

# Certificate of analysis

Internal spec. no: SP.FV-

**Product:** Kan Jang Andrographis capsules

**Batch no:** 3400195

Batch no. bulk: .....

Extr. Andrographis: .....

Pack. type: .....

Extr. Eleutherococcus: .....

Country: .....

Parameter of analysis on packed	Method	Reference	Result	
			Start	End
Appearance	Ocular	Transparent capsule with green/beige filling	Ej transparent vit kapsel	
Loss on drying	Ph. Eur. Curr. Ed. 2.8.17	$\leq 7\%$	4%	
Diameter	Caliper	7.6 mm $\pm$ 0.2 mm	7,5 mm	
Length	Caliper	21.7 mm $\pm$ 0.3 mm	21,4 mm	
Uniformity of mass	Ph. Eur. Curr. Ed. 2.9.5	Average = 555 mg $\pm$ 7.5%	525 mg	
Uniformity of mass deviations	Ph. Eur. Curr. Ed. 2.9.5	$n \leq 2$ deviates 7.5-15%	2st	
		$n = 0$ deviates $>15\%$		
Disintegration	Ph. Eur. Curr. Ed. 2.9.1	$\leq 30$ min	45 min	
<b>External</b>				
Microbial contamination	Ph. Eur. Curr. Ed. 5.1.8	Ph. Eur. Cat B		

Parameter of analysis on bulk	Method	Reference	Result
Identity	SM-010	= ref	= Ref
Assay: UPLC - Andrographolide	SM-125	-	13,8 mg/capsule
UPLC - 14-Deoxy-11,12-didehydroandr.	SM-125	-	1,8 mg/capsule
$\Sigma$ Andrographolides	SM-125	12 - 18 mg/capsule	16 mg/capsule
UPLC - Neoandrographolide	SM-125	n.a.	3,9 mg/capsule
Assay: HPLC - Eleutheroside B	SM-066	-	0,12 mg/capsule
HPLC - Eleutheroside E	SM-066	-	0,13 mg/capsule
$\Sigma$ Eleutheroside B and E	SM-066	0.15-0.51 mg/capsule	0,25 mg/capsule
<b>Amount of native extract</b>			
Eleutherococcus	SM-136	37.5 mg/capsule $\pm 10\%$	
Andrographis	SM-136	375 mg/capsule $\pm 10\%$	
<b>External</b>			
Pyrrolizidine alkaloids	SOP 805521 Phytolab	$\leq 0.25 \mu\text{g/capsule}^*$	

\*With daily dose of 4 capsules

**Date of analysis:** .....

**Date of release:** .....

**Analyst, sign:** ...../.....

**QP-responsible:** .....

**Comments:**

**Manufacturing date:**

**Expiry date (three years):**

# Kan Jang Capsule

## HPTLC

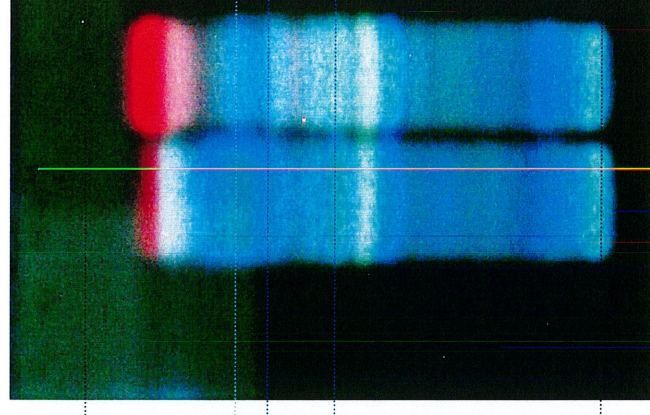
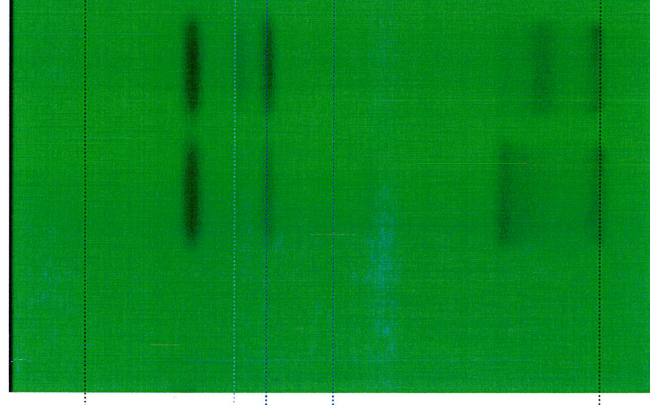
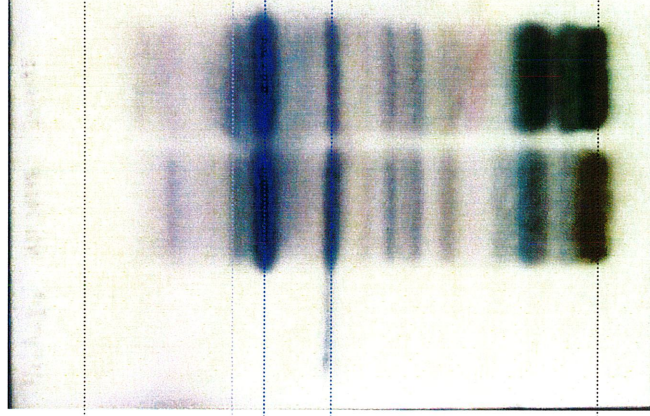
### 3400195

Method: SM-010

VIS

Ref Test Ref  
Neo-Andr 3400195 30280

254nm



Front

Start

Absorbent: Silica gel 60 F<sub>254</sub> precoated HPTLC plates  
Solvent system: Ethylacetate : methanol : water (38 : 7 : 4)  
Spray reagents: vanillin-sulphuric acid solution

Sign: 

Date: 2021-05-06



**Mikrolab Stockholm AB****Rapport**

Utfärdat av ackrediterat laboratorium

**Svenska Örtmedicinska Ins AB**

Susanna Panosyan  
Kövlingevägen 21  
312 50 Vallberga

Datum  
2021-04-28

Kundnummer      Provnummer  
20031              **K2102825-00**

**PROVUPPGIFTER**

Produkt: Kanjang  
Artikelnummer: N/A  
Batchnummer: 3400195  
Undersökningstyp: Totalantal odling/fasta produkter  
Ankomstdatum: 2021-04-23  
Testdatum: 2021-04-23  
Testad mängd: 45g  
Analyskrav enligt: Se metod  
Provtagare: Håkan Lejon

Capsule.

ANALYSRESULTAT	Metod	Resultat	Enhet
Aeroba bakterier	M0002	<10	CFU/g
Mögelsvampar	M0002	<10	CFU/g
Jästsvampar	M0002	<10	CFU/g
Escherichia coli	M0017	Ej påvisad	/1g
G-neg. bakterier	M0016	<10	CFU/g
Salmonella species	M0018	Ej påvisad	/25 g

**UTLÅTANDE OCH UPPLYSNINGAR**

TAMC: <10 CFU/g  
TYMC: <10 CFU/g  
Analys enligt gällande EP 2.6.12/2.6.13 och USP <61>/<62>

Sollentuna  
Datum: 2021-04-28

Susanna Nilsson  
Analysansvarig

\* Efter metodbeteckning, anger att metoden ej är ackrediterad.

  
Linda Storbjörk  
Laboratorieansvarig

Resultaten avser endast testade produkter.

Upplysningar om mätosäkerhet för kvantitativa mikrobiologiska analyser lämnas på begäran.

Adress:  
Mikrolab Stockholm AB  
Kung Hans Väg 3  
192 68 Sollentuna

Telefon  
08-297900  
E-post: sollentuna.lab@alsglobal.com

Styrelsens säte:  
Sollentuna  
Organisationsnummer  
556794-2171

**SampleName Kan Jang Andro****Rapport tablett**

Current Date 2021-05-06  
 Processing Method  
 Start Date 2021-05-05 16:13:06  
 System Name H\_CLASS  
 Run Time 35.00 Minutes

**Eleutherosid B**  
**Eleutherosid E**

Batch\_No 3400195

Software Empower 3 Software Build 3471  
 Channel PDA\_210.0nm, PDA\_220.0nm  
 Tablet\_Weight  
 Column no.: 427571

**Name: Eleutherosid B**

	SampleName	Batch_No	Injection Volume (ul)	SampleWeight	RT	Area	Height	Name	Procent_Amount
1	Kan Jang Andro	3400195	10.00	30.18800	5.368	397829	32101	Eleutherosid B	0.0223
2	Kan Jang Andro	3400195	10.00	30.18800	5.485	374764	27891	Eleutherosid B	0.0210
3	Kan Jang Andro	3400195	10.00	30.18800	5.499	412101	32830	Eleutherosid B	0.0231
Mean					5.450				0.0221
Std. Dev.					0.07				0.0010
% RSD					1.3				4.75

