



# 시험성적서

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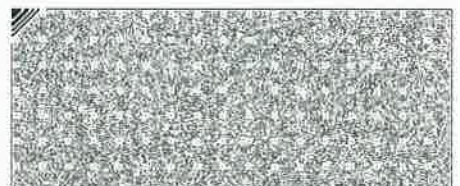
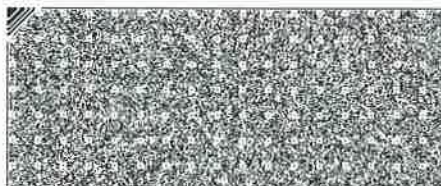
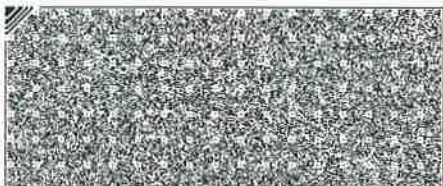
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2019년 08월 28일

한국건설생활환경시험연구원



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## 7. 시험결과

### 1) 시험방법(KS P 1907-1)

#### (1) 표준물질 및 시험물질

- ① Nitroglycerin(순도: 0.974 %, Lot No. H0J138, USP, USA)
- ② Cyclosporin A(순도: 99.9 %, Lot No. C574E, TCI, Japan)
- ③ Tacrolimus(순도: 95.1 %, Lot No. LRAC1117, Sigma-Aldrich, USA)
- ④ 페링가니트 0.1% 주사(Nitroglycerin 1.0 mg/mL, Lot No. 5771202, Elyson, Germany)

#### (2) 표준물질 검량선 조제농도

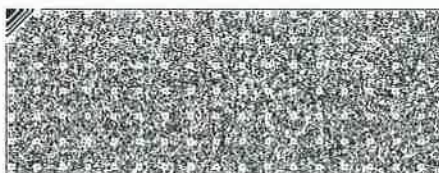
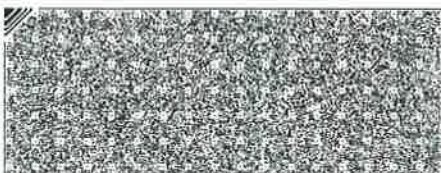
- ① Nitroglycerin: 1.000 µg/mL, 5.000 µg/mL, 10.000 µg/mL, 20.000 µg/mL, 100.000 µg/mL
- ② Cyclosporin A: 5.000 µg/mL, 10.000 µg/mL, 50.000 µg/mL, 100.000 µg/mL, 200.000 µg/mL, 1000.000 µg/mL
- ③ Tacrolimus: 2.500 µg/mL, 5.000 µg/mL, 10.000 µg/mL, 15.000 µg/mL, 20.000 µg/mL

#### (3) 시험군의 구성

시험물질	시험물질 조제농도(µg/mL)	시험용액 채취 시간(h)
Nitroglycerin	100.000	
Cyclosporin A	50.000	1 h, 2 h, 3 h, 4 h
Tacrolimus	10.000	

- (4) 시험방법: 5 % 덱스트로스용액을 사용하여 조제된 시험물질(Nitroglycerin, Cyclosporin A, Tacrolimus)을 정량이송펌프를 이용하여 시험물질(약물)에 따라 주입 속도를 설정한다. 약물 수액이 수액 튜브를 통과하여 처음 회수되기 시작하는 시점을 0으로 하고 각 시점(1 h, 2 h, 3 h, 4 h) 별 시험용액 10 mL를 회수한다. 회수된 시험용액은 0.2 µm syringe filter로 여과 후, 메탄올로 희석 전처리하여 HPLC 분석하여 약물흡착도를 산출한다.

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(5) 약물흡착도 산출식

$$\text{약물흡착도(\%)} = \frac{C_0 - C_f}{C_0} \times 100$$

C<sub>0</sub>: 초기 조제한 수액의 약물 측정농도(μg/mL)

C<sub>f</sub>: 수액 튜브 통과 후 수액의 약물 측정농도(μg/mL)

2) 기기분석방법

(1) 기기 및 시약

- ① HPLC: YL9100(Younglin, Korea)
- ② 저울: EPG 214C(OHAUS, USA)
- ③ 정량이송펌프: Model7518-00, Masterflex, USA
- ④ Syringe filter(0.2 μm, Lot No. 610251CD, ADVANTEC, Japan)
- ⑤ Methanol(Lot No. 0000113893, J.T. Baker, USA)

(2) HPLC 분석조건

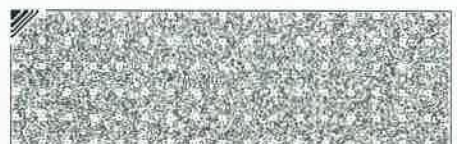
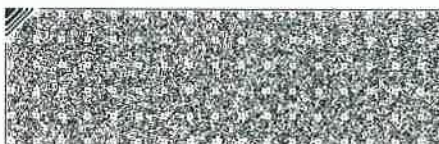
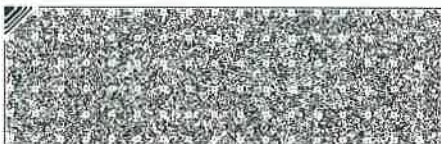
① Nitroglycerin

- Column: Sunfire C18(4.6 mm×150 mm, 3.5 μm, Waters, UK)
- Mobile phase: A(Acetonitrile 100 %)/B(Distilled water 100 %) = 55/45
- Flow rate: 1.0 mL/min
- Injection volume: 20 μL
- Column temperature: 40 °C
- Detector: PDA(205 nm)

② Cyclosporin A

- Column: Sunfire C18(4.6 mm×150 mm, 3.5 μm, Waters, UK)
- Mobile phase: A(Acetonitrile 100 %)/B(Distilled water 100 %) = 90/10
- Flow rate: 1.0 mL/min
- Injection volume: 10 μL

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- Column temperature: 60 °C
- Detector: PDA(210 nm)

### ③ Tacrolimus

- Column: Sunfire C18(4.6 mm×150 mm, 3.5 μm, Waters, UK)
- Mobile phase: A(Acetonitrile 100 %) = 100
- Flow rate: 1.0 mL/min
- Injection volume: 25 μL
- Column temperature: 40 °C
- Detector: PDA(210 nm)

## 3) 시험결과

(1) HPLC 분석법 검증(Table 1-1 ~ Table 1-3, Table 2-1 ~ Table 2-3, Figure 1 ~ Figure 3)

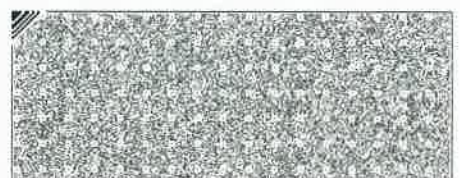
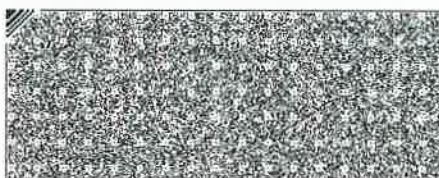
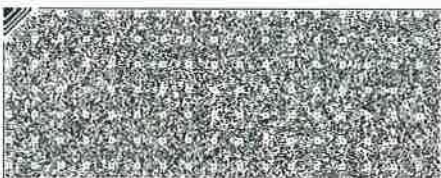
### ① 검량선의 직선성

분석법 검증 시 HPLCS를 이용하여 시험물질 Nitroglycerin(1.000 μg/mL, 5.000 μg/mL, 10.000 μg/mL, 20.000 μg/mL, 100.000 μg/mL), Cyclosporin A(5.000 μg/mL, 10.000 μg/mL, 50.000 μg/mL, 100.000 μg/mL, 200.000 μg/mL, 1000.000 μg/mL) 및 Tacrolimus(2.500 μg/mL, 5.000 μg/mL, 10.000 μg/mL, 15.000 μg/mL, 20.000 μg/mL)의 검량선을 작성하였으며, R<sup>2</sup>는 각각 0.9999875, 0.9998628 및 0.9999240으로 직선성을 보였다.

### ② 정확도(Accuracy)

조제된 1.000 μg/mL 및 100.000 μg/mL 농도의 Nitroglycerin 표준용액을 각각 7 회 측정된 결과, 상대오차(% Error)는 각각 -8.4 % ~ -5.3 %, 0.1 % ~ 3.7 %의 결과를 보였으며, Cyclosporin A의 표준용액 1.000 μg/mL 및 100.000 μg/mL 농도를 각각 7 회 측정된 결과, 상대오차(% Error)는 각각 0.9 % ~ 4.2 %, -0.7 % ~ 2.7 %의 결과를 보였다. 조제된 1.000 μg/mL 및 100.000 μg/mL 농도의 Tacrolimus 표준용액을 각각 7 회 측정된 결과, 상대오차(% Error)는 각각 -3.8 % ~ 2.6 %, -3.0 % ~ 4.7 %의 결과를 보였다.

