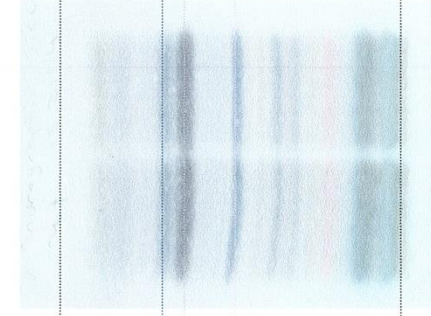
VIS

Ref
087

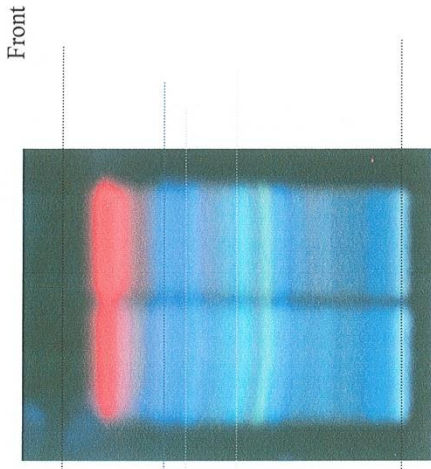
Test
114

254nm

366nm



DDD-and
R_f: 0,70
Andr
R_f: 0,64
Neo-and
R_f: 0,48



Front

Start

Absorbent: Silica gel 60 F₂₅₄ precoated HPTLC plates
Solvent system: Ethylacetate : methanol : water (38 : 7 : 4)
Spray reagents: vanillin-sulphuric acid solution

Sign: *Mattias*

Date: 2011-10-21



Processing Method Andrographis

Start Date 2011-10-24 10:55:58 CEST

SampleName Andr 1521114

**Name Andrographolide,
Deoxy-didehydroandrographolide,
Neoandrographolide**

Current Date 2011-10-24

Software Empower 2 Software Build 2154

Column no.: Acquity UPLC BEH C18 1.7µm
01773000715504

Channel 205 nm, 223 nm, 254 nm

Run Time 5.00 Minutes

**Component Results
Name: Andrographolide**

	SampleName	Vial	Injection	SampleWeight	RT	Area	Height	Name	Percent_amount
1	Andr 1521114	1:A,4	3	2.10560	1.968	479849	298198	Andrographolide	3.381
2	Andr 1521114	1:A,4	1	2.10560	1.970	479741	298176	Andrographolide	3.381
3	Andr 1521114	1:A,4	2	2.10560	1.971	480825	299764	Andrographolide	3.388
Mean									3.383
Std. Dev.									0.004
% RSD									0.12

**Component Results
Name: Neoandrographolide**

	SampleName	Vial	Injection	SampleWeight	RT	Area	Height	Name	Percent_amount
1	Andr 1521114	1:A,4	3	2.10560	2.919	177917	159208	Neoandrographolide	1.487
2	Andr 1521114	1:A,4	2	2.10560	2.919	178163	159333	Neoandrographolide	1.489
3	Andr 1521114	1:A,4	1	2.10560	2.920	177943	159193	Neoandrographolide	1.487
Mean									1.487
Std. Dev.									0.001
% RSD									0.08

**Component Results
Name: Deoxy-didehydroandrographolide**

	SampleName	Vial	Injection	SampleWeight	RT	Area	Height	Name	Percent_amount
1	Andr 1521114	1:A,4	3	2.10560	3.186	72694	52211	Deoxy-didehydroandrographolide	0.641
2	Andr 1521114	1:A,4	2	2.10560	3.187	72912	52385	Deoxy-didehydroandrographolide	0.643
3	Andr 1521114	1:A,4	1	2.10560	3.188	72656	52187	Deoxy-didehydroandrographolide	0.641
Mean									0.642
Std. Dev.									0.001
% RSD									0.19

Results _____ **%**

Andrographolide: _____ **3,38%**

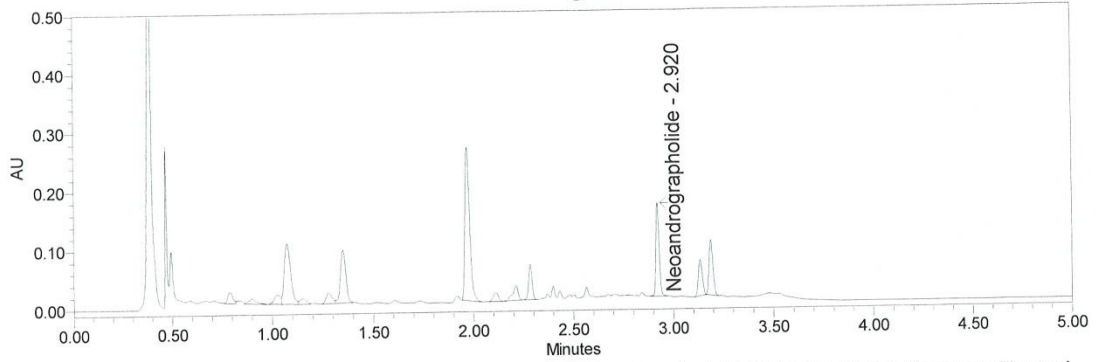
Neoandrographolide: _____ **1,49%**

Deoxy-11,12-didehydroandrographolide: _____ **0,64%**

Total : _____ **5,51%**

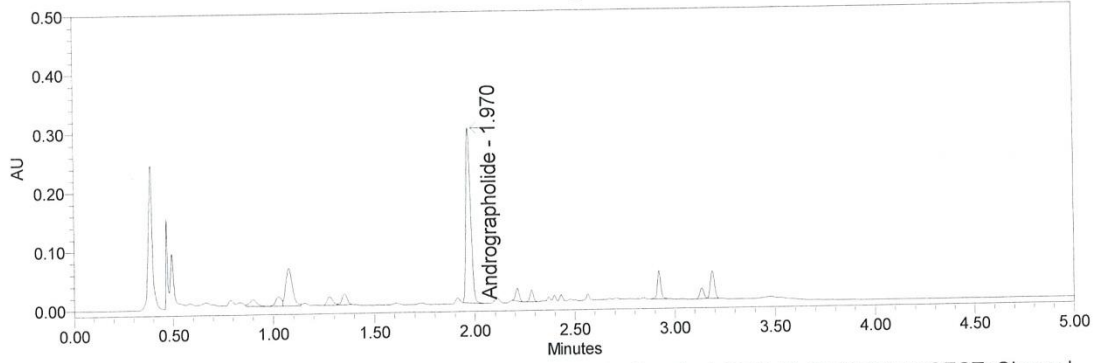
Sign: _____

Chromatogram



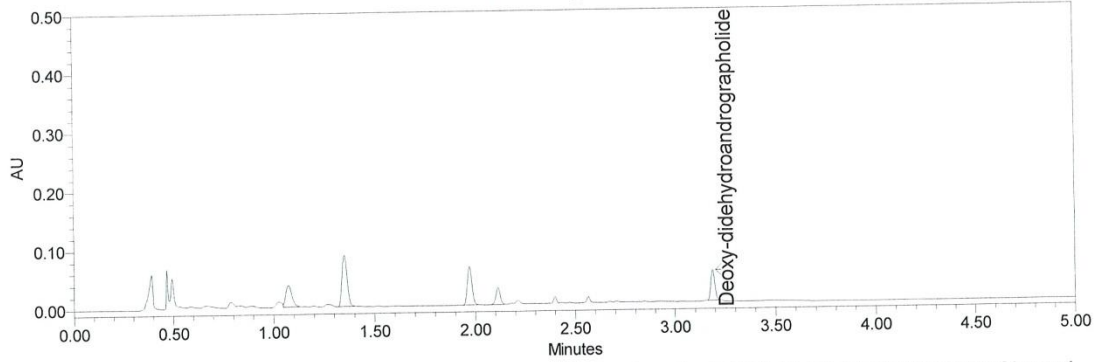
SampleName Andr 1521114; Vial 1:A,4; Injection 1; Date Acquired 2011-10-24 11:49:48 CEST; Channel Name 205 nm