**Name: Eleutherosid E**

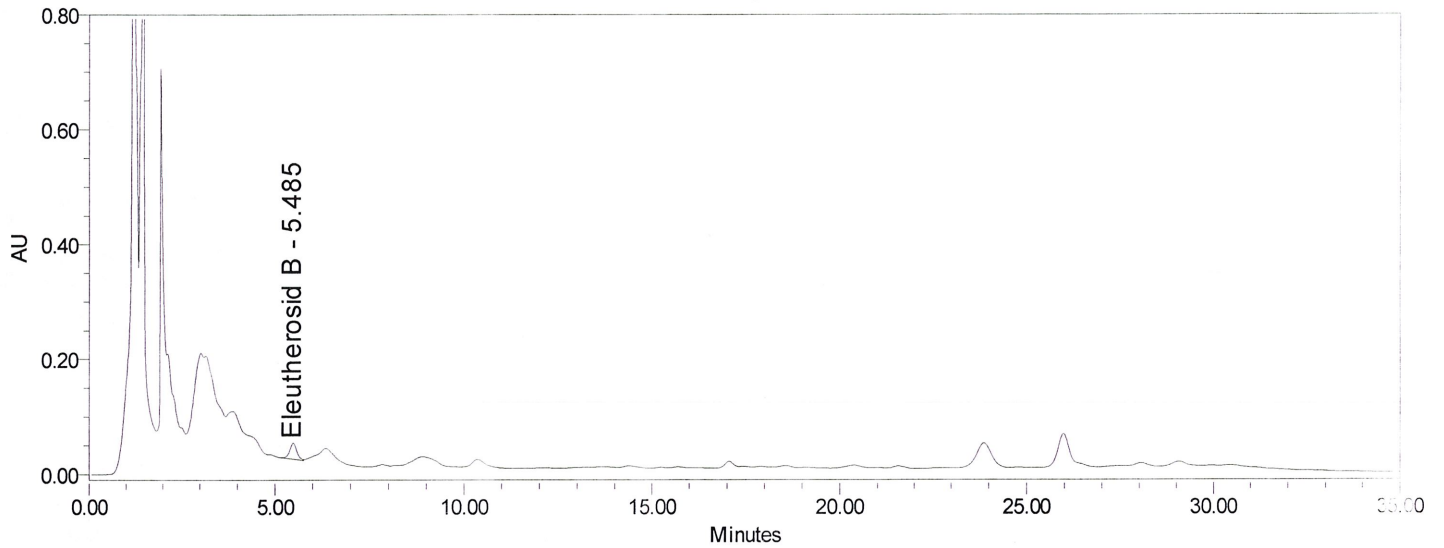
	SampleName	Batch_No	Injection Volume (ul)	SampleWeight	RT	Area	Height	Name	Procent_Amount
1	Kan Jang Andro	3400195	10.00	30.18800	16.980	572241	39768	Eleutherosid E	0.0242
2	Kan Jang Andro	3400195	10.00	30.18800	17.016	574688	40088	Eleutherosid E	0.0243
3	Kan Jang Andro	3400195	10.00	30.18800	17.053	570466	39164	Eleutherosid E	0.0241
Mean					17.016				0.0242
Std. Dev.					0.04				0.0001
% RSD					0.2				0.37

<u>Results</u>	<u>mg/tablet</u>	<u>calculated</u>	<u>% found</u>
<u>Eleutherosid B:</u>	0,12 mg/capsule		
<u>Eleutherosid E:</u>	0,13 mg/capsule		
<u>Eleutherosides:</u>	0,25 mg/capsule		

Sig.: 

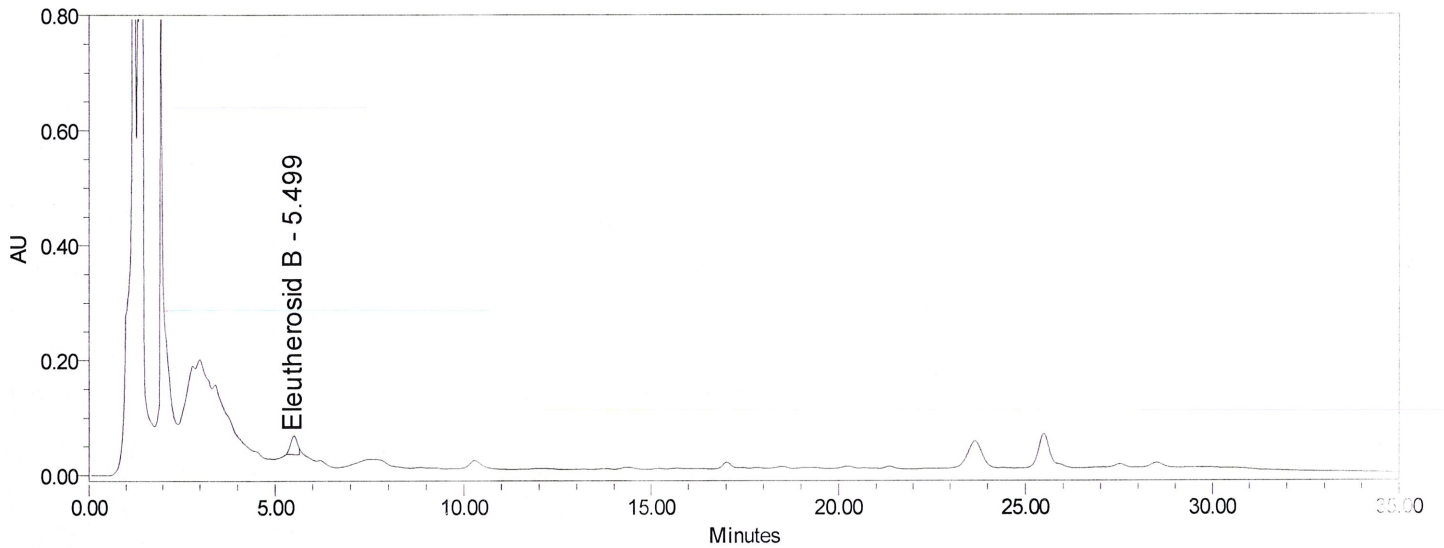


## Chromatogram




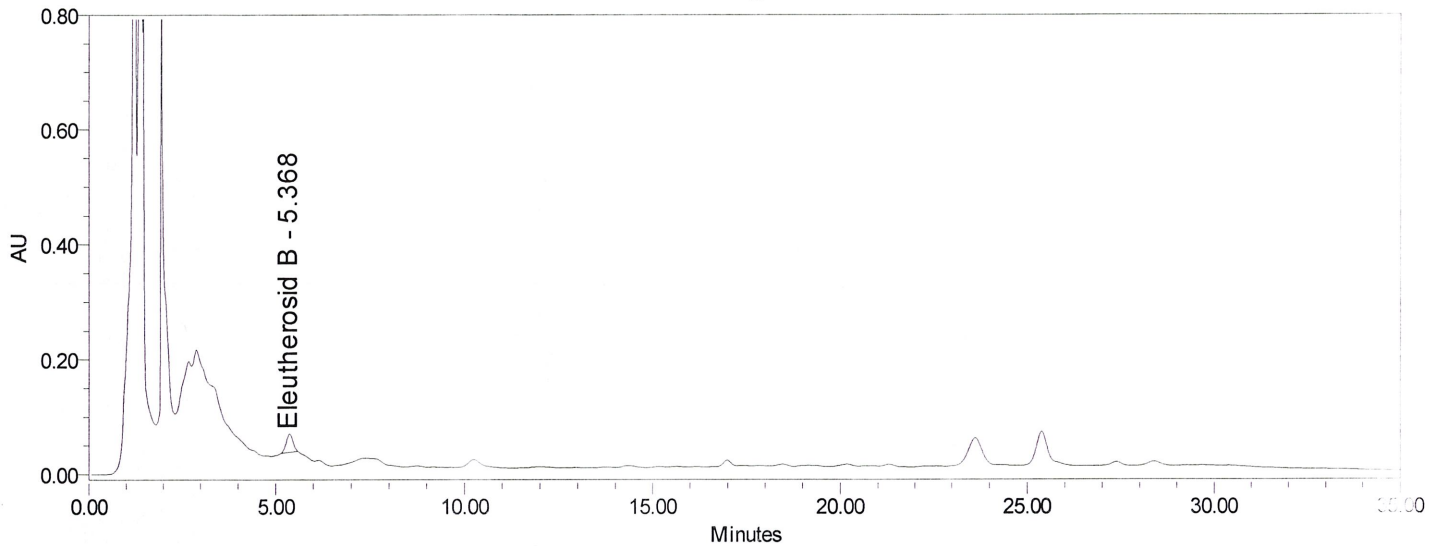
SampleName Kan Jang Andro; Batch\_No 3400195; Vial 1:A,3; Date Acquired 2021-05-05 22:51:35  
CEST; Channel Name PDA\_220.0nm