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## ③ 정밀도(Precision)

조제된 1.000 µg/mL 및 100.000 µg/mL 농도의 Nitroglycerin 표준용액을 각각 7 회 측정한 결과, Nitroglycerin에 대한 변이계수(CV)는 각각 1.4 % 및 1.3 %의 결과를 보였으며, Cyclosporin A의 표준용액 1.000 µg/mL 및 100.000 µg/mL 농도를 각각 7 회 측정한 결과, Cyclosporin A에 대한 변이계수(CV)는 각각 1.3 % 및 1.2 %의 결과를 보였다. Tacrolimus에 대한 변이계수(CV)는 조제된 표준용액 1.000 µg/mL 및 100.000 µg/mL 농도를 각각 7 회 측정한 결과, 각각 2.5 % 및 2.3 %의 결과를 보였다.

## ④ 검출한계

Nitroglycerin, Cyclosporin A 및 Tacrolimus에 대한 정량분석 검증 결과, 검출한계는 각각 0.044 µg/mL, 0.212 µg/mL 및 0.204 µg/mL이었다.

## ⑤ 정량한계

Nitroglycerin, Cyclosporin A 및 Tacrolimus에 대한 정량분석 검증 결과, 정량한계는 각각 0.132 µg/mL, 0.642 µg/mL 및 0.618 µg/mL이었다.

## (2) 시험결과(Table 3-1 ~ Table 3-3)

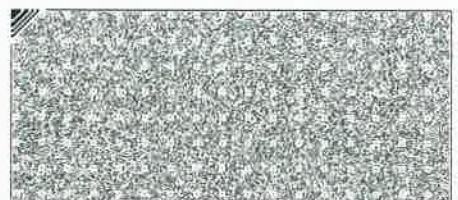
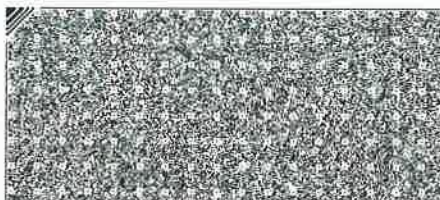
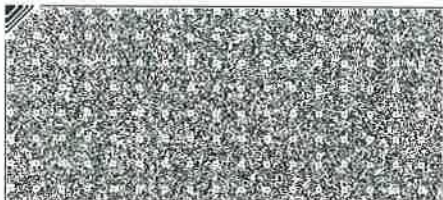
### ① Nitroglycerin

약물 Nitroglycerin의 수액 튜브에 대한 흡착도 시험결과, 초기 조제한 수액의 약물 측정농도(0 h) 및 수액 튜브 통과 후 채취 시점(1 h, 2 h, 3 h, 4 h)에서의 약물 측정농도는 각각 98.647 µg/mL, 95.740 µg/mL, 91.108 µg/mL, 93.360 µg/mL, 103.762 µg/mL의 농도분석 결과를 보였다. 각 시점 (1 h, 2 h, 3 h, 4 h) 별 개별 흡착도는 각각 2.9 %, 7.6 %, 5.4 %, 0 %의 결과를 보였다.

### ② Cyclosporin A

약물 Cyclosporin A의 수액 튜브에 대한 흡착도 시험결과, 초기 조제한 수액의 약물 측정농도(0 h) 및 수액 튜브 통과 후 채취 시점(1 h, 2 h, 3 h, 4 h)에서의 약물 측정농도는 각각 48.908 µg/mL, 46.647 µg/mL, 47.392 µg/mL, 48.026 µg/mL, 48.146 µg/mL의 농도분석 결과를 보였다. 각 시점 (1 h, 2 h, 3 h, 4 h) 별 개별 흡착도는 각각 4.6 %, 3.1 %, 1.8 %, 1.6 %의 결과를 보였다.

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## ③ Tacrolimus

약물 Tacrolimus의 수액 튜브에 대한 흡착도 시험결과, 초기 조제한 수액의 약물 측정농도(0 h) 및 수액 튜브 통과 후 채취 시점(1 h, 2 h, 3 h, 4 h)에서의 약물 측정농도는 각각 9.581 µg/mL, 8.928 µg/mL, 9.083 µg/mL, 9.717 µg/mL, 9.693 µg/mL의 농도분석 결과를 보였다. 각 시점 (1 h, 2 h, 3 h, 4 h) 별 개별 흡착도는 각각 6.8 %, 5.2 %, 0 %, 0 %의 결과를 보였다.

## 4) 결론

약물 Nitroglycerin, Cyclosporin A 및 Tacrolimus에 대한 수액 튜브의 약물 흡착도 시험 결과, 개별 시간(1 h, 2 h, 3 h, 4 h)에서의 평균 약물흡착도는 각각 4.0 %, 2.8 % 및 3.0 %의 결과를 보였다.

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## 5) Tables

Table 1-1. Accuracy and precision of Nitroglycerin analysis using HPLC

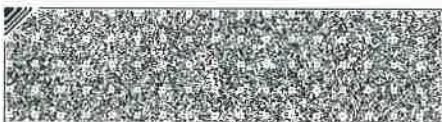
Rep.	Concentration(µg/mL)		%Error <sup>1)</sup> (%)	Mean % Error <sup>2)</sup>	CV <sup>3)</sup> (%)	Mean CV (%)
	Nominal conc.	Measured conc.				
1	1.000	0.920	-8.0	3.9	1.4	1.4
2		0.945	-5.5			
3		0.918	-8.2			
4		0.939	-6.1			
5		0.947	-5.3			
6		0.916	-8.4			
7		0.935	-6.5			
1	100.000	100.531	0.5	1.3	1.3	1.3
2		100.456	0.5			
3		100.371	0.4			
4		100.463	0.5			
5		100.103	0.1			
6		100.266	0.3			
7		103.748	3.7			

1)  $(\text{Measured conc.} - \text{Nominal conc.}) / \text{Nominal conc.} \times 100$

2) Mean of % Error absolute value

3) S.D. of measured conc. / Mean of measured conc.  $\times 100$

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Table 1-2. Accuracy and precision of Cyclosporin A analysis using HPLC

Rep.	Concentration(µg/mL)		%Error <sup>1)</sup> (%)	Mean % Error <sup>2)</sup>	CV <sup>3)</sup> (%)	Mean CV (%)
	Nominal conc.	Measured conc.				
1	5.000	5.131	2.6	1.6	1.3	1.3
2		5.127	2.5			
3		5.149	3.0			
4		5.024	0.5			
5		5.045	0.9			
6		5.209	4.2			
7		5.154	3.1			
1	1000.000	997.529	-0.2	1.6	1.2	1.3
2		997.180	-0.3			
3		992.997	-0.7			
4		994.123	-0.6			
5		1027.249	2.7			
6		1005.149	0.5			
7		1005.244	0.5			

1)  $(\text{Measured conc.} - \text{Nominal conc.}) / \text{Nominal conc.} \times 100$

2) Mean of % Error absolute value

3)  $\text{S.D. of measured conc.} / \text{Mean of measured conc.} \times 100$

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Table 1-3. Accuracy and precision of Tacrolimus analysis using HPLC

Rep.	Concentration(µg/mL)		%Error <sup>1)</sup> (%)	Mean % Error <sup>2)</sup>	CV <sup>3)</sup> (%)	Mean CV (%)
	Nominal conc.	Measured conc.				
1	2.500	2.480	-0.8	2.4	2.5	2.4
2		2.438	-2.5			
3		2.522	0.9			
4		2.565	2.6			
5		2.412	-3.5			
6		2.418	-3.3			
7		2.404	-3.8			
1	20.000	20.472	2.4	2.3	2.3	2.4
2.42		20.314	2.6			
3		20.229	1.1			
4		20.192	1.0			
5		19.398	-3.0			
6		20.439	2.2			
7		20.936	4.7			

1) (Measured conc.-Nominal conc.)/Nominal conc. × 100

2) Mean of % Error absolute value

3) S.O. of measured conc./Mean of measured conc. × 100

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Table 2-1. LOD and LOQ of Nitroglycerin using HPLC

Rep.	Nominal conc. (µg/mL)	Area of Peak	S.D. <sup>1)</sup>	Slope of Calibration Curve <sup>2)</sup>	R <sup>2</sup> of calibration curve	LOD <sup>3)</sup> (µg/mL)	LOQ <sup>4)</sup> (µg/mL)
1		38.772					
2		39.725					
3		38.676					
4	1.000	39.517	0.507	38.38296	0.9999875	0.044	0.132
5		39.793					
6		38.618					
7		39.326					

1) S.D. of peak area, 2) Slope of calibration curve for the analytical method validation