Chromatogram




SampleName Andr 1521114; Vial 1:A,4; Injection 1; Date Acquired 2011-10-24 11:49:48 CEST; Channel Name 223 nm

Chromatogram



SampleName Andr 1521114; Vial 1:A,4; Injection 1; Date Acquired 2011-10-24 11:49:48 CEST; Channel Name 254 nm

Sign: 

PhytoLab GmbH & Co.KG Dutendorfer Straße 5-7 91487 Vestenbergsgreuth

Swedish Herbal Institute
Eva Vencel
Kövlingevägen 21
312 50 Vallberga
Sweden

PhytoLab GmbH & Co.KG
Dutendorfer Straße 5-7
91487 Vestenbergsgreuth
Germany
Contact at PhytoLab:
Annette Reichel
Tel: +49 9163 88-188
Fax: +49 9163 88-379
annette.reichel@phytolab.de

Date: 31.10.11

Cust.No: 91778



Certificate of analysis

Report-No.: 13248486- 40 001
Cust.-lot: 15 21114
Sample labelling: Andrographis siccum
Sample description: green, fine powder
Packing: pe container with screw closure
Receipt of sample: 21.10.11

Test	Unit	Limit	Testresult
Microbiology: Category B, Herbal medicinal products containing, for example, extracts and/ or herbal drugs, with or without excipients, where the method of processing (for example, extraction) or, where appropriate, in the case of herbal drugs, of pre-treatment reduces the levels of organisms to below those stated for this category, according to Ph. Eur. 7.0, 5.1.8, SOP 803911:			Conform
Total aerobic microbial count (TAMC), Ph. Eur. 7.0, 2.6.12, SOP 300007	CFU/g	< = 50,000	50
Moulds (quantitative), Ph. Eur. 7.0, 2.6.12, SOP 300014	CFU/g		< 10
Yeasts (quantitative), Ph. Eur. 7.0, 2.6.12, SOP 300023	CFU/g		< 10
Total combined yeasts and moulds count (TYMC), Ph. Eur. 7.0, 2.6.12, SOP 300033	CFU/g	< = 500	< 10
Bile-tolerant gram-negative bacteria (semiquantitative, PN method), Ph. Eur. 7.0, 2.6.31, SOP 300044	CFU/g	< = 100	< 10
Escherichia coli (absence test), Ph. Eur.7.0, 2.6.31, SOP 300058	/g	Absent	Absent
Salmonella (absence test), Ph. Eur. 7.0, 2.6.31, SOP 300122	/25 g	Absent	Absent


Information on the method employed and on method characteristics is available to customers on request. The results apply to the supplied sample. Copying of the document is only permissible without any modification of the document.

Certificate of analysis

Report-No.: 13248486- 40 001
Cust.-lot: 15 21114
Sample labelling: Andrographis siccum

Test	Unit	Limit	Testresult
------	------	-------	------------

Vestenbergsreuth, 31.10.11



Dr. Claudia Borst

2011.10.31 / h/v

PhytoLab GmbH & Co.KG Dutendorfer Straße 5-7 91487 Vestenbergsgreuth

Swedish Herbal Institute
Eva Vencel
Kövlingevägen 21
312 50 Vallberga
Sweden

PhytoLab GmbH & Co.KG
Dutendorfer Straße 5-7
91487 Vestenbergsgreuth
Germany
Contact at PhytoLab:
Annette Reichel
Tel: +49 9163 88-188
Fax: +49 9163 88-379
annette.reichel@phytolab.de

Date: 31.10.11

Cust.No: 91778



Certificate of analysis

Report-No.: 13248486- 40001
Cust.-lot: 15 21114
Sample labelling: Andrographis siccum
Sample description: green, fine powder
Packing: pe container with screw closure
Receipt of sample: 21.10.11

Test	Unit	Limit	Testresult
Microbiology: Category B, Herbal medicinal products containing, for example, extracts and/ or herbal drugs, with or without excipients, where the method of processing (for example, extraction) or, where appropriate, in the case of herbal drugs, of pre-treatment reduces the levels of organisms to below those stated for this category, according to Ph. Eur. 7.0, 5.1.8, SOP 803911:			Conform
Total aerobic microbial count (TAMC), Ph. Eur. 7.0, 2.6.12, SOP 300007	CFU/g	< = 50,000	50
Moulds (quantitative), Ph. Eur. 7.0, 2.6.12, SOP 300014	CFU/g		< 10
Yeasts (quantitative), Ph. Eur. 7.0, 2.6.12, SOP 300023	CFU/g		< 10
Total combined yeasts and moulds count (TYMC), Ph. Eur. 7.0, 2.6.12, SOP 300033	CFU/g	< = 500	< 10
Bile-tolerant gram-negative bacteria (semiquantitative, PN method), Ph. Eur. 7.0, 2.6.31, SOP 300044	CFU/g	< = 100	< 10
Escherichia coli (absence test), Ph. Eur.7.0, 2.6.31, SOP 300058	/g	Absent	Absent
Salmonella (absence test), Ph. Eur. 7.0, 2.6.31, SOP 300122	/25 g	Absent	Absent

Information on the method employed and on method characteristics is available to customers on request. The results apply to the supplied sample. Copying of the document is only permissible without any modification of the document.



Certificate of analysis

Report-No.: 13248486- 40001
Cust.-lot: 15 21114
Sample labelling: Andrographis siccum

Test	Unit	Limit	Testresult
------	------	-------	------------

Vestenbergsreuth, 31.10.11

C Borst

Dr. Claudia Borst

Svenska Örtmedicinska Institutet
Eva Vencel
Kovlingevägen 21
SE-312 50 Vallberga

Eurofins Pharma A/S
Strandesplanaden 110
DK-2655 Vallensbæk Strand
Denmark

Tel. +45 70 22 42 66
Fax +45 70 22 42 55
eurofins@eurofins.dk
www.eurofins.dk

Date
02 November 2011
Our ref.
942687/SLH

Analytical report

Sample received	Test sample
20 October 2011	Andrograhis extract siccum

Customer's journal no/ project title:

-

Label(s): Batch no. 15 21114

Information from client: -


Methods: Specific references are listed with the test results

Reference: -

Results: Results are reported on page 2-3

Comments: Samples are analysed by the laboratory:
Dr. Fintelmann und Dr. Meyer, GMBH, Germany

Signatures


Sandy Leth
MSc (Pharm)