## Chromatogram

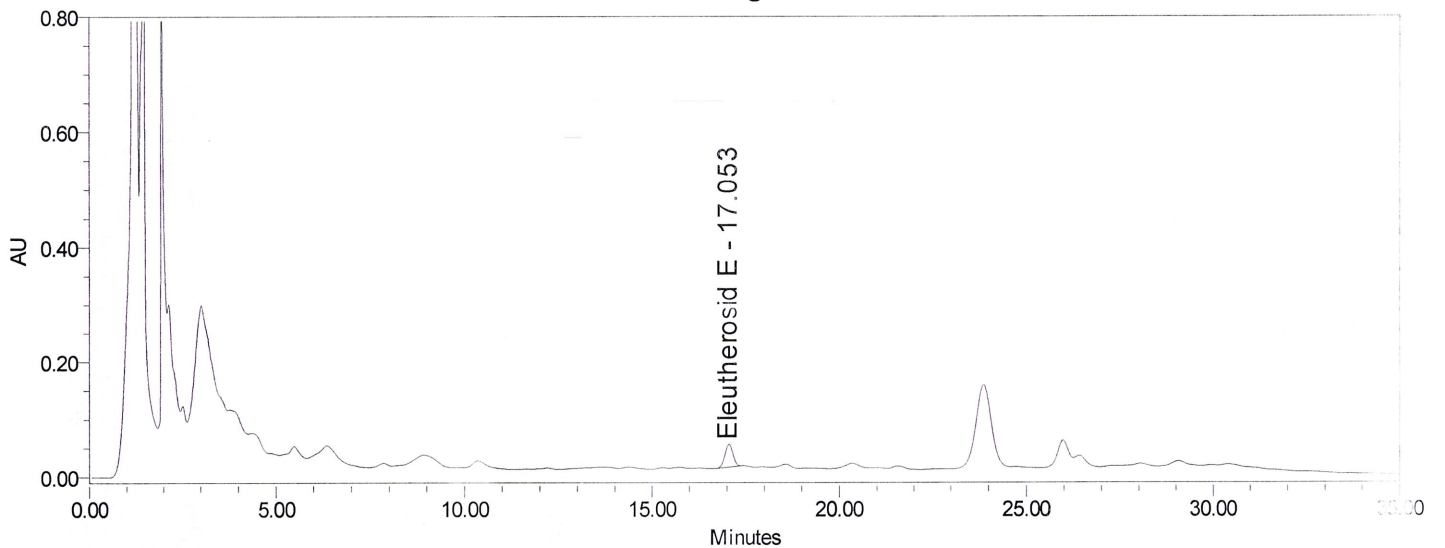


SampleName Kan Jang Andro; Batch\_No 3400195; Vial 1:A,3; Date Acquired 2021-05-05 23:52:43  
CEST; Channel Name PDA\_220.0nm

Sig.: 

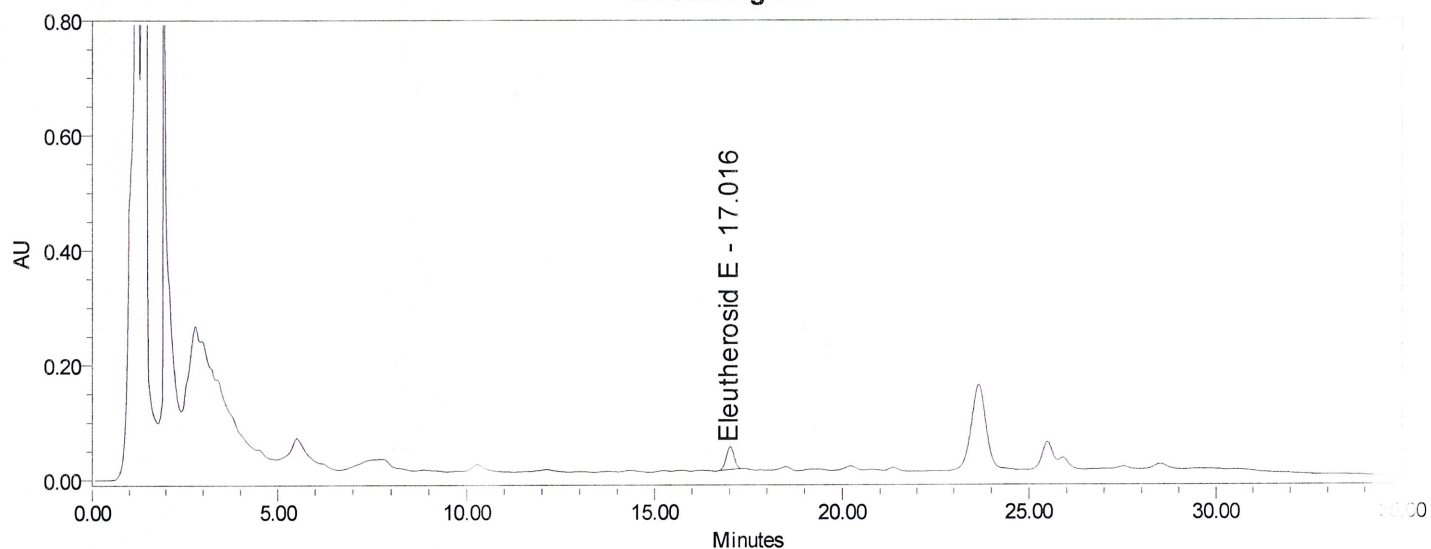
**Chromatogram**

SampleName Kan Jang Andro; Batch\_No 3400195; Vial 1:A,3; Date Acquired 2021-05-06 00:53:53  
CEST; Channel Name PDA\_220.0nm

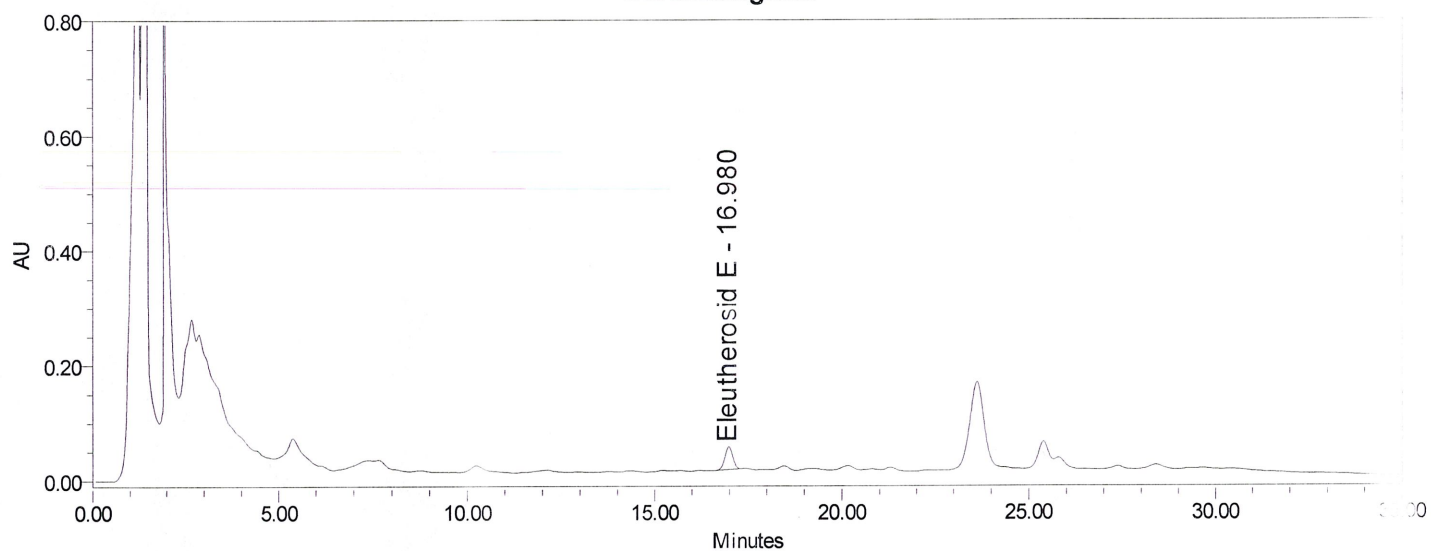
**Chromatogram**

SampleName Kan Jang Andro; Batch\_No 3400195; Vial 1:A,3; Date Acquired 2021-05-05 22:51:35  
CEST; Channel Name PDA\_210.0nm


Sig.: 

**Chromatogram**

SampleName Kan Jang Andro; Batch\_No 3400195; Vial 1:A,3; Date Acquired 2021-05-05 23:52:43  
CEST; Channel Name PDA\_210.0nm

**Chromatogram**

SampleName Kan Jang Andro; Batch\_No 3400195; Vial 1:A,3; Date Acquired 2021-05-06 00:53:53  
CEST; Channel Name PDA\_210.0nm

Sig.: 