3) LOD: Limit of detection(Mean S.D./slope of calibration curve×3.3),

4) LOQ: Limit of quantitation(Mean S.D./slope of calibration curve×10)

Table 2-2. LOD and LOQ of Cyclosporin A using HPLC

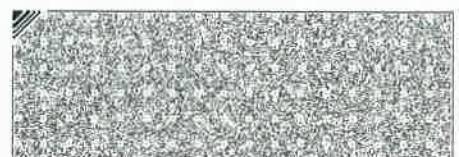
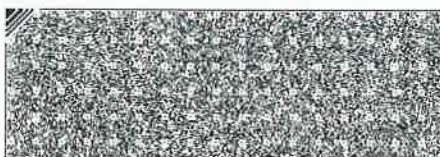
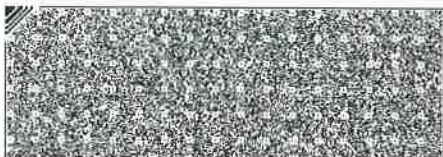
Rep.	Nominal conc. (µg/mL)	Area of Peak	S.D. <sup>1)</sup>	Slope of Calibration Curve <sup>2)</sup>	R <sup>2</sup> of calibration curve	LOD <sup>3)</sup> (µg/mL)	LOQ <sup>4)</sup> (µg/mL)
1		73.023					
2		72.968					
3		73.272					
4	5.000	71.500	0.916	14.26093	0.9998628	0.212	0.642
5		71.791					
6		74.127					
7		73.342					

1) S.D. of peak area, 2) Slope of calibration curve for the analytical method validation

3) LOD: Limit of detection(Mean S.D./slope of calibration curve×3.3)

4) LOQ: Limit of quantitation(Mean S.D./slope of calibration curve×10)

----- 다음페이지 계속 -----



# 시험성적서

성적서번호 : CT19-089635K

Table 2-3. LOD and LOQ of Tacrolimu using HPLC

Rep.	Nominal conc. (µg/mL)	Area of Peak	S.D. <sup>1)</sup>	Slope of Calibration Curve <sup>2)</sup>	R <sup>2</sup> of calibration curve	LOD <sup>3)</sup> (µg/mL)	LOQ <sup>4)</sup> (µg/mL)
1		30.172					
2		29.541					
3		30.800					
4	2.500	31.458	0.934	15.11059	0.9999240	0.204	0.618
5		29.142					
6		29.227					
7		29.027					

1) S.D. of peak area, 2) Slope of calibration curve for the analytical method validation

3) LOD: Limit of detection(Mean S.D./slope of calibration curve×3.3)

4) LOQ: Limit of quantitation(Mean S.D./slope of calibration curve×10)

—— 다음페이지 계속 ——



# 시험성적서

성적서번호 : CT19-089635K

Table 3-1. Concentration analysis of Nitroglycerin in 5 % dextrose

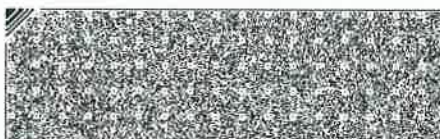
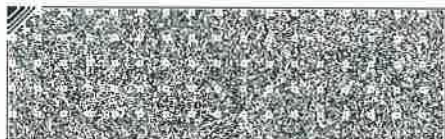
Time (h)	Measured conc. (µg/mL)	Dilution effect	Compensated conc. (µg/mL) <sup>1)</sup>	Mean compensated conc. (µg/mL)	Absorption rate(%) <sup>2)</sup>	Mean absorption rate(%)
0 h	19.744	5	98.720	98.647	-	
	19.676		98.380			
	19.768		98.840			
1 h	19.138	5	95.690	95.740	2.9	
	19.182		95.910			
	19.124		95.620			
2 h	18.404	5	92.020	91.108	7.6	4.0
	18.113		90.565			
	18.148		90.740			
3 h	19.331	5	96.655	93.360	5.4	
	18.350		91.750			
	18.335		91.675			
4 h	20.989	5	104.945	103.762	0 <sup>3)</sup>	
	20.602		103.010			
	20.666		103.330			

1) Measured conc. (µg/mL) × Dilution effect

2) (Mean compensated conc. At 0 h - Mean compensated conc. at x h) / Mean compensated conc. at 0 h × 100

3) Negative value represented as 0

----- 다음페이지 계속 -----



# 시험성적서

성적서번호 : CT19-089635K

Table 3-2. Concentration analysis of Cyclosporin A in 5 % dextrose

Time (h)	Measured conc. (µg/mL)	Dilution effect	Compensated conc. (µg/mL) <sup>1)</sup>	Mean compensated conc. (µg/mL)	Absorption rate(%) <sup>2)</sup>	Mean absorption rate(%)
0 h	24.452	2	48.904	48.908	-	
	24.747		49.494			
	24.163		48.326			
1 h	23.611	2	47.222	46.647	4.6	
	22.816		45.632			
	23.544		47.088			
2 h	24.198	2	48.396	47.392	3.1	2.8
	23.034		46.068			
	23.856		47.712			
3 h	24.725	2	49.450	48.026	1.8	
	24.408		48.816			
	22.906		45.812			
4 h	24.617	2	49.234	48.146	1.6	
	23.911		47.822			
	23.691		47.382			

1) Measured conc. (µg/mL) × Dilution effect

2) (Mean compensated conc. At 0 h- Mean compensated conc. at x h)/Mean compensated conc. at 0 h x 100

----- 다음페이지 계속 -----



# 시험성적서

성적서번호 : CT19-089635K

Table 3-3. Concentration analysis of Tacrolimus in 5 % dextrose

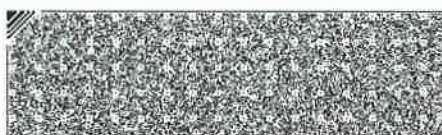
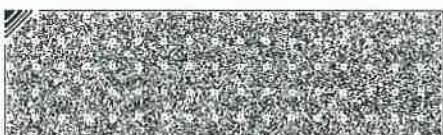
Time (h)	Measured conc. (µg/mL)	Dilution effect	Compensated conc. (µg/mL) <sup>1)</sup>	Mean compensated conc. (µg/mL)	Absorption rate(%) <sup>2)</sup>	Mean absorption rate(%)
0 h	4.833	2	9.666	9.581	-	
	4.739		9.478			
	4.800		9.600			
1 h	4.401	2	8.802	8.928	6.8	
	4.429		8.858			
	4.562		9.124			
2 h	4.665	2	9.330	9.083	5.2	3.0
	4.459		8.918			
	4.501		9.002			
3 h	4.921	2	9.842	9.717	0 <sup>3)</sup>	
	4.804		9.608			
	4.850		9.700			
4 h	4.815	2	9.630	9.693	0	
	4.834		9.668			
	4.891		9.782			

1) Measured conc. (µg/mL) × Dilution effect

2) Mean compensated conc. At 0 h - Mean compensated conc. at x h / Mean compensated conc. at 0 h × 100

3) Negative value represented as 0

----- 다음페이지 계속 -----



# 시험성적서

성적서번호 : CT19-089635K

## 6) Figures

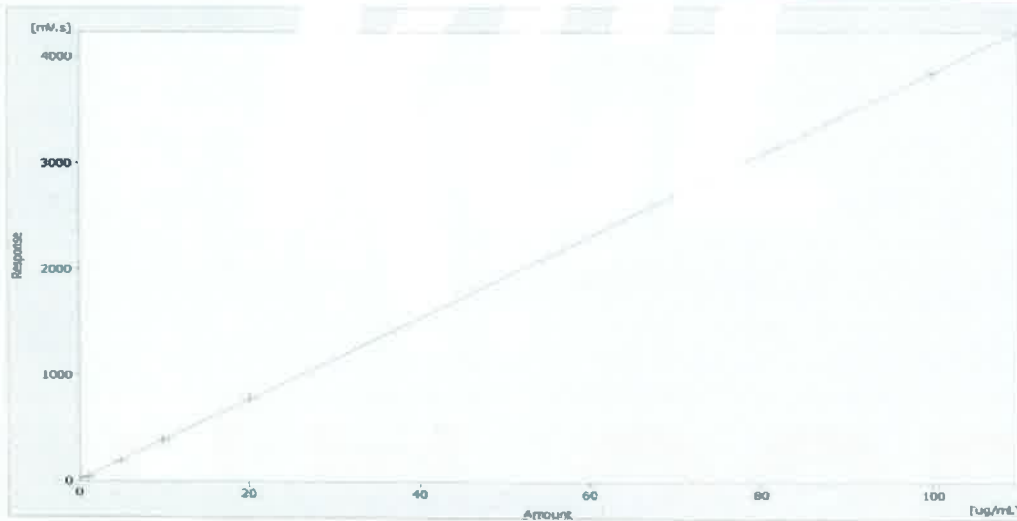
2019-08-Calibration C:\Users\????\Desktop\2019(GT19-GT19)\CT19-089635\Nitroglycerin\_Validation\CT19-089635\_validation\_20190814\_Nitroglycerin\Page 1 of 1

### Calibration Report

Nitroglycerin - Signal 1 - 4.053 min.