Fintelmann und Meyer GMP GmbH

Eurofins Fintelmann und Meyer GMP GmbH
Großmoorbogen 25
D-21079 Hamburg
GERMANY

Eurofins Fintelmann und Meyer GMP GmbH | Großmoorbogen 25 | D-21079 Hamburg

Svenska Örtmedicinska Institutet
attn. Mrs. Eva Vencel
Kövlingsvägen 21
31250
SCHWEDEN

Tel: +49 40 49 294 670
Fax: +49 40 49 294 699

info@fintelmann-meyer.de
www.fintelmann-meyer.de

Report date 01.11.2011
Page 1/2

Analytical report AR-11-FG-009993-01



Sample Code 714-2011-00017541

Reference	Andrographis extract siccum Batch nr. 15 21114 19.10.2011
Sample sender	Mrs. Eva Vencel
Prescriber	Eurofins Pharma A/S
Reception date time	21.10.2011
Client sample code	9426-8701
Packaging	plastic container
Reception temperature	room temperature
Storage conditions	room temperature
Start analysis	21.10.2011
End analysis	01.11.2011

Test results

FGL15	Ethanol		
Method	EP 7.2, on the basis of method 2.4.24		
Ethanol		0.9	%

JUDGEMENT

With regard to the analysed parameters the tested sample material meets the respective requirements of the customer.

"Analysis required by Eurofins Pharma A/S"

The results of examination refer exclusively to the checked samples.
Duplicates - even in parts - must be submitted by the test laboratory to archive form.
Eurofins Fintelmann und Meyer GMP GmbH | Großmoorbogen 25 | D-21079 Hamburg
Business Unit Manager: Dr. Heide Hoyer-Horst | Dr. Jutta-Bär Baranek | Please if performance shall be Hamburg,
Germany. Place of jurisdiction shall be Hamburg, Germany.
Our General Terms & Conditions of Sales are applicable.
VAT No.: DE 399767948
Nondiscriminatory Lendingbank Hannover - Kfz. Nr. 121 394 626 - IBZ 2 769 300 09 | BIK: 250205050000110356125
BIC: NOLADE33XXX
Our General Terms & Conditions of Sales are applicable.

Signature



Dr. H. Neumann-Hensel / B. Kohnke / K. Oelkers / Dr. T. Rathjen
(General manager) (Department management)

 eurofins
Eurofins Pharma AG
Strandsepland 100
29655 Valentinshafen
Tel. 70 22 45 80

2011.11.02

The results of observation or for suitability for the checked samples.
Duplications - even in parts - must be achieved by the test laboratory in written form.
Eurofins Fintelmann und Meyer GMP GmbH - Ombudsmann 25 - D-31078 Harburg
Business Unit Manager: Dr. Heide Kuhnert-Hensel / Dr. Andrea Treichel-Hensel. Place of performance shall be Harburg,
Germany. Place of jurisdiction shall be Harburg, Germany.
Our General Terms & Conditions of Sales are applicable.
VAT No.: DE 259792648
Wirtschaftskammer Hannover - Vst. Nr.: 151 354 425 - St. Z 290 500 33 - IAN: DE992569033161335825
BIC: NOLAE233000
Our General Terms & Conditions of Sales are applicable.

2011. 11.02 / *SN*

Certificate of analysis

Doc. no.

ANJE.003

Internal spec. no.

SP.EX-003E

Product:

Batch no.: 15 21077.....

Eleutherococcus sent. extr. siccum

Batch no., previous extract: 1421061.....

Batch no., drug: 1010237.....

Parameter of analysis	Method	Reference	Result
Appearance	Occular	= ref	= ref
Loss on drying	Ph Eur Curr Ed	< 5%	1,0%
pH in 5% H ₂ O-solution	Ph Eur Curr Ed	4,5 - 6	5,03
Identity (TLC)	SM-018	= ref	= ref
Identity of markers	SM-094	=standards	= ref
HPLC			
Eleutherosid B + E in native	SM-073	1,2-2,9%	1,78%
Eleutherosid B + E in total extr.			0,89%
Potassium sorbate	SM-046	0,05-0,25%	0,10%
Mettylparahydroxybensoat	SM-046	0,05-0,25%	0,09%
		Reference	Result
Ratio			9:1
Nativ ratio		17 - 30:1	17:1
		Reference	Result
Microbiology	PhEur Curr Ed	Ph. Eur. Cat 3B	Conform
Ethanol	PhEur Curr Ed	<1% ^{1005.02/4}	<1%

Date of analysis: 11.02.16.....

Date of release: 2011-03-08.....

Analyst signature: [Signature].....

QP-responsible: [Signature].....

Comments:	Manufacturing date <u>2011.02.17</u>
	Expiry date (two years) <u>2013-03</u>

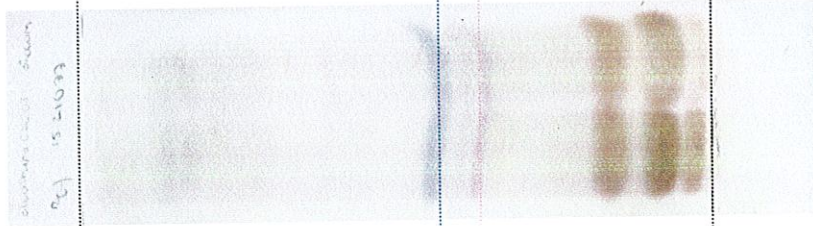
Checked by: (QC)	Eva Vencel <u>[Signature]</u>	Date: <u>08.10.21</u> ...	Issue no: 11
Authorised by (QA):	Charlotte Nilsson <u>[Signature]</u>	Date: <u>08.10.21</u> ...	Supersedes no: 10
Authorised by (QP):	Dan Magnusson <u>[Signature]</u>	Date: <u>08.10.21</u>	

Eleutherococcus siccum TLC 15 21077

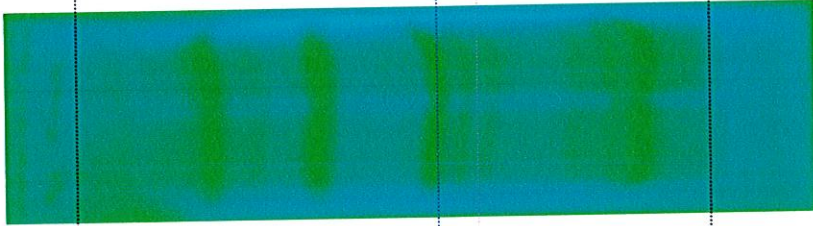
Metod: SM-018

VIS

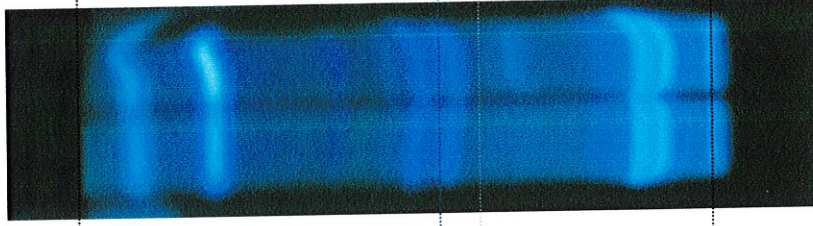
Ref 888
Test 077



254nm



366nm



Front

Start

Eleuth B Rf: 0,44
Eleuth E Rf: 0,36

Absorbent: Silica gel 60 F₂₅₄ precoated TLC plates
Solvent system: chloroform : methanol : water (70 : 40 : 10)
Spray reagents: vanillin-phosphoric acid