**Second identification with PDA**

Current Date 2021-05-06

Software Empower 3 Software Build 3

System Name H\_CLASS

Processing Method Eleuth\_PDA

Run Time 35.00 Minutes

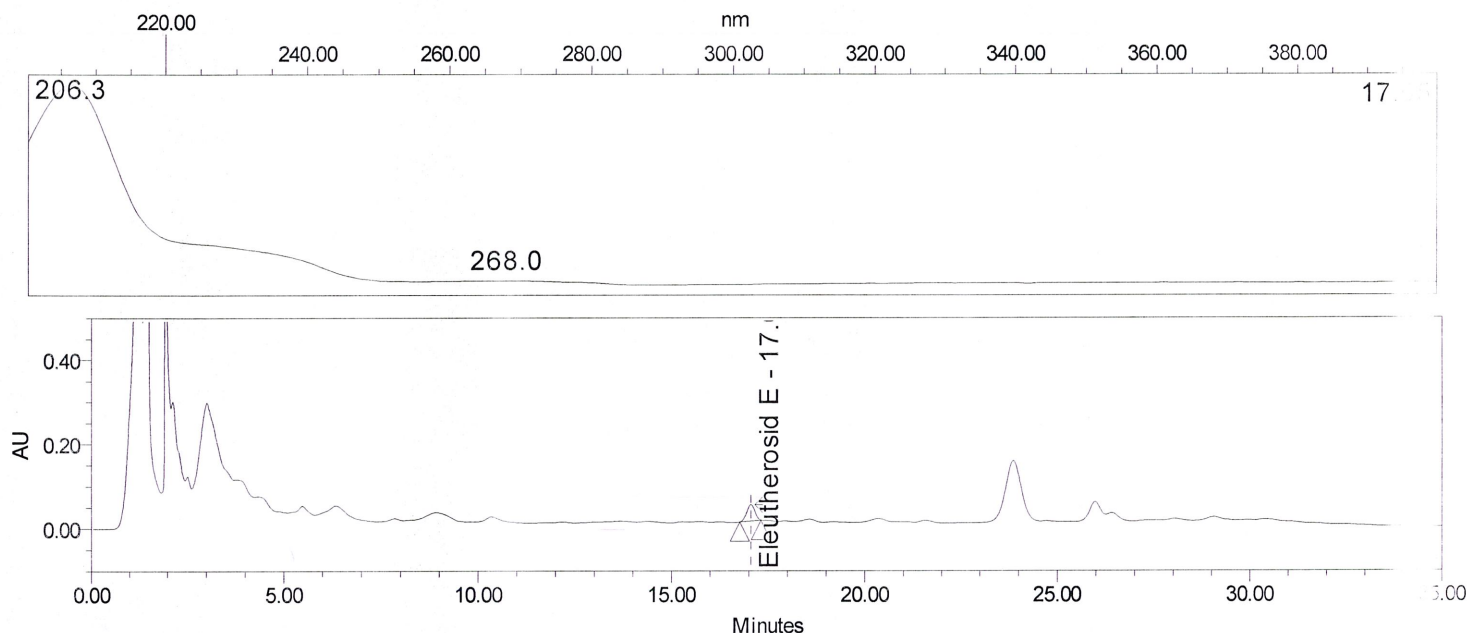
Start Date 2021-05-05 16:13:06

**Eleutherosid B,  
Eleutherosid E****SampleName Kan Jang Andro**

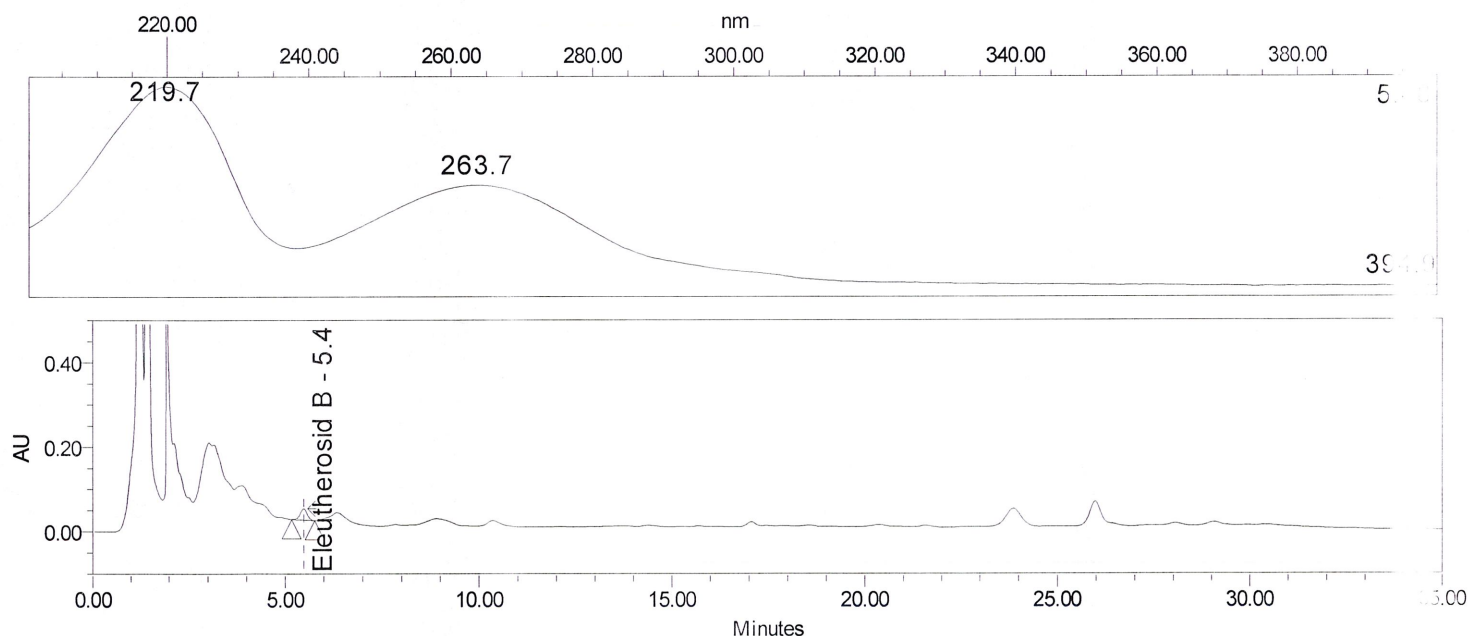
Batch\_No 3400195

**Spectrum Index Plot**

Eleutherosid E - 17.053

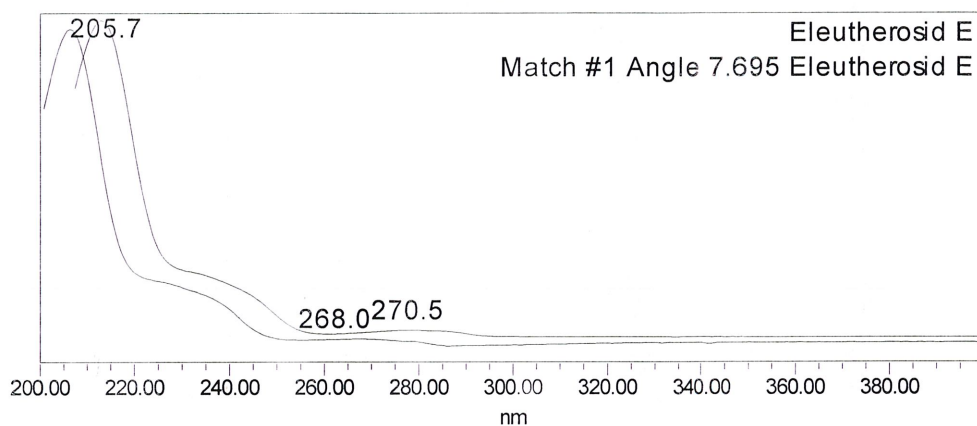
**Spectrum Index Plot**

Eleutherosid B - 5.483



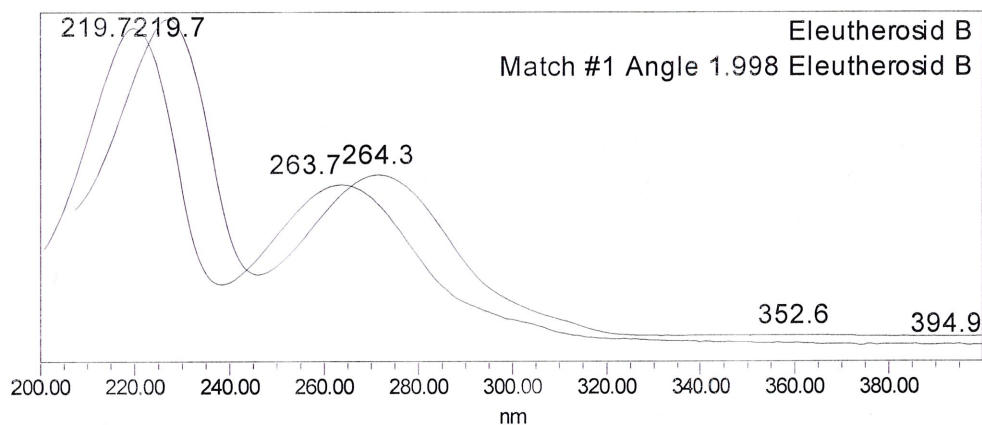
Sign: \_\_\_\_\_

## Match Plot



SampleName Kan Jang Andro Batch\_No 3400195 Vial 1:A,3 Injection 1 Date  
Acquired 2021-05-05 22:51:35 CEST Name Eleutherosid E Match1 Angle  
7.695 Match1 Threshold 90.000 Match1 Spect. Name Eleutherosid E


