

OATC-181121-FTK-KR0001

Clinical Trial Result Report

‘VITAMIN SHOWER FILTER’ Skin Patch
Primary Irritation Test

Requesting Institute: FILTECHKOREA CO.,LTD.



05. 12. 2018

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Submission Letter

The OATC Skin Clinical Trial Center received consignment for the primary irritation testing of the 'VITAMIN SHOWER FILTER' skin patches requested by FILTECHKOREA CO.,LTD. and following the cosmetics guideline of the Ministry of Food and Drug safety, Declaration of Helsinki and the OATC Skin Clinical Trial Center's standard operation procedure(SOP), we faithfully carried out the test and report the results as follows:

05. 12. 2018



Testing Institute :	OATC Co., Ltd. Skin Clinical Trial Center	CEO	Sang G	
	OATC Co., Ltd. Skin Clinical Trial Center	Center Chief	Ih Seop Chang	
Research Investigator :	OATC Co., Ltd. Skin Clinical Trial Center	Vice President	Won Kyu Hong	

Information on the Testing Institute and Requesting Institute

Test Name	'VITMIN SHOWER FILTER' Skin Patch Primary Irritation Test
Test Control No.	OATC-181121-FTK-KR0001
Test Period	21. 11. 2018 ~ 23. 11. 2018
Report Date	05. 12. 2018

Requesting Institute	Name	FILTECHKOREA CO.,LTD.
	Address	8-19, Songsanpodo-ro 307 beon-gil, Songsan-myeon, Hwaseong-si, Gyeonggi-do, Republic of korea
	Contact Person	Seung Gwan Kong
	Phone No.	031-355-7102
Testing Institute	Name	OATC Co., Ltd. Skin Clinical Trial Center
	Address	1130, Beoman-ro, Geumcheon-gu, Seoul, Republic of Korea
	Name of Head	Ih Seop Chang

Research Investigator	Name	Won Kyu Hong
	Associated Entity	OATC Co., Ltd. Skin Clinical Trial Center

Quality Assurance Statement

Test Name	'VITAMIN SHOWER FILTER' Skin Patch Primary Irritation Test
Test Control No.	OATC-181121-FTK-KR0001
Test Period	21. 11. 2018 ~ 23. 11. 2018

This clinical trial was conducted in accordance with the test plan in consultation with the client, the cosmetics guidelines of the Ministry of Food and Drug safety, Declaration of Helsinki, the OATC Skin Clinical Trial Center Standard Operation Procedure(SOP), and the test results have been faithfully reflected. In addition, all procedures of this test were checked by a quality assurance officer.

1. Do you keep the basic documents (multiple selection possible)?

- Test plan
 Contract
 Agreement
 Case Report Form (CRF)
 Tester resume
 Survey for subject
 Blind release procedure
 Subject compensation regulation
 Reports of serious adverse reaction

2. Summary of test procedure

Division	Number of Subjets
Plan	Over 30
Participating	30
Dropped out	0 / reason for dropping out ()
Completed	30

3. Did the test for the clinical trial proceed according to the test plan?

- Yes No

4. Did the test proceed according to the Standard Operation Procedure(SOP)?

- Yes No

5. Did all subjects sign and date their handwritten consent to participate in the approved study?

- Yes No

(If receiving consent from an agent: Yes No,

reason: _____)

6. Has there been any abnormal occurrence, severity, or specific changes to note?

(If yes, attach and submit)