Sign: *Mattias*

Date: 2011-02-21



SampleName Eleuth 1521077

Current Date 2011-02-18
 Software Empower 2 Software Build 2154
 Column no.: 812269
 Run Time 45.00 Minutes
 Channel 254 nm, 262 nm

Processing Method Konsmedel_extr

Potassiumsorbate Methyl-4-hydroxybenzoate

Start Date 2011-02-17 13:17:40 CET

Component Results Name: Potassiumsorbate

	SampleName	RT	Injection Volume (uL)	SampleWeight	Area	Height	Name	Percent_amount
1	Eleuth 1521077	28.640	10.00	380.50000	3492182	60841	Potassiumsorbate	0.097
2	Eleuth 1521077	28.673	10.00	380.50000	3511265	61224	Potassiumsorbate	0.097
3	Eleuth 1521077	28.713	10.00	380.50000	3511119	60950	Potassiumsorbate	0.097
Mean					3504855			0.097
Std. Dev.					10975			0.000
% RSD					0.3			0.29

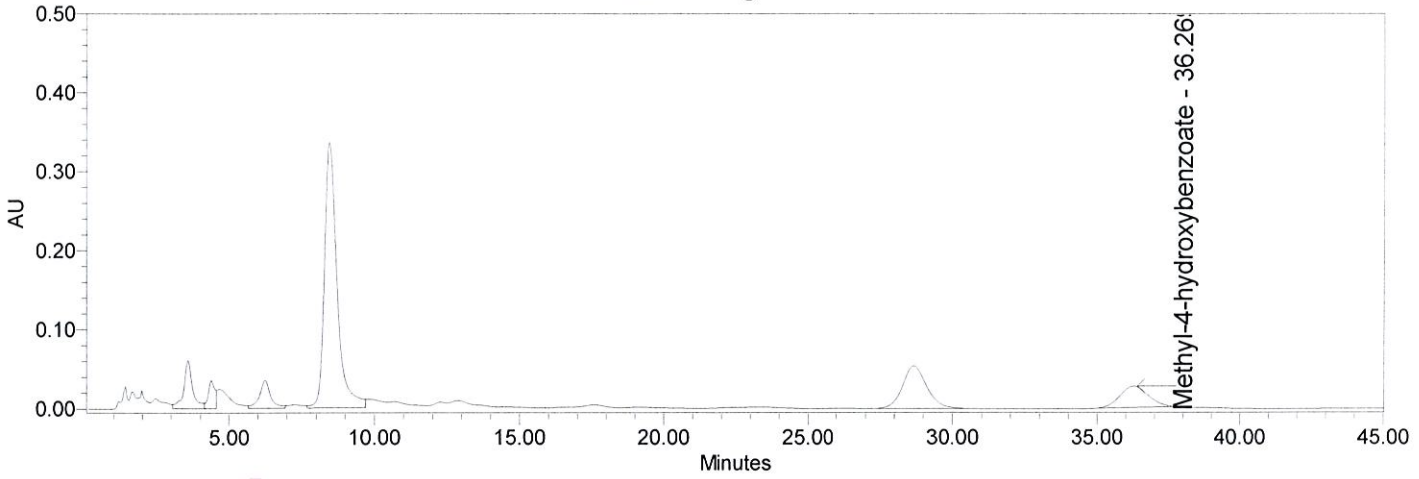
Component Results Name: Methyl-4-hydroxybenzoate

	SampleName	RT	Injection Volume (uL)	SampleWeight	Area	Height	Name	Percent_amount
1	Eleuth 1521077	36.214	10.00	380.50000	1935028	27296	Methyl-4-hydroxybenzoate	0.095
2	Eleuth 1521077	36.269	10.00	380.50000	1849160	26945	Methyl-4-hydroxybenzoate	0.091
3	Eleuth 1521077	36.338	10.00	380.50000	1907624	27212	Methyl-4-hydroxybenzoate	0.094
Mean					1897271			0.093
Std. Dev.					43860			0.002
% RSD					2.3			2.18

<u>Results</u>	<u>%</u>	<u>Theoretical</u>	<u>Yield</u>
<u>Potassiumsorbate:</u>	0,097%	0,165%	59%
<u>Methyl-4-hydroxybenzoate:</u>	0,093%	0,169%	55%