## Match Plot

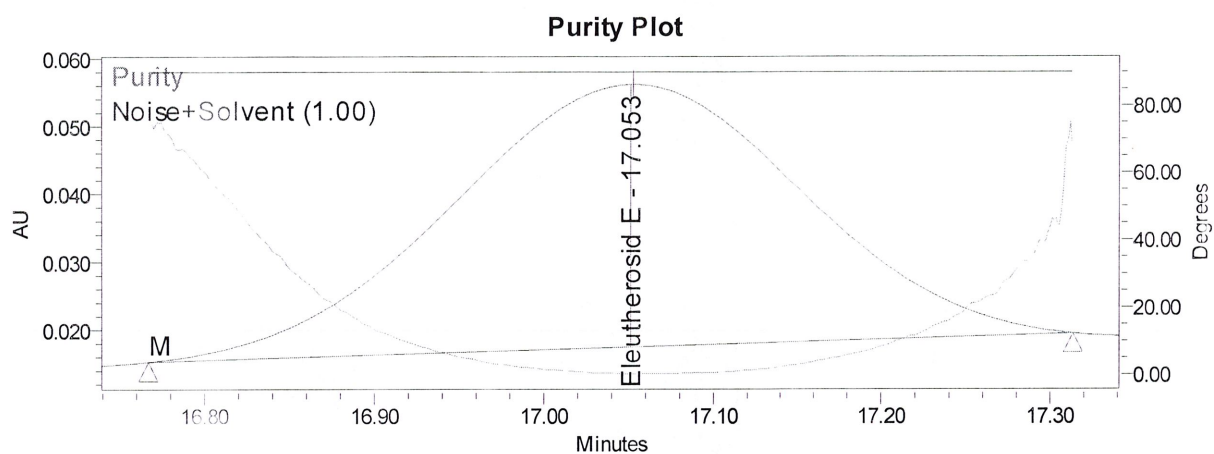


SampleName Kan Jang Andro Batch\_No 3400195 Vial 1:A,3 Injection 1 Date  
Acquired 2021-05-05 22:51:35 CEST Name Eleutherosid B Match1 Angle  
1.998 Match1 Threshold 52.885 Match1 Spect. Name Eleutherosid B

PDA Result Table

	Name	RT	Purity1 Angle	Purity1 Threshold	Match1 Spect. Name	Match1 Angle	Match1 Threshold
1	Eleutherosid B	5.483	5.239	90.000	Eleutherosid B	1.998	52.885
2	Eleutherosid E	17.053	6.078	90.000	Eleutherosid E	7.695	90.000

Sign.: 



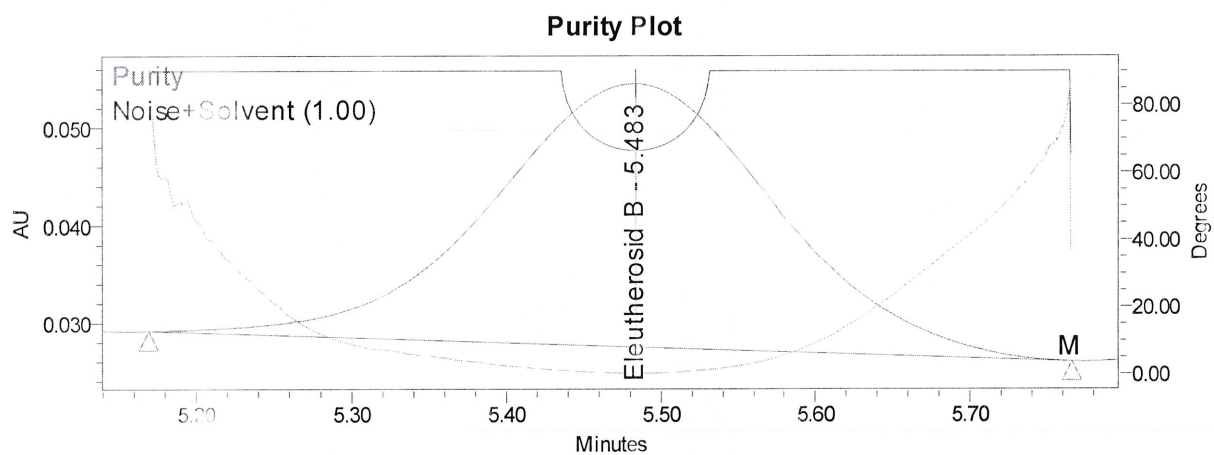
PA: 6.078 TH: 90.000

SampleName: Kan Jang Andro Batch\_No 3400195 Vial: 1:A,3 Injection: 1 Date

Acquired: 2021-05-05 22:51:35 CEST Purity1 Angle: 6.078 Purity1 Threshold: 90.000

Purity

Noise+Solvent (1.00)



PA: 5.239 TH: 90.000

SampleName: Kan Jang Andro Batch\_No 3400195 Vial: 1:A,3 Injection: 1 Date

Acquired: 2021-05-05 22:51:35 CEST Purity1 Angle: 5.239 Purity1 Threshold: 90.000

Purity

Noise+Solvent (1.00)

Sign.: 



**SampleName Kan Jang**

Current Date 2021-05-05

Software Empower 3 Software Build 347

Column no.: Acquity UPLC BEH C18 1.7µ  
01773000715504

Channel 205 nm, 254 nm, 223

Run Time 5.00 Minutes

Processing Method Andrographis

Start Date 2021-05-05 09:47:18 CEST

Tablet\_weight:

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

Batch\_No 3400195

**Component Results****Name: Andrographolide**

	SampleName	Batch_No	SampleWeight	RT	Area	Height	Name	Percent_amount
1	Kan Jang	3400195	3.88400	2.077	686188	293954	Andrographolide	2,625
2	Kan Jang	3400195	3.88400	2.079	686984	294074	Andrographolide	2,628
3	Kan Jang	3400195	3.88400	2.081	688935	294607	Andrographolide	2,635
Mean				2.1				2,629
Std. Dev.				0.0				
% RSD				0.1				

**Component Results****Name: Neoandrographolide**

	SampleName	Batch_No	SampleWeight	RT	Area	Height	Name	Percent_amount
1	Kan Jang	3400195	3.88400	3.033	162998	128980	Neoandrographolide	0,738
2	Kan Jang	3400195	3.88400	3.034	163340	129369	Neoandrographolide	0,740
3	Kan Jang	3400195	3.88400	3.034	163731	129927	Neoandrographolide	0,742
Mean				3.0				0,740
Std. Dev.				0.0				
% RSD				0.0				

**Component Results****Name: Deoxy-didehydroandrographolide**

	SampleName	Batch_No	SampleWeight	RT	Area	Height	Name	Percent_amount
1	Kan Jang	3400195	3.88400	3.315	71523	39793	Deoxy-didehydroandrographolide	0,342
2	Kan Jang	3400195	3.88400	3.317	71383	39808	Deoxy-didehydroandrographolide	0,341
3	Kan Jang	3400195	3.88400	3.317	71387	39914	Deoxy-didehydroandrographolide	0,341
Mean				3.3				0,342
Std. Dev.				0.0				
% RSD				0.0				

Results	mg/tbl	calculated	%found
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Andrographolide:	13,8 mg/tbl		
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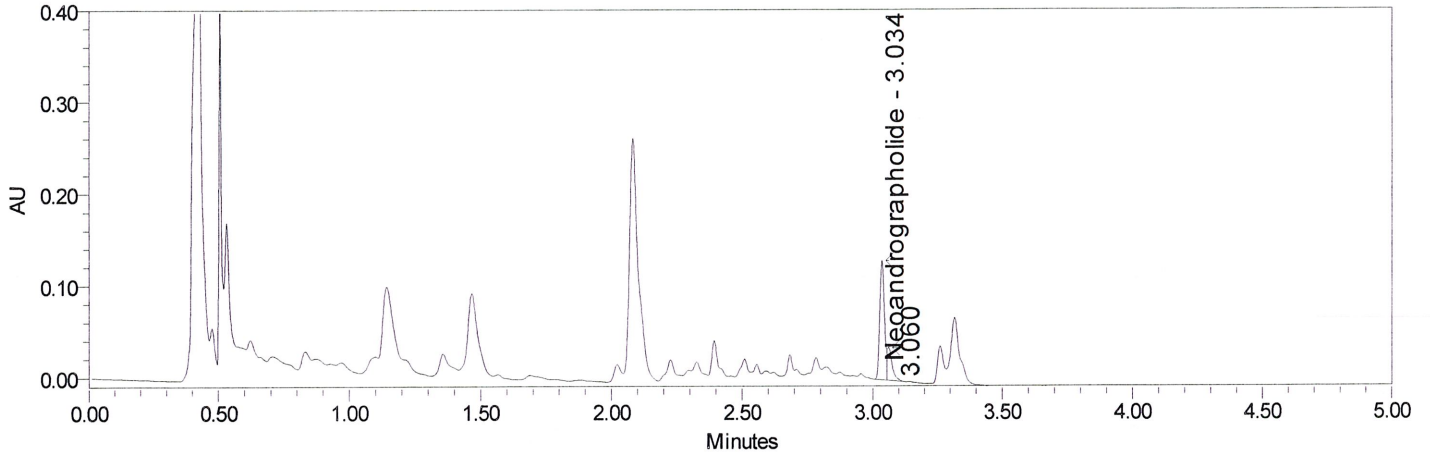
Deoxy-11,12-didehydroandrographolide:	1,8 mg/tbl		
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Total andr and DDD-andr:	15,6 mg/tbl		
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Neoandrographolide:	3,9 mg/tbl		
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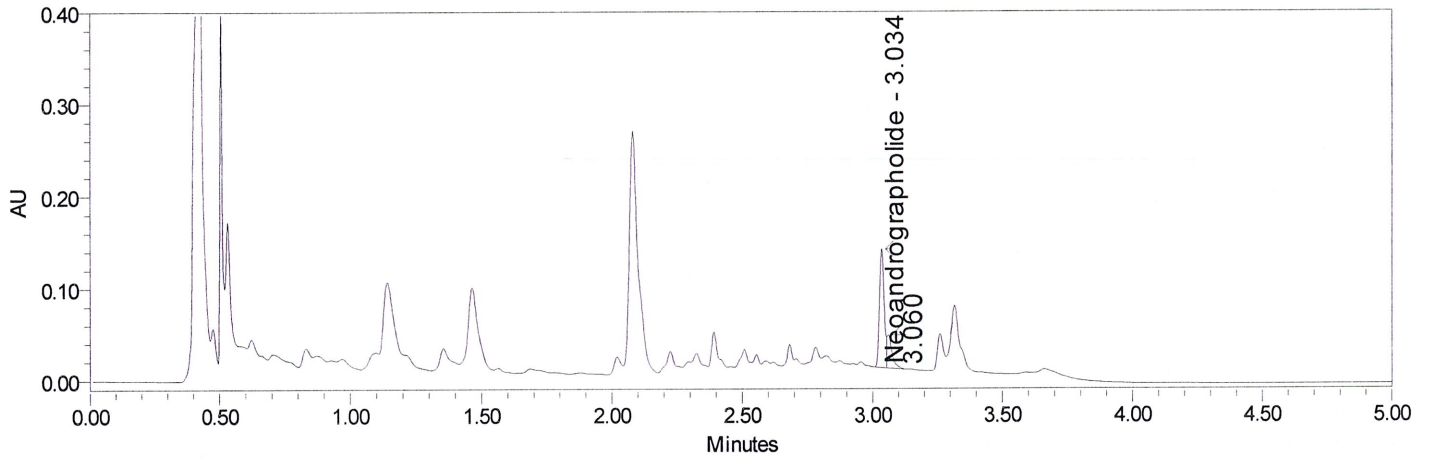
Sign:

### Chromatogram



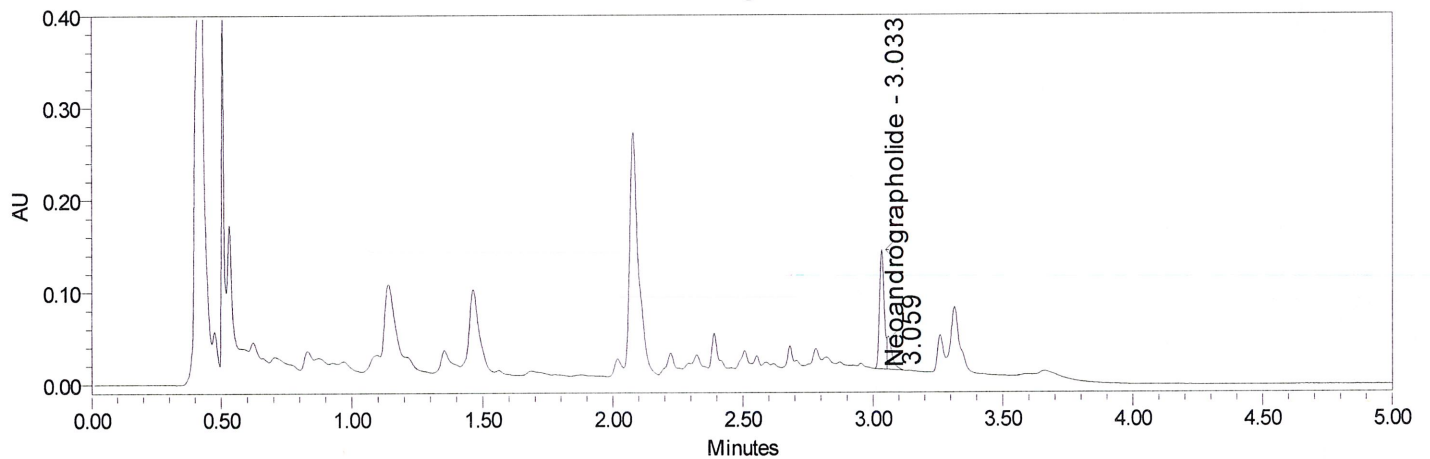
SampleName Kan Jang; Batch\_No 3400195; Vial 1:A,1; Injection 1; Date Acquired 2021-05-05 09:49:02 CEST; Channel Name 205 nm

### Chromatogram




SampleName Kan Jang; Batch\_No 3400195; Vial 1:A,1; Injection 2; Date Acquired 2021-05-05 09:54:53 CEST; Channel Name 205 nm

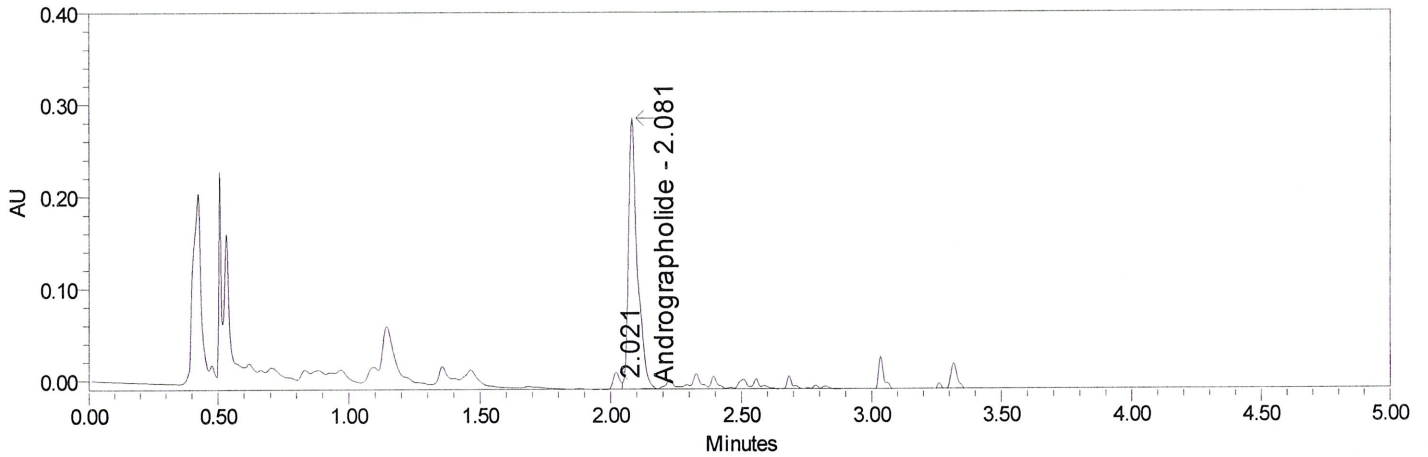
### Chromatogram



SampleName Kan Jang; Batch\_No 3400195; Vial 1:A,1; Injection 3; Date Acquired 2021-05-05 10:00:44 CEST; Channel Name 205 nm

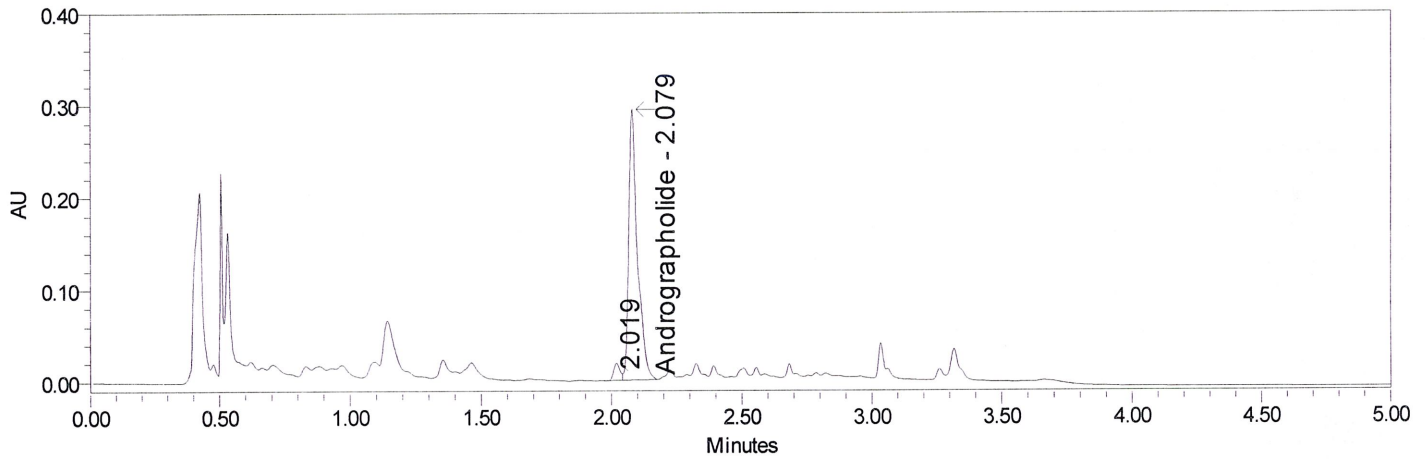
Sign: 