Peak Type: Ordnr  
 Left Window: 0.2 min  
 Right Window: 0.2 min  
 Response Base: Area  
 Curve Fit Type: Linear  
 Origin: Data Start Used  
 Weighting Method: None  
 Subst. Equation:  $Y = 38.38295 X + 3.45818$   
 Correction Coef: 0.8888875  
 Residuals: 7.90518 [mV.s]  
 Linearisation X: None  
 Linearisation Y: None

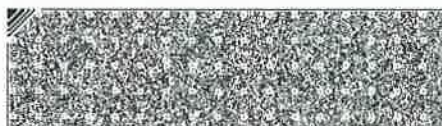
	Response	Amount	Resp. Factor	Rec. No.	Used
1	37.4031	1.0000	0.0267	1	<input checked="" type="checkbox"/>
2	188.1663	5.0000	0.0266	1	<input checked="" type="checkbox"/>
3	357.8285	10.0000	0.0258	1	<input checked="" type="checkbox"/>
4	784.3896	20.0000	0.0255	1	<input checked="" type="checkbox"/>
5	3639.4435	100.0000	0.0280	1	<input checked="" type="checkbox"/>
6	0.0000	0.0000	0.0000	7	<input type="checkbox"/>
7	0.0000	0.0000	0.0000	0	<input type="checkbox"/>
8	0.0000	0.0000	0.0000	0	<input type="checkbox"/>
9	0.0000	0.0000	0.0000	0	<input type="checkbox"/>
10	0.0000	0.0000	0.0000	0	<input type="checkbox"/>
11	0.0000	0.0000	0.0000	0	<input type="checkbox"/>
12	0.0000	0.0000	0.0000	0	<input type="checkbox"/>
13	0.0000	0.0000	0.0000	0	<input type="checkbox"/>
14	0.0000	0.0000	0.0000	0	<input type="checkbox"/>
15	0.0000	0.0000	0.0000	0	<input type="checkbox"/>
16	0.0000	0.0000	0.0000	0	<input type="checkbox"/>
17	0.0000	0.0000	0.0000	0	<input type="checkbox"/>
18	0.0000	0.0000	0.0000	0	<input type="checkbox"/>
19	0.0000	0.0000	0.0000	0	<input type="checkbox"/>
20	0.0000	0.0000	0.0000	0	<input type="checkbox"/>
21	0.0000	0.0000	0.0000	0	<input type="checkbox"/>
22	0.0000	Blank	0.0000	0	<input type="checkbox"/>



1/18

Figure 1. Calibration report of Nitroglycerin standard solution in analysis method review

----- 다음페이지 계속 -----



# 시험성적서

성적서번호 : CT19-089635K

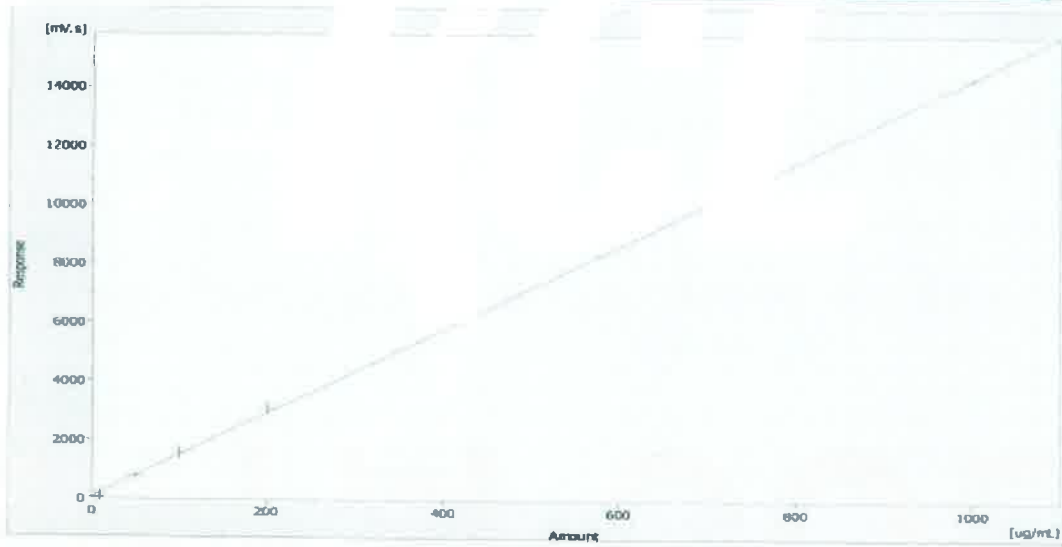
2019-0Calibration C:\Users\77777\Desktop\2019\CT19-089635K\Cyclosporin A\ Validation\CT19-089635K\_Validation\_20190808\_Cyclosporin Page 1 of 1

## Calibration Report

Cyclosporin A - Signal 1 - 3.307 min

Peak Type : Ordnr  
 Left Window : 0.2 min  
 Right Window : 0.2 min  
 Response Base : Area  
 Curve Fit Type : Linear  
 Origin : Zero not used  
 Weighting Method : None  
 Subs. Equation :  $Y = 14.26000^* X + 77.90801$   
 Correlation Coef. : 0.999828  
 Residual : 83.0805 [mV.s]  
 Linearation X : None  
 Linearation Y : None

	Response	Amount	Resp Factor	Rec No	Used
1	72.3465	5.0000	0.0665	1	<input type="checkbox"/>
2	142.3226	10.0000	0.0703	1	<input type="checkbox"/>
3	771.7011	50.0000	0.0648	1	<input type="checkbox"/>
4	1592.3977	100.0000	0.0644	1	<input type="checkbox"/>
5	3080.0680	200.0000	0.0647	1	<input type="checkbox"/>
6	14304.1251	1000.0000	0.0699	1	<input type="checkbox"/>
7	0.0000	0.0000	0.0000	0	<input type="checkbox"/>
8	0.0000	0.0000	0.0000	0	<input type="checkbox"/>
9	0.0000	0.0000	0.0000	0	<input type="checkbox"/>
10	0.0000	0.0000	0.0000	0	<input type="checkbox"/>
11	0.0000	0.0000	0.0000	0	<input type="checkbox"/>
12	0.0000	0.0000	0.0000	0	<input type="checkbox"/>
13	0.0000	0.0000	0.0000	0	<input type="checkbox"/>
14	0.0000	0.0000	0.0000	0	<input type="checkbox"/>
15	0.0000	0.0000	0.0000	0	<input type="checkbox"/>
16	0.0000	0.0000	0.0000	0	<input type="checkbox"/>
17	0.0000	0.0000	0.0000	0	<input type="checkbox"/>
18	0.0000	0.0000	0.0000	0	<input type="checkbox"/>
19	0.0000	0.0000	0.0000	0	<input type="checkbox"/>
20	0.0000	0.0000	0.0000	0	<input type="checkbox"/>
21	0.0000	Blank	0.0000	0	<input type="checkbox"/>



서명

Figure 2. Calibration report of Cyclosporin A standard solution in analysis method review

----- 다음페이지 계속 -----





# 시험성적서

성적서번호 : CT19-089635K

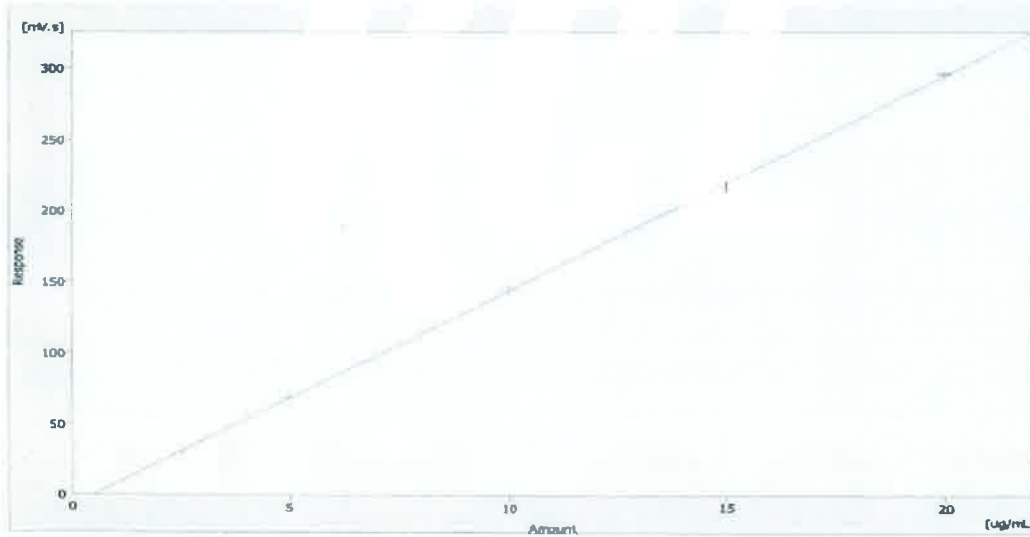
2019-08-16\Calibration C\Users\7777\Desktop\2019\CT19-G119\CT19-089635K\_Tacrolimus\_validation\CT19-089635K\_validation\_20190816\_Tacrolimus.c\page 1 of 1