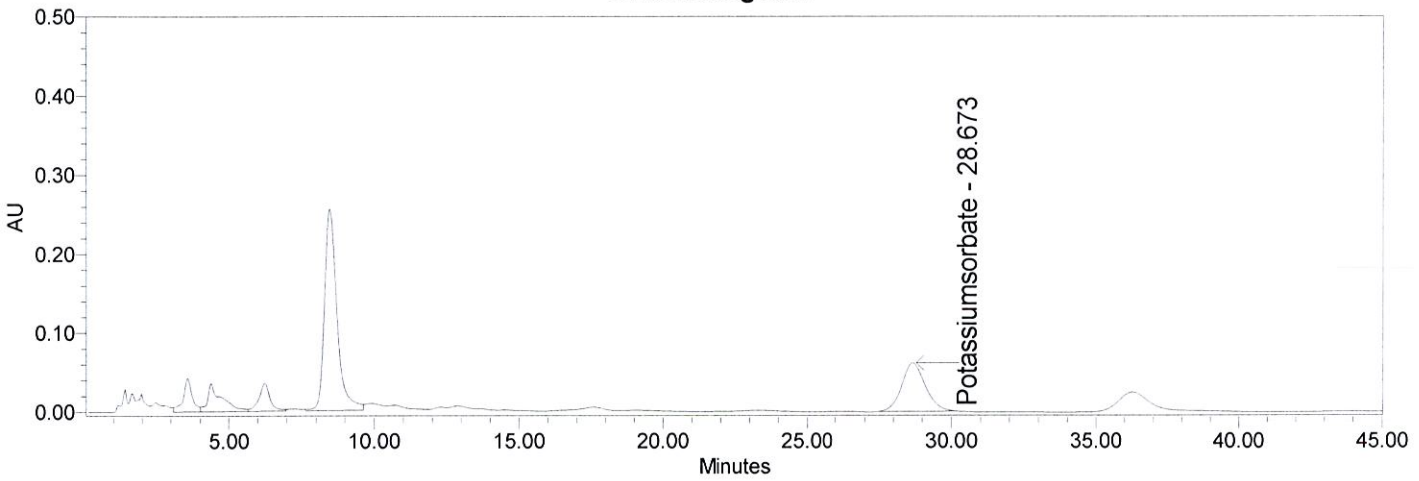
Sign.: Ms

Chromatogram



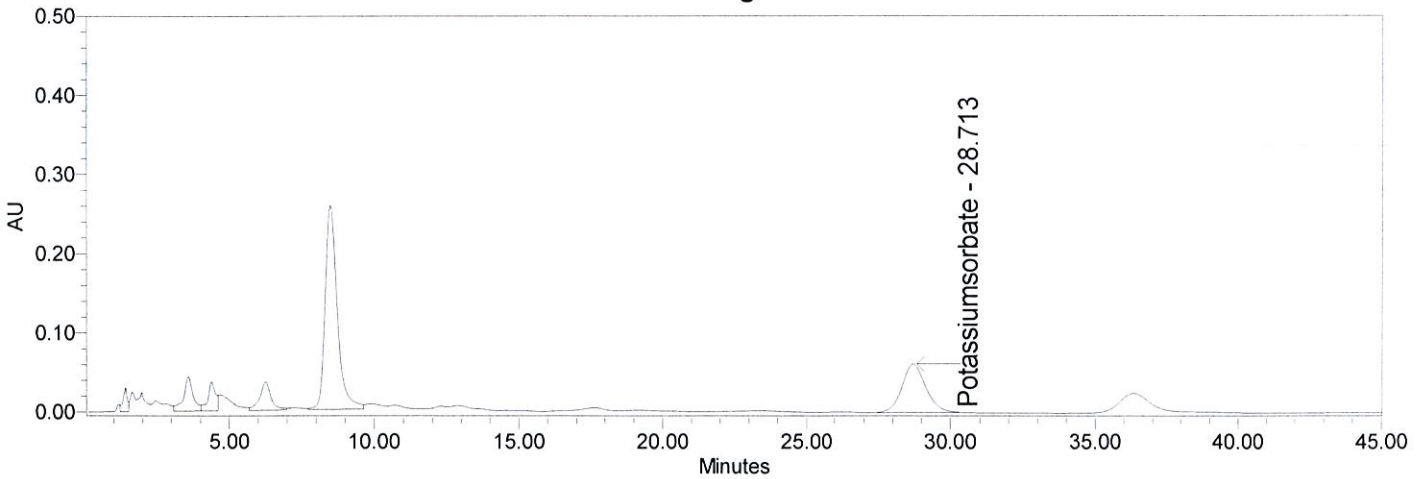
SampleName Eleuth 1521077; Vial 4; Date Acquired 2011-02-17 20:55:16 CET; Channel Name 254 nm

Chromatogram



SampleName Eleuth 1521077; Vial 4; Date Acquired 2011-02-17 20:55:16 CET; Channel Name 262 nm

Chromatogram



SampleName Eleuth 1521077; Vial 4; Date Acquired 2011-02-17 21:41:19 CET; Channel Name 262 nm

Sign.: Ma



SampleName Eleuth 1521077

Rapport_extrakt

Software Empower 2 Software Build 215
 Column no.: 937031
 Run Time 35.00 Minutes
 Channel PDA_210.0nm, PDA_220.0nm
 System Name HPLC

Current Date 2011-02-17
 Processing Method Acax_validerad
 Start Date 2011-02-16 13:34:43

Eleutherosid B
Eleutherosid E

Name: Eleutherosid B

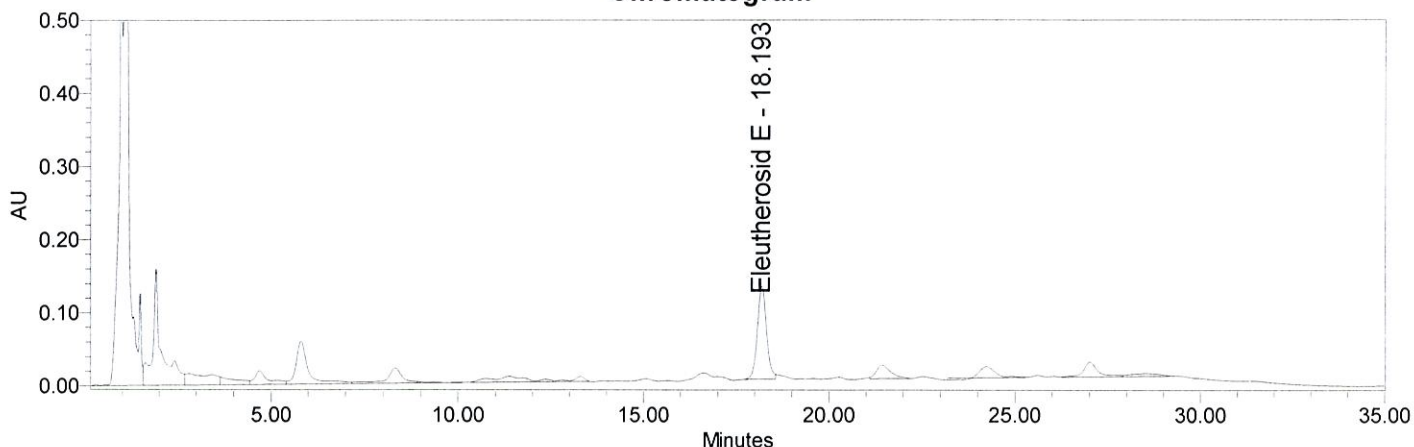
	SampleName	Injection Volume (ul)	SampleWeight	Dilution	RT	Area	Height	Name	Procent_Amount
1	Eleuth 1521077	20.00	83.20000	1.00000	5.746	1485129	84983	Eleutherosid B	0.384
2	Eleuth 1521077	20.00	83.20000	1.00000	5.797	1522082	84010	Eleutherosid B	0.394
3	Eleuth 1521077	20.00	83.20000	1.00000	5.808	1487197	84077	Eleutherosid B	0.384
Mean									0.387
Std. Dev.									0.006
% RSD									1.44

Name: Eleutherosid E

	SampleName	Injection Volume (ul)	SampleWeight	Dilution	RT	Area	Height	Name	Procent_Amount
1	Eleuth 1521077	20.00	83.20000	1.00000	18.193	2174703	127252	Eleutherosid E	0.507
2	Eleuth 1521077	20.00	83.20000	1.00000	18.215	2165848	129793	Eleutherosid E	0.504
3	Eleuth 1521077	20.00	83.20000	1.00000	18.236	2160819	131999	Eleutherosid E	0.503
Mean									0.505
Std. Dev.									0.002
% RSD									0.36

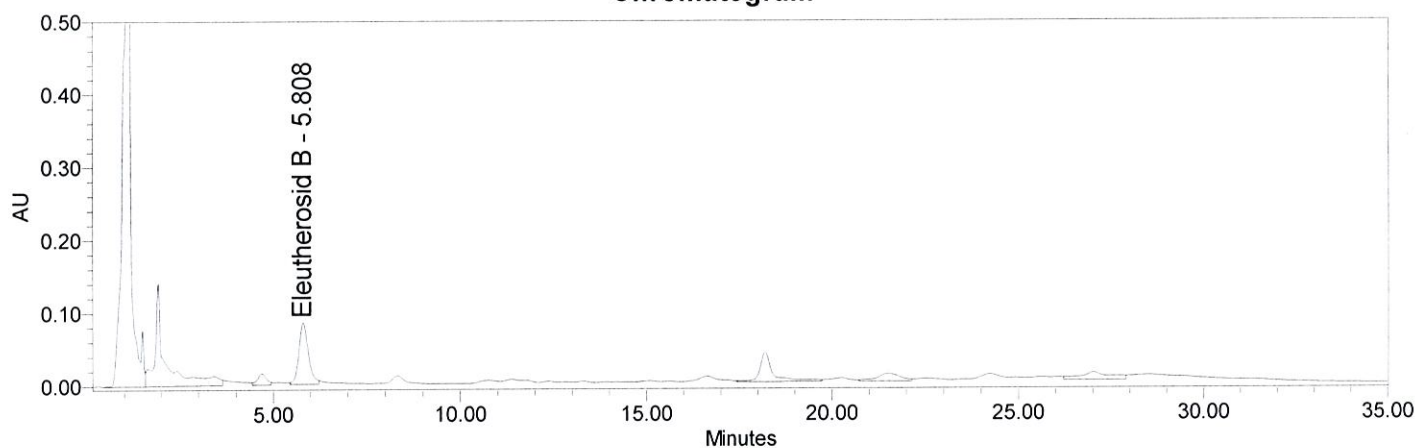
Results	%	Theoretical	Yield
Eleutherosid B:	0,39%	0,38	
Eleutherosid E:	0,50%	0,46	
Eleutherosides:	0,89%	0,84	106%