### Chromatogram



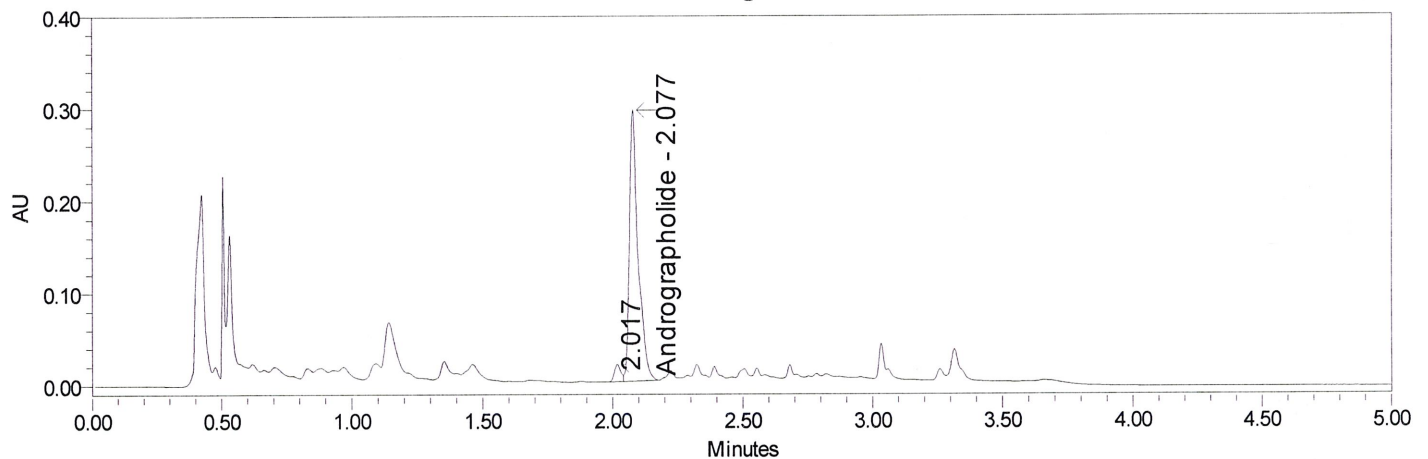
SampleName Kan Jang; Batch\_No 3400195; Vial 1:A,1; Injection 1; Date Acquired 2021-05-05 09:49:02 CEST; Channel Name 223 nm

### Chromatogram




SampleName Kan Jang; Batch\_No 3400195; Vial 1:A,1; Injection 2; Date Acquired 2021-05-05 09:54:53 CEST; Channel Name 223 nm

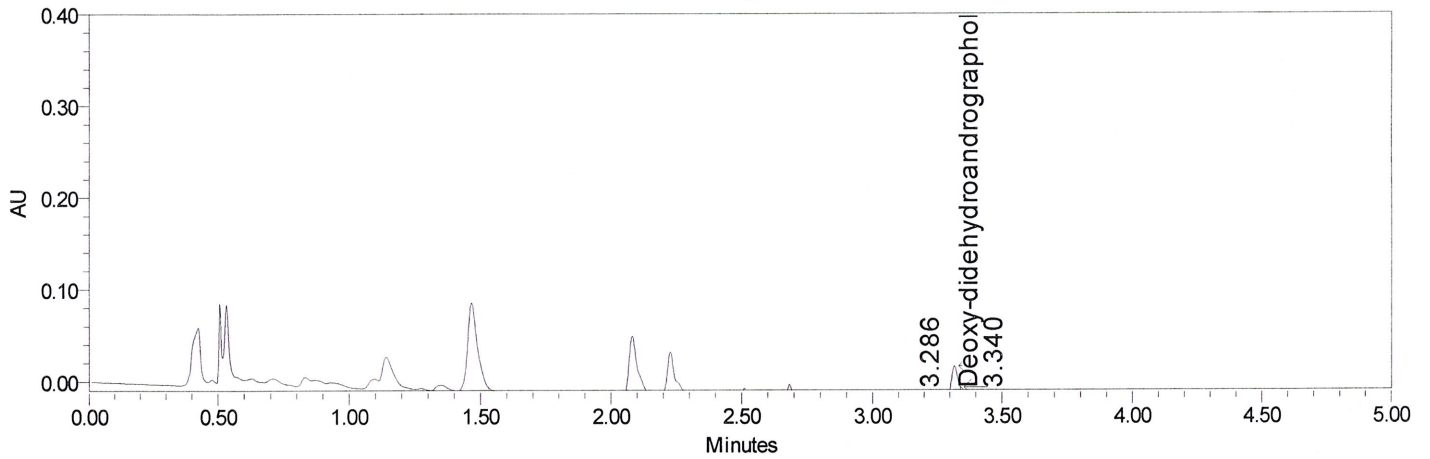
### Chromatogram



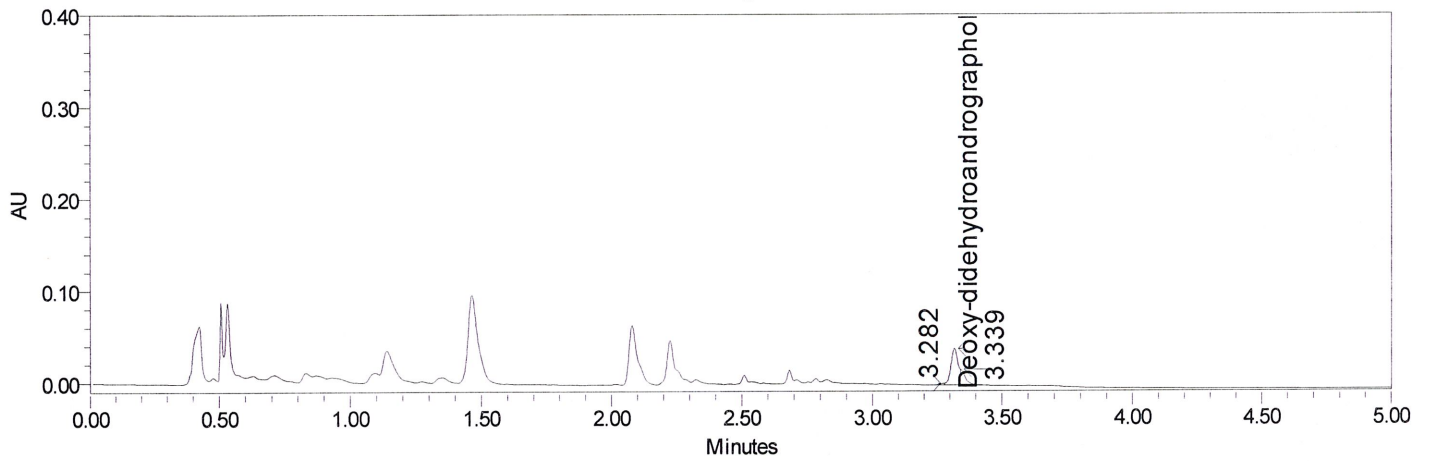
SampleName Kan Jang; Batch\_No 3400195; Vial 1:A,1; Injection 3; Date Acquired 2021-05-05 10:00:44 CEST; Channel Name 223 nm

Sign: 

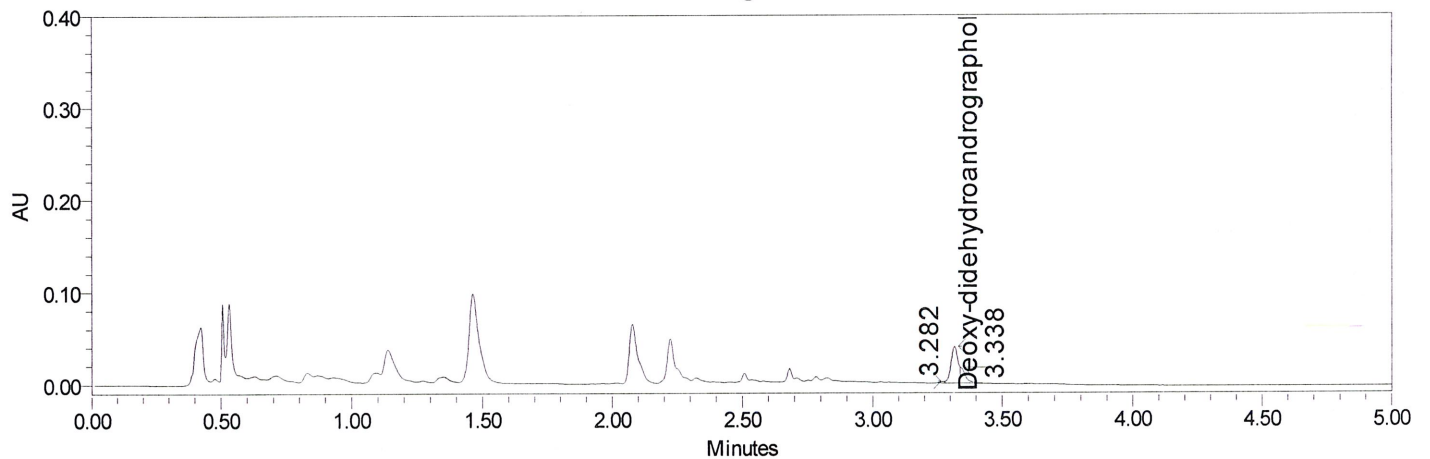


**Chromatogram**


SampleName Kan Jang; Batch\_No 3400195; Vial 1:A,1; Injection 1; Date Acquired 2021-05-05 09:49:02 CEST; Channel Name 254 nm