## Calibration Report

Tacrolimus - Signal - 2.7 min

Peak Type  Other  
 Left Window  0.2 min  
 Right Window  0.2 min  
 Response Base  Area  
 Curve Fit Type  Linear  
 UF4n  Zero not used  
 Weighting Method  None  
 Stat. Equation   $Y = 15.11059 \cdot X - 7.30589$   
 Correlation Coef  0.9999240  
 Residual  1.19277 [mV.s]  
 Linearisation X  None  
 Linearisation Y  None

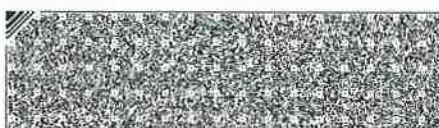
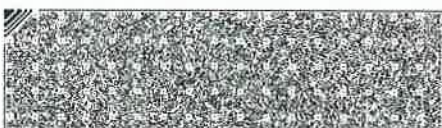
Response	Amount	Resp. Factor	Rec. File	Used
1	2.5000	0.0818	1	<input checked="" type="checkbox"/>
2	5.0000	0.0737	1	<input checked="" type="checkbox"/>
3	10.0000	0.0662	1	<input checked="" type="checkbox"/>
4	15.0000	0.0587	1	<input checked="" type="checkbox"/>
5	20.0000	0.0575	1	<input checked="" type="checkbox"/>
6	0.0000	0.0000	0	<input type="checkbox"/>
7	0.0000	0.0000	0	<input checked="" type="checkbox"/>
8	0.0000	0.0000	0	<input checked="" type="checkbox"/>
9	0.0000	0.0000	0	<input checked="" type="checkbox"/>
10	0.0000	0.0000	0	<input checked="" type="checkbox"/>
11	0.0000	0.0000	0	<input checked="" type="checkbox"/>
12	0.0000	0.0000	0	<input checked="" type="checkbox"/>
13	0.0000	0.0000	0	<input checked="" type="checkbox"/>
14	0.0000	0.0000	0	<input checked="" type="checkbox"/>
15	0.0000	0.0000	0	<input checked="" type="checkbox"/>
16	0.0000	0.0000	0	<input checked="" type="checkbox"/>
17	0.0000	0.0000	0	<input checked="" type="checkbox"/>
18	0.0000	0.0000	0	<input checked="" type="checkbox"/>
19	0.0000	0.0000	0	<input checked="" type="checkbox"/>
20	0.0000	0.0000	0	<input checked="" type="checkbox"/>
DL	Blank	0.0000	0	<input checked="" type="checkbox"/>



*D7/1/18*

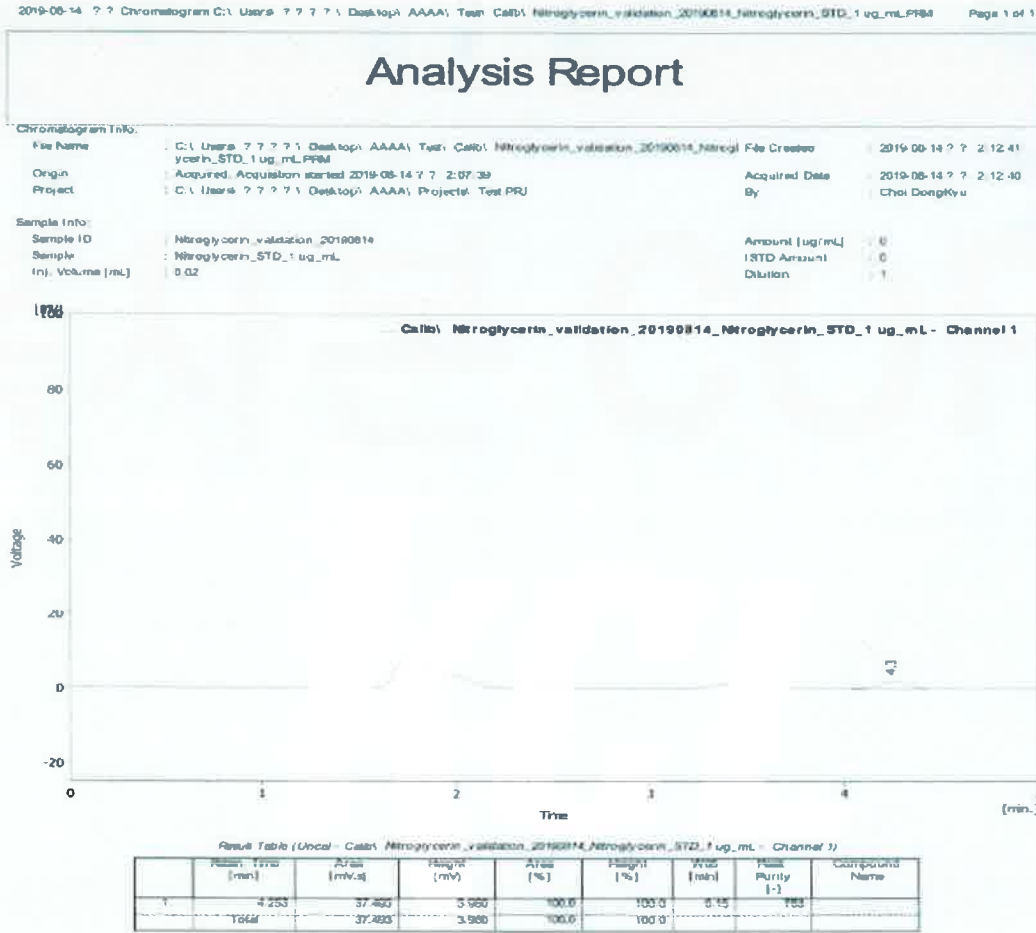
Figure 3. Calibration report of Tacrolimus standard solution in analysis method review

----- 다음페이지 계속 -----



# 시험성적서

성적서번호 : CT19-089635K



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Figure 4. Nitroglycerin standard solution(1.000 µg/mL) for analysis method review

----- 다음페이지 계속 -----



# 시험성적서

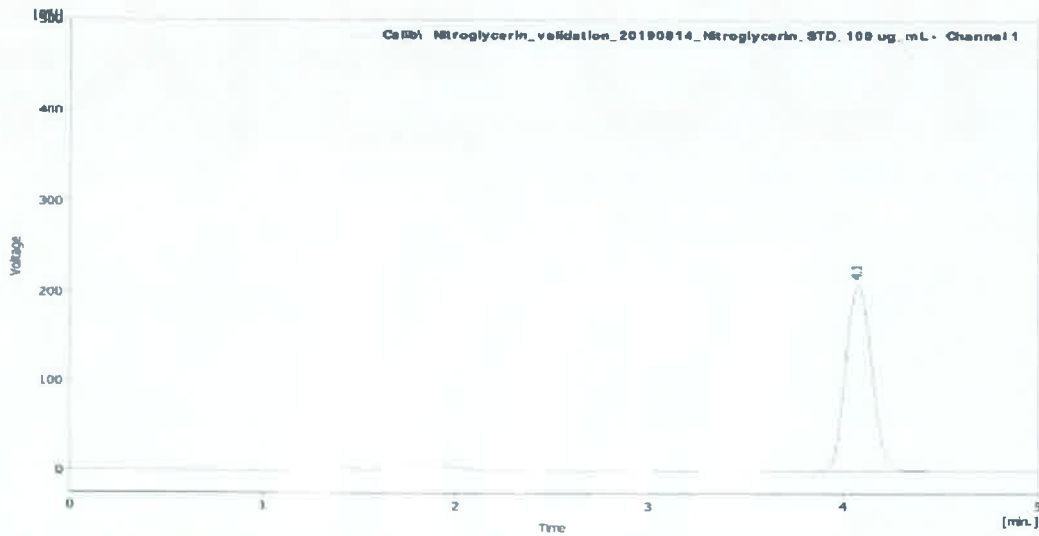
성적서번호 : CT19-089635K

2019-08-14 7:27 Chromatogram C:\Users\????\Desktop\AAAA\Test\Calbi\Nitroglycerin\_validation\_20190814\_Nitroglycerin STD\_100 ug mL.PRM Page 1 of 1