Chromatogram

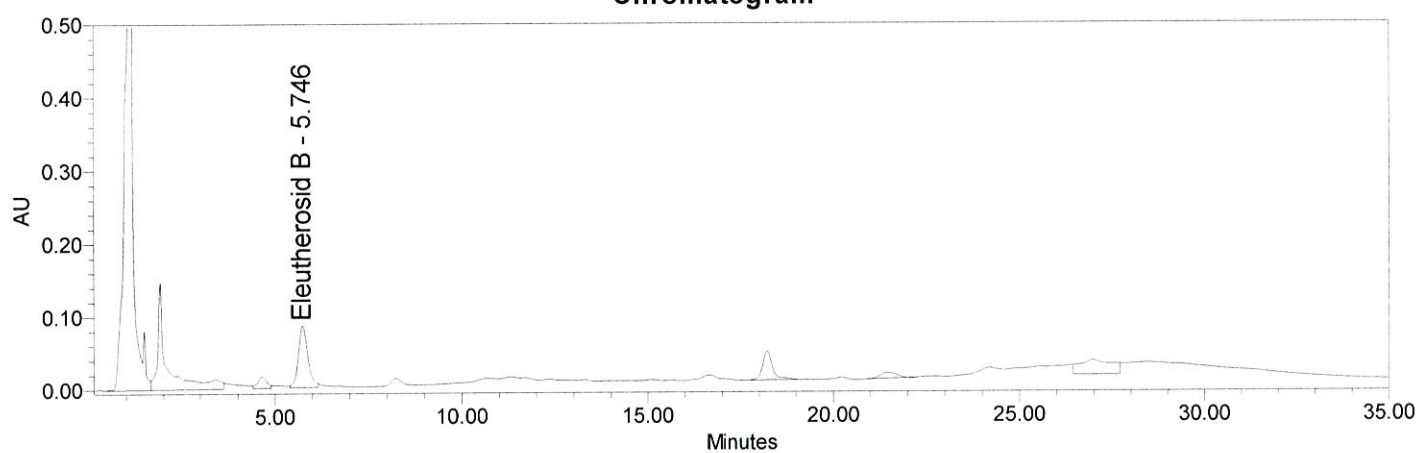


SampleName Eleuth 1521077; Vial 4; Date Acquired 2011-02-16 20:30:21 CET; Channel Name PDA_210.0nm

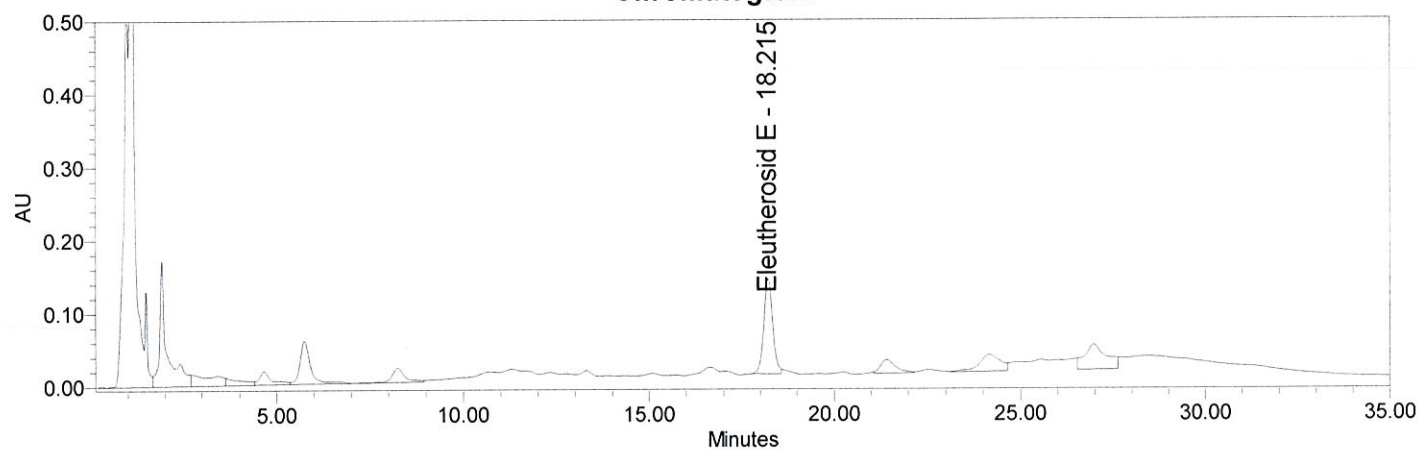
Sign.:

Chromatogram

SampleName Eleuth 1521077; Vial 4; Date Acquired 2011-02-16 20:30:21 CET; Channel Name PDA_220.0nm

Chromatogram

SampleName Eleuth 1521077; Vial 4; Date Acquired 2011-02-16 21:16:16 CET; Channel Name PDA_220.0nm

Chromatogram

SampleName Eleuth 1521077; Vial 4; Date Acquired 2011-02-16 21:16:16 CET; Channel Name PDA_210.0nm

Sign.: 