Yes No

7. Is the subject's information in the Case Report Form (CRF) (multiple selection possible)?

Subject initial Date of birth Subject gender Subject age

8. Are the various documents related to the clinical application research stored in a separate safe place?

Yes No

05. 12. 2018

 Research Investigator: Won Kyu Hong



Quality Assurance Officer: Eun Ji Lim



Clinical trial Results Summary

Test Name	'VITAMON SHOWER FILTER' Skin Patch Primary Irritation Test
Test Control No.	OATC-181121-FTK-KR0001
Testing Institute	OATC Skin Clinical Trial Center
Test Period	21. 11. 2018 ~ 23. 11. 2018
Test Product	VITAMIN SHOWER FILTER
Subjects	Adults aged 20~60 who conform to the inclusion criteria and do not apply to the exclusion criteria
Number of Subjects	Valid evaluation number of people : 30, Drop-out people: 0
Test Method	<ol style="list-style-type: none"> 1. Area applied Applied to flat areas in the back of the subject avoiding the spine area and areas with discoloring or skin damage 2. Evaluation Visual assessment by dermatologist 3. Determine occurrence of irritation Frosch & Kligman, CTFA guideline, Draize method were referenced for determination
Test Results	<p>This clinical trial test was conducted on 30 men and women aged between 20~60 who were applied 'VITAMIN SHOWER FILTER' skin patch for the primary irritation test.</p> <ol style="list-style-type: none"> 1) The test product 'VITAMIN SHOWER FILTER' was applied for 24 hours and after removing it, they were visually evaluated, 30 minutes and 24 hours after removal, by a dermatologist and found to be non-irritating.

1. Test Objective

This test was conducted to evaluate primary irritation of 'VITAMIN SHOWER FILTER' skin patch provided by requesting institute FILTECHKOREA CO.,LTD.

2. Test Product Information

- 1) Test product information

Table 1. Test Product Information

Test Product Name	Test Product Control No.	Form
VITAMIN SHOWER FILTER	181121-K-5	Cream

- 2) Maintenance and storing of test product

When the test products are received, the information is recorded in the sample ledger, then stored in the sample storage room for 1 month after testing. Test products distributed to subjects are retrieved at the end of the testing period and are all disposed without storing.

- 3) Test product safety

The requesting institute is responsible for any adverse reaction from the test products during the test period and must provide compensation. However, medical check-up, examination, hospital bills that are not related to this test shall be borne by the subjects.

3. Institutional Review Board(IRB) Assessment

- 1) The clinical trial regulation

This clinical trial was conducted ethically based on the Declaration of Helsinki and in Korea "Bioethics and Biosafety Law".

- 2) Institutional Review Board(IRB) Assessment

This clinical trial was submitted to the Institutional Review Board and was approved on 16. 11, 2018. There were no specific changes and the end of the study was reported to the Institutional Review Board after completion of the study.

4. Selection of Subject

1) Inclusion Criteria

- (1) Adult men and women between the ages of 20~60
- (2) Fully understands the explanation provided by the research investigator his assigned personnel and is able to prepare and sign the consent form voluntarily
- (3) Healthy person who does not have rapid or chronic physical disease including skin disease
- (4) Who can be followed during the test period

2) Exclusion Criteria

- (1) Women who are pregnant or lactating and women who are potentially pregnant
- (2) Those who use steroid containing external preparations for the treatment of skin disease for over 1 month
- (3) Those who have taken the same test less than 3 months ago
- (4) Sensitive, overly sensitive skin holders
- (5) People who have spots, acne, erythema, pore dilatation on the test site
- (6) Anyone else who the research investigator deems unsuitable for the test

3) Drop-out Criteria

In the following cases, the researcher suspended the test cases, excluded them from the test results and they were record as such in the final report.

- (1) When the subject expressed desire to stop participation
- (2) Skin ailments or adverse reactions appeared on the test area
- (3) If the subject experienced excessive UV exposure to the test site during the test period or due to excessive drinking, smoking causing difficulties with the evaluation
- (4) If the subject is difficult to follow-up due to personal circumstances during the test

4) Confidentiality agreement and obligation to be sincere

- (1) The confidentiality of the subject participating in the study is guaranteed. However, test data may be used to the extent of medical, academic research or marketing purposes to the subject's identity not being revealed.
- (2) The subject must keep all information obtained through this test confidential until the end of the test.
- (3) All subjects participating in the test must prepare the documents sincerely.

5) Selection of subjects

This human body application test was conducted on 30 adult men and women between the ages of 20~60 who met the selection standard and were not applicable for the exception standard.

5. Test Method

This clinical trial was conducted in a temperature/humidity controlled area(indoor temperature 20~25℃, humidity 40~60%) within the OATC Co., Ltd. Skin Clinical Trial Center.

1) Test Method

(1) Test product patch area

Flat area of the subject on the back but avoiding