## Analysis Report

**Chromatogram Info**  
 File Name C:\Users\????\Desktop\AAAA\Test\Calbi\Nitroglycerin\_validation\_20190814\_Nitroglycerin STD\_100 ug mL.PRM 2019-08-14 7:23:55  
 Origin Acquired, Acquisition started 2019-08-14 7:23:52  
 Project C:\Users\????\Desktop\AAAA\Project\ Test.PRM By Choi Dongkyu

**Sample Info**  
 Sample ID Nitroglycerin\_validation\_20190814 Amount [ug/mL] 0  
 Sample Nitroglycerin STD\_100 ug mL STD Amount 0  
 Inj. Volume [uL] 0.02 Dilution 1



Result Table (Uncal - Calbi Nitroglycerin\_validation\_20190814\_Nitroglycerin STD\_100 ug mL - Channel 1)

Peak	Retention Time [min]	Area [a.u.]	Height [mV]	Area [%]	Height [%]	W0.5 [min]	Peak Purity [%]	Compound Name
1	4.061	3832.444	413.847	100.0	100.0	0.15	711	
Total		3832.444	413.847	100.0	100.0			

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Figure 5. Nitroglycerin standard solution(100.000 µg/mL) for analysis method review

----- 다음페이지 계속 -----



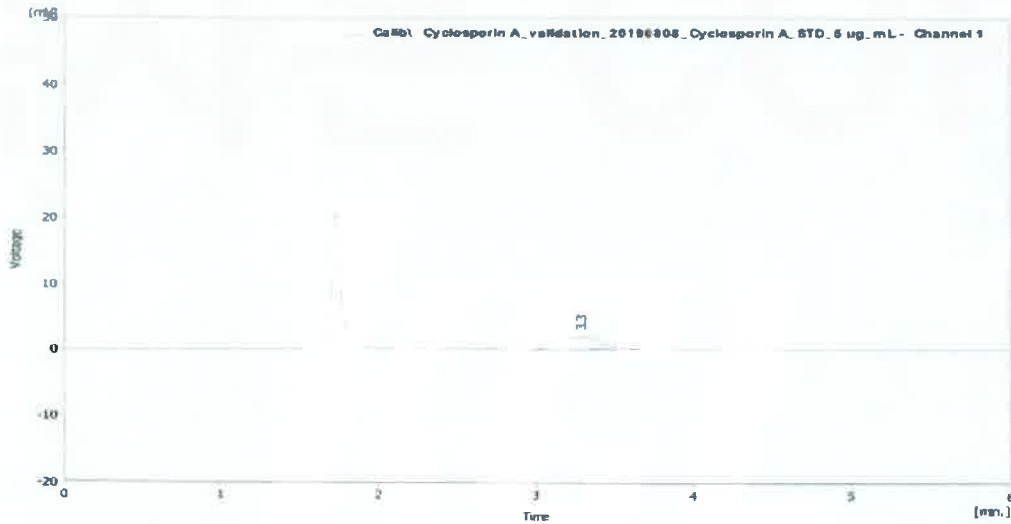
# 시험성적서

성적서번호 : CT19-089635K

2019-08-06 7:??Chromatogram C:\Users\????\Desktop\AAAA\Test\Cell\ Cyclosporin A\_validation\_20190806\_Cyclosporin A\_STD\_5 ug\_mL.PRM Page 1 of 1

## Analysis Report

<b>Chromatogram Info</b>		<b>File Name</b>	C:\Users\????\Desktop\AAAA\Test\Cell\ Cyclosporin A_validation_20190806_Cyclosporin A_STD_5 ug_mL.PRM	<b>File Created</b>	2019-08-06 7:?? 8:10:00
<b>Origin</b>	C:\Users\????\Desktop\AAAA\Projects\Tel.FRU	<b>Acquired</b>	2019-08-06 7:?? 8:04:04	<b>Acquired Date</b>	2019-08-06 7:?? 8:10:00
<b>Project</b>	C:\Users\????\Desktop\AAAA\Projects\Tel.FRU	<b>By</b>	Choi DongKyu		
<b>Sample Info</b>		<b>Sample ID</b>	Cyclosporin A_validation_20190806	<b>Amount [ug/mL]</b>	0
<b>Sample</b>	Cyclosporin A_STD_5 ug_mL	<b>STD Amount</b>	0		
<b>Inj. Volume [mL]</b>	0.01	<b>Dilution</b>	1		



Peak Table (Uncal - Cell\ Cyclosporin A\_validation\_20190806\_Cyclosporin A\_STD\_5 ug\_mL - Channel 1)

Peak	Reten. Time [min]	Area [mV.s]	Height [mV]	Area [%]	Height [%]	W05 [min]	Peak Purity [-]	Compound Name
1	3.307	72.088	3.934	100.0	100.0	0.30	100	
	Total	72.088	3.934	100.0	100.0			

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Figure 6. Cyclosporin A standard solution(5.000 µg/mL) for analysis method review

----- 다음페이지 계속 -----



# 시험성적서

성적서번호 : CT19-089635K

2019-08-09 7 Chromatogram C:\Users\7 7 7 7\Desktop\AAAA\Test\Calib\Cyclosporin A\_validation\_20190808\Cyclosporin A\_STD\_1000 ug\_mL.PRM Page 1 of 1

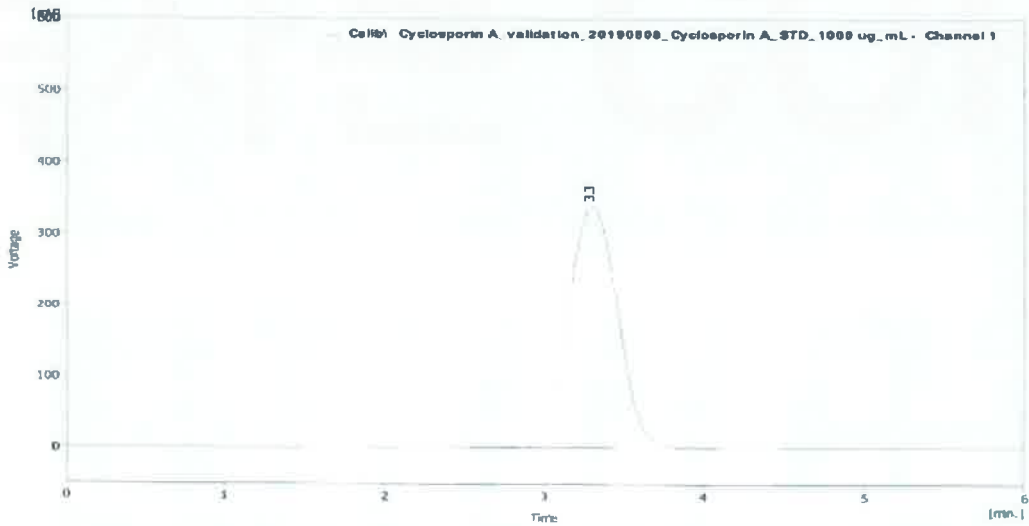
## Analysis Report

**Chromatogram Info**

File Name	C:\Users\7 7 7 7\Desktop\AAAA\Test\Calib\Cyclosporin A_validation_20190808\Cyclosporin A_STD_1000 ug_mL.PRM	File Created	2019-08-09 8:41:38
Origin	Acquired, Acquisition started 2019-08-08 7 7 8 35 36	Acquired Date	2019-08-09 8:41:37
Project	C:\Users\7 7 7 7\Desktop\AAAA\Projects\Test PRU	By	Choi Dongkyu

Sample Info		Amount [ug/mL]	#
Sample ID	Cyclosporin A_validation_20190808	STD Amount	#
Sample	Cyclosporin A_STD_1000 ug_mL	Dilution	1
IN Volume [mL]	0.01		



Result Table (Uncal - Calib\Cyclosporin A\_validation\_20190808\Cyclosporin A\_STD\_1000 ug\_mL - Channel 1)

Peak	Retention Time [min.]	Area [mV.s]	Height [mV]	Area [%]	Height [%]	Width [min.]	Peak Purity [%]	Compound Name
1	3.320	675.735	675.735	100.0	100.0	0.34	Std	
Total		675.735	675.735	100.0	100.0			

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Figure 7. Cyclosporin A standard solution(1000.000 µg/mL) for analysis method review