**Chromatogram**

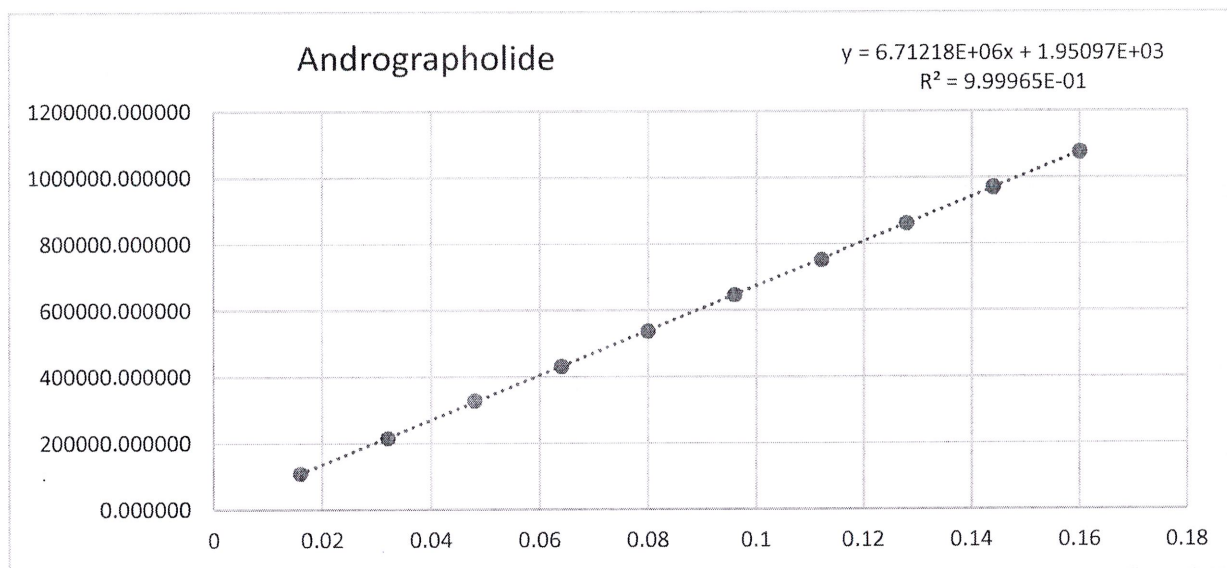
SampleName Kan Jang; Batch\_No 3400195; Vial 1:A,1; Injection 2; Date Acquired 2021-05-05 09:54:53 CEST; Channel Name 254 nm

**Chromatogram**

SampleName Kan Jang; Batch\_No 3400195; Vial 1:A,1; Injection 3; Date Acquired 2021-05-05 10:00:44 CEST; Channel Name 254 nm

Sign: 

Sample Name: Kan Jang Andrographis  
Batch No: 3400195



Injection	Sample Weight	Peakarea	Conc
1	3.884	686188	2.625E-02
2	3.884	686984	2.628E-02
3	3.884	688935	2.635E-02
Average	3.884	687369	2.629E-02

**Percent amount**  
**2.629**

Tablet weight: 525 mg

Tablet content: 13.80 mg/tab

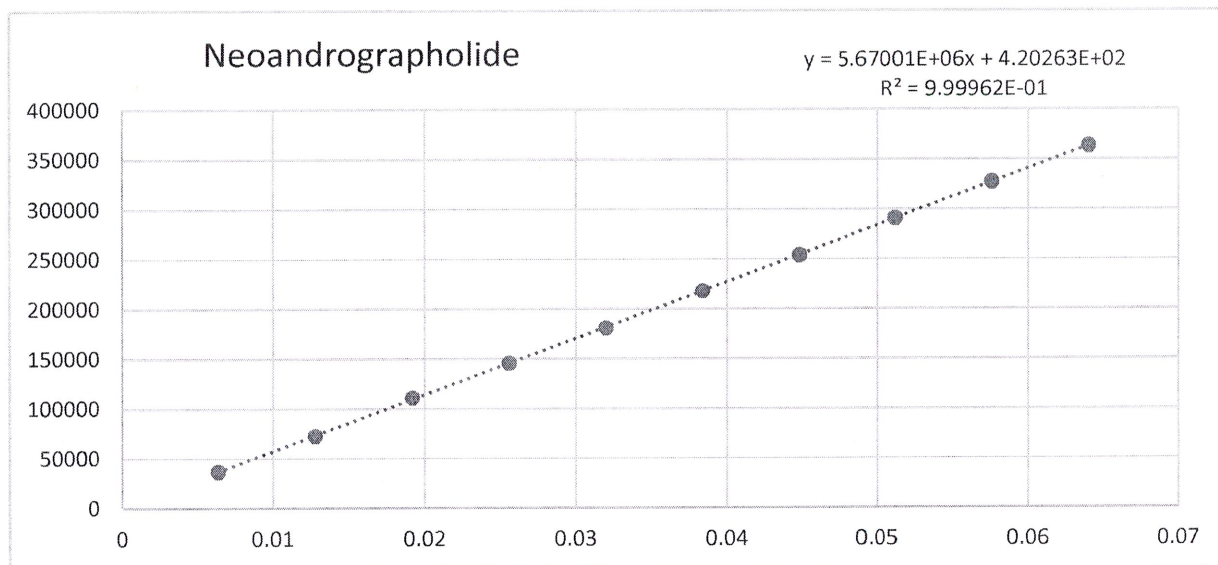
Date: 2021-05-05

Sign: \_\_\_\_\_

*HL*

Sample Name: Kan Jang Andrographis

Batch No: 3400195



Injection	Sample Weight	Peakarea	Conc
1	3.884	162998	7.382E-03
2	3.884	163340	7.398E-03
3	3.884	163731	7.416E-03
Average	3.884	163356	7.399E-03

Percent amount  
0.740

Tablet weight: 525 mg

Tablet content: 3.88 mg/tab

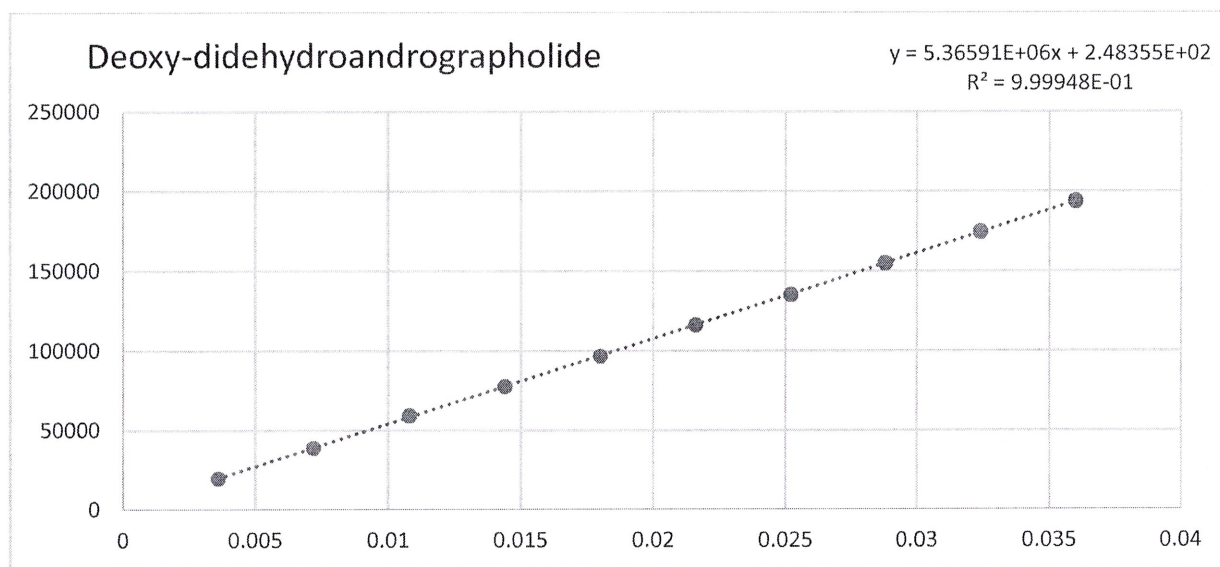
Date: 2021-05-05

Sign: 



Sample Name: Kan Jang Andrographis

Batch No: 3400195



Injection	Sample Weight	Peakarea	Conc
1	3.884	71523	3.42E-03
2	3.884	71383	3.41E-03
3	3.884	71387	3.41E-03
Average	3.884	71431	3.42E-03

Percent amount

0.342

Tablet weight: 525 mg

Tablet content: 1.79 mg/tab

Date: 2021-05-05

Sign: \_\_\_\_\_

*Handwritten signature*