Second identification with PDA

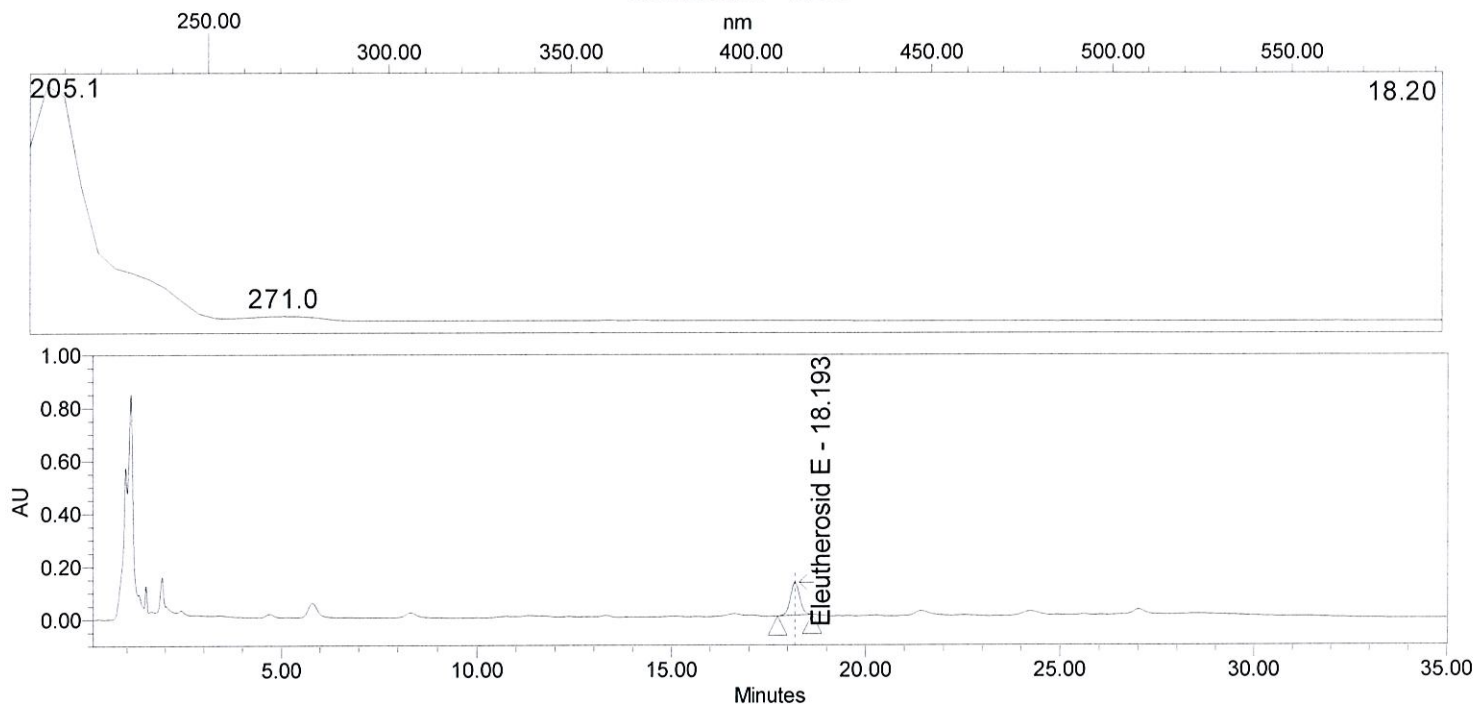
Current Date 2011-02-17
 Software Empower 2 Software Build 2
 Column no.: 937031
 System Name HPLC

Processing Method Acanth_PDA
 Run Time 35.00 Minutes
 Start Date 2011-02-16 13:34:43 CET