----- 다음페이지 계속 -----



# 시험성적서

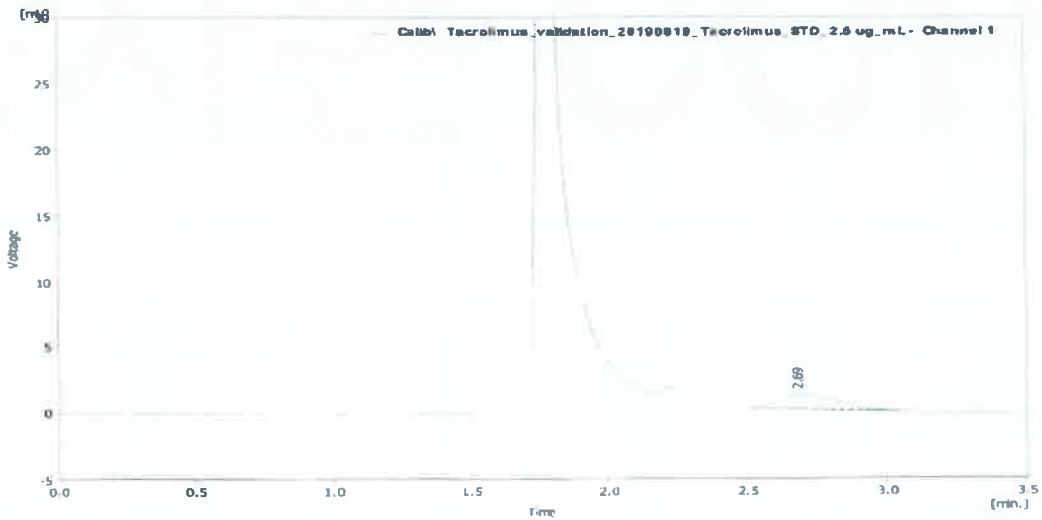
성적서번호 : CT19-089635K

2019-08-19 7:7 Chromatogram C:\Users\77777\Desktop\AAAA\Test\Calb\Tacrolimus\_validation\_20190819\_Tacrolimus\_STD\_2.5 ug/mL.PRM Page 1 of 1

## Analysis Report

**Chromatogram Info:**  
 File Name: C:\Users\77777\Desktop\AAAA\Test\Calb\Tacrolimus\_validation\_20190819\_Tacrolimus\_STD\_2.5 ug/mL.PRM File Created: 2019-08-19 7:7 10:23:47  
 Origin: msl STD\_2.5 ug/mL.PRM Acquired Date: 2019-08-19 7:7 10:20:14  
 Project: C:\Users\77777\Desktop\AAAA\Projects\Test.PRM By: Choi DongKyu

**Sample Info:**  
 Sample ID: Tacrolimus\_validation\_20190819 Amount (ug/mL): 0  
 Sample: Tacrolimus\_STD\_2.5 ug/mL STD Amount: 0  
 Inj. Volume (uL): 0.025 Dilution: 1:1



Result Table (Uncal - Calb\ Tacrolimus\_validation\_20190819\_Tacrolimus\_STD\_2.5 ug/mL - Channel 1)

Peak	Retain Time (min)	Area (mV.s)	Height (mV)	Area (%)	Height (%)	W05 (min)	Peak Purity (%)	Compound Name
1	2.085	35.570	2.085	100.0	100.0	0.25	99	
Total		35.570	2.085	100.0	100.0			

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Figure 8. Tacrolimus standard solution(2.500 µg/mL) for analysis method review

----- 다음페이지 계속 -----



# 시험성적서

성적서번호 : CT19-089635K

2019-08-19 7 ? ? 1Chromatogram C:\Users\7 ? ? ? ? \Desktop\AAAA\Test\Celb\Tacrolimus\_validation\_20190819\_Tacrolimus\_STD\_20 ug\_mL.PRM Page 1 of 1

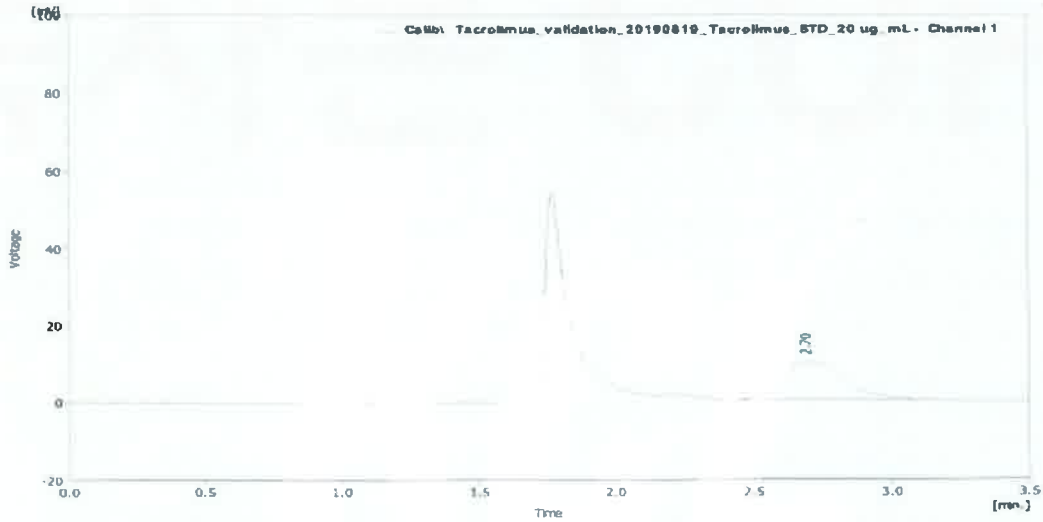
## Analysis Report

**Chromatogram Info:**

File Name: C:\Users\7 ? ? ? ? \Desktop\AAAA\Test\Celb\Tacrolimus\_validation\_20190819\_Tacrolimus\_STD\_20 ug\_mL.PRM File Created: 2019-08-19 ? ? 10:38:58  
 Origin: Acquired: Acquisition started 2019-08-19 ? ? 10:38:26 Acquired Date: 2019-08-19 ? ? 10:38:57  
 Project: C:\Users\7 ? ? ? ? \Desktop\AAAA\Project\ Test PRJ By: Choi DongMyu

**Sample Info:**

Sample ID: Tacrolimus\_validation\_20190819 Amount (ug/mL): 0  
 Sample: Tacrolimus\_STD\_20 ug\_mL ISTD Amount: 0  
 Inj. Volume (uL): 0.025 Dilution: 1



Area Table (Unit: Ca\cb\ Tacrolimus\_validation\_20190819\_Tacrolimus\_STD\_20 ug\_mL - Channel 1)

Peak	Time [min]	Area [mV*s]	Height [mV]	Area [%]	Height [%]	W05 [min]	Peak Purity [%]	Compound Name
1	2.700	256.148	19.809	100.0	100.0	0.28	999	
Total		256.148	19.809	100.0	100.0			

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Figure 9. Tacrolimus standard solution(20.000 µg/mL) for analysis method review

----- 다음페이지 계속 -----



# 시험성적서

성적서번호 : CT19-089635K

2019-08-22 7:53:09 Chromatogram C:\Users\7777\Desktop\AAAA\Test\Data\Nitroglycerin\_Test\_20190822\_Nitroglycerin\_4hr\_100ug\_mL\_1.PRM Page 1 of 1

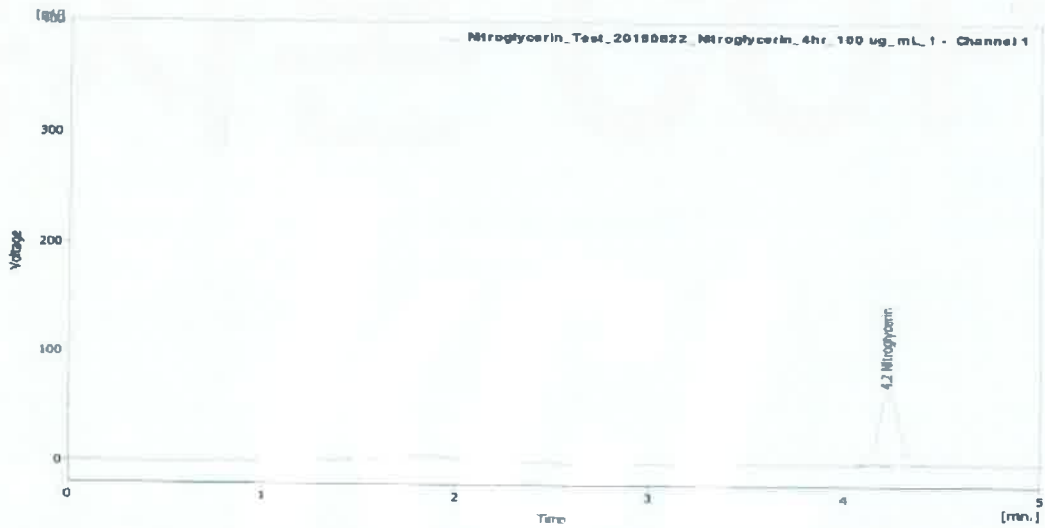
## Analysis Report

**Chromatogram Info**

File Name: C:\Users\7777\Desktop\AAAA\Test\Data\Nitroglycerin\_Test\_20190822\_Nitroglycerin\_4hr\_100ug\_mL\_1.PRM File Created: 2019-08-22 7:53:10  
 Origin: n\_4hr\_100ug\_mL\_1.PRM Acquired: Acquisition started 2019-08-22 7:48:07  
 Project: C:\Users\7777\Desktop\AAAA\Project\Test\PRM Acquired Date: 2019-08-22 7:53:09  
 By: Choi Dongryu