**Eleutherosid B,
 Eleutherosid E
 SampleName Eleuth 1521077**

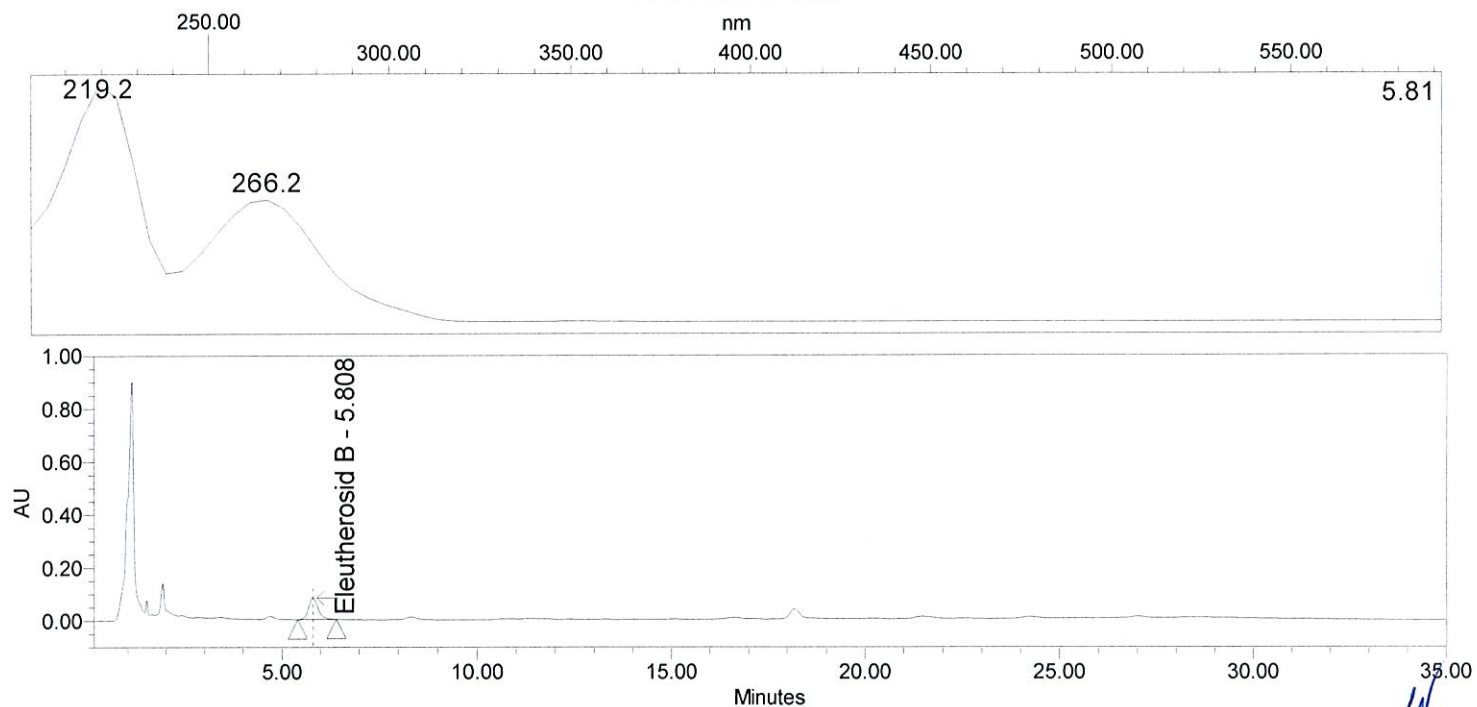
Spectrum Index Plot

Eleutherosid E - 18.193



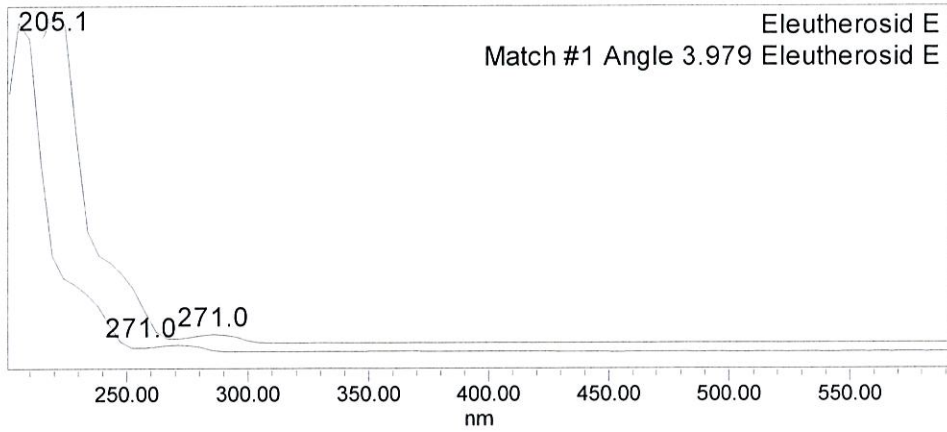
Spectrum Index Plot

Eleutherosid B - 5.808



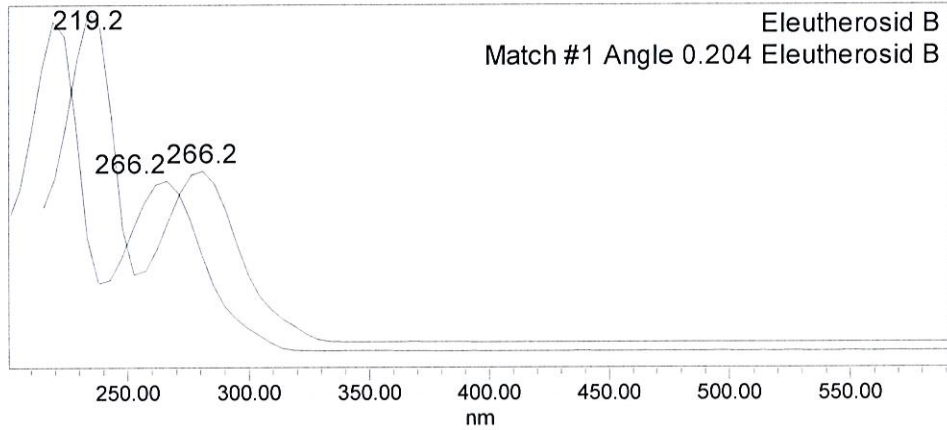
Sign.: 

Match Plot



SampleName Eleuth 1521077 Vial 4 Injection 1 Date Acquired 2011-02-16
 20:30:21 CET Name Eleutherosid E Match1 Angle 3.979 Match1 Threshold 1.204
 Match1 Spect. Name Eleutherosid E

Match Plot



SampleName Eleuth 1521077 Vial 4 Injection 1 Date Acquired 2011-02-16
 20:30:21 CET Name Eleutherosid B Match1 Angle 0.204 Match1 Threshold 1.120
 Match1 Spect. Name Eleutherosid B

PDA Result Table

	Name	RT	Purity1 Angle	Purity1 Threshold	Match1 Spect. Name	Match1 Angle	Match1 Threshold
1	Eleutherosid B	5.808	0.301	1.236	Eleutherosid B	0.204	1.120
2	Eleutherosid E	18.193	1.293	1.382	Eleutherosid E	3.979	1.204

Sign.: 

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312 50 Vallberga
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Germany
Contact at PhytoLab:
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Tel: +49 9163 88-188
Fax: +49 9163 88-379
annette.reichel@phytolab.de

Date: 7.03.11

Cust.No: 91778



Certificate of analysis

Report-No.: 12461844- 40 001
Cust.-lot: 1521077
Sample labelling: Eleutherococcus sicc. extr
Sample description: brown powder
Packing: PE-container with screw closure
Receipt of sample: 24.02.11

Test	Unit	Limits	Testresult
Microbiology: Category B, Herbal medicinal products containing, for example, extracts and/ or herbal drugs, with or without excipients, where the method of processing (for example, extraction) or, where appropriate, in the case of herbal drugs, of pre-treatment reduces the levels of organisms to below those stated for this category, according to Ph. Eur. 6.7, 5.1.8, SOP 803911:			Conform
Total aerobic microbial count (TAMC), SOP 300007	CFU/g	< = 50,000	180
Moulds, SOP 300014	CFU/g		< 10
Yeasts, SOP 300023	CFU/g		30
Total combined yeasts and moulds count (TYMC), SOP 300033	CFU/g	< = 500	30
Bile-tolerant gram-negative bacteria (semiquantitative, PN method), SOP 300044	CFU/g	< = 100	< 10
Escherichia coli (absence test), SOP 300058	/g	Absent	Absent
Salmonella (qualitative), SOP 300122	/25 g	Absent	Absent

Information on the method employed and on method characteristics is available to customers on request. The results apply to the supplied sample. Copying of the document is only permissible without any modification of the document.

Vestenbergsgreuth, 7.03.11



Elke Lenzer

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Elke Lenzer

2011.03.07
W

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Denmark

Tel. +45 70 22 42 66
Fax +45 70 22 42 55
eurofins@eurofins.dk
www.eurofins.dk

Date
01 March 2011
Our ref.
940848/SLH

Analytical report

Sample received	Test sample
23 February 2011	Eleutherococcus extract siccum

Customer's journal no/ project title:

-

Label(s): Batch no. 1521077

Information from client: -


Methods: Specific references are listed with the test results.

Reference: -

Results: Results are reported on page 2-3.

Comments: Samples are analysed by the laboratory:
Dr. Fintelmann und Dr. Meyer, GMBH, Germany

Signatures


Sandy Leth
MSc (Pharm)

Eurofins Fintelmann und Meyer GMP GmbH · Großmoorbogen 25 · D-21079 Hamburg

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www.fintelmann-meyer.de

Report date 28.02.2011

Page 1/2

Analytical report AR-11-FG-001467-01



Sample Code 714-2011-00002782

Reference	Eleutherococcus extrakt siccum Batch nr:15 21077 16.02.2011
Sample sender	Mrs. Eva Vencel
Prescriber	Eurofins Pharma A/S
Reception date time	24.02.2011
Client sample code	Our reference number:9408-4801
Packaging	plastic container
Reception temperature	room temperature
Storage conditions	room temperature
Start analysis	24.02.2011
End analysis	28.02.2011

Test results

FGL15	Ethanol		
Method	EP 7.0, on the basis of method 2.4.24		
Ethanol		<1	%

JUDGEMENT

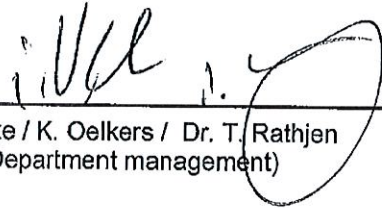
With regard to the analysed parameters the tested sample material meets the respective requirements of the customer.

"Analysis required by Eurofins Pharma A/S"

Fintelmann und Meyer GMP GmbH

Analytical report AR-11-FG-001467-01
Sample Code 714-2011-00002782


Signature



Dr. H. Neumann-Hensel / B. Kohnke / K. Oelkers / Dr. T. Rathjen
(General manager) (Department management)



2011.04.07
ly

01. Mar. 2011




Fintelmann und Meyer GMP GmbH

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Großmoorbogen 25
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GERMANY

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Report date 28.02.2011

Page 1/2

Analytical report AR-11-FG-001467-01



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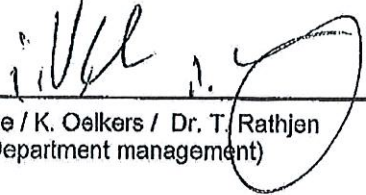
"Analysis required by Eurofins Pharma A/S"

2011.03.01

M

Fintelmann und Meyer GMP GmbHAnalytical report AR-11-FG-001467-01
Sample Code 714-2011-00002782

Signature



Dr. H. Neumann-Hensel / B. Kohnke / K. Oelkers / Dr. T. Rathjen
(General manager) (Department management)

 eurofins
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Tlf. 70 22 42 96

01. Mar. 2011

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Date
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Our ref.
940848/SLH

Analytical report

Sample received	Test sample
23 February 2011	Eleutherococcus extract siccum

Customer's journal no/ project title:

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Label(s): Batch no. 1521077

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Reference: -

Results: Results are reported on page 2-3.

Comments: Samples are analysed by the laboratory:
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