**Sample Info:**

Sample ID: Nitroglycerin\_Test\_20190822 Amount (ug/mL): 0  
 Sample: Nitroglycerin\_4hr\_100ug\_mL\_1 STD Amount: 0  
 Inj. Volume (mL): 0.02 Dilution: 1



Result Table (ESTD - Nitroglycerin\_Test\_20190822\_Nitroglycerin\_4hr\_100ug\_mL\_1 - Channel 1)

Peak	Reten. Time [min]	Response	Amount [ug/mL]	Amount [%]	Peak Purity [-]	Peak Type	Compound Name	Name Match [-]	Std Match [-]	Std Match [-]
1	4.230	364.271	20.000	100.0	95	Other	Nitroglycerin			
Total			20.000	100.0						

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Figure 10. Nitroglycerin(100.000 µg/mL) in 5 % dextrose solution for sampling time at 4 h

----- 다음페이지 계속 -----





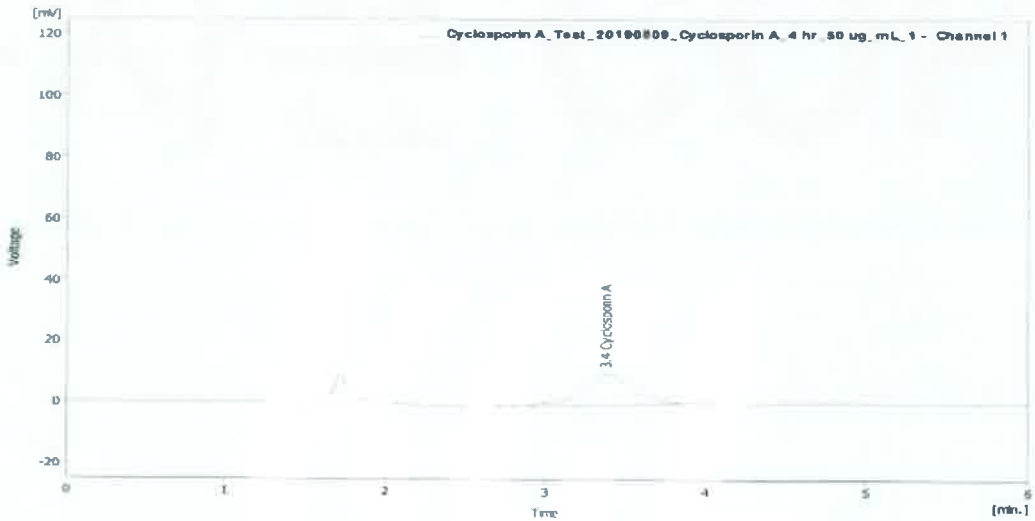
# 시험성적서

성적서번호 : CT19-089635K

2019-08-13 7:7 Chromatogram C:\Users\????\Desktop\AAAA\Test\Date\Cyclosporin A\_Test\_20190809\Cyclosporin A\_4 hr\_50 ug\_mL\_1.PRM Page 1 of 1

## Analysis Report

Chromatogram Info:		File Created	2019-08-09 7:7 5:38:35
File Name	C:\Users\????\Desktop\AAAA\Test\Date\Cyclosporin A_Test_20190809\Cyclosporin A_4 hr_50 ug_mL_1.PRM	Acquired Date	2019-08-09 7:7 5:38:34
Origin	Acquired, Acquisition started 2019-08-09 7:7 5:32:33	By	Choi Dongkyu
Project	C:\Users\????\Desktop\AAAA\Projects\Test PRJ		
Sample Info:		Amount [ug/mL]	0
Sample ID	Cyclosporin A_Test_20190809	ISTD Amount	0
Sample	Cyclosporin A_4 hr_50 ug_mL_1	Dilution	1
Inj. Volume [mL]	0.01		



Result Table (ESTD - Cyclosporin A\_Test\_20190809\_Cyclosporin A\_4 hr\_50 ug\_mL\_1 - Channel 1)

Peak	Retain. Time (min)	Response	Amount [ug/mL]	Amount (%)	Peak Purity (%)	Peak Type	Compound Name	Name Match [-]	Est. Match Name [-]	Est. Match [-]
1	3.397	451.232	24.617	100.0	760	Ident	Cyclosporin A			
Total			24.617	100.0						

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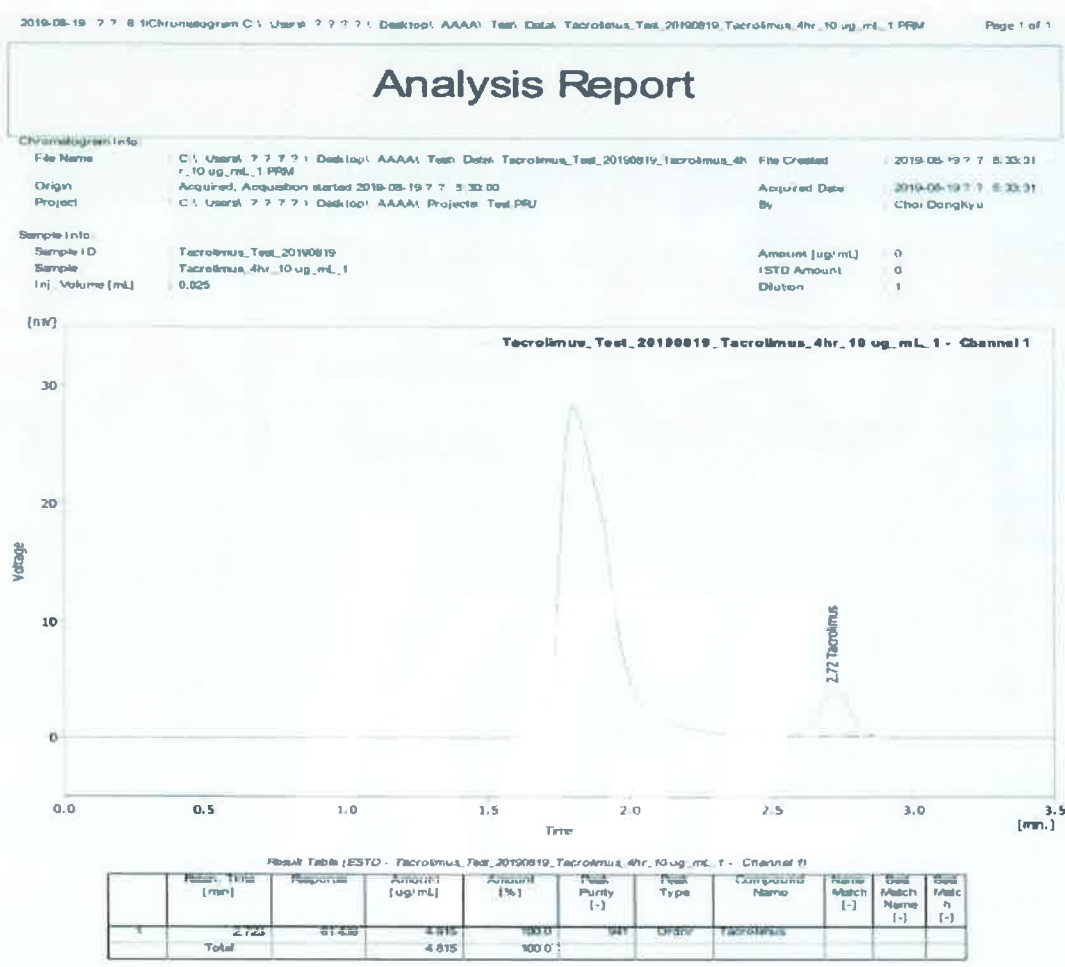
Figure 11. Cyclosporin A(50.000 µg/mL) in 5 % dextrose solution for sampling time at 4 h

----- 다음페이지 계속 -----



# 시험성적서

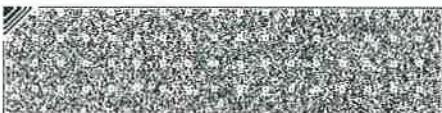
성적서번호 : CT19-089635K



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Figure 12. Tacrolimus(10.000 µg/mL) in 5 % dextrose solution for sampling time at 4 h

----- 다음페이지 계속 -----



# 시험성적서

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Figure 13. TPE tube

----- 끝 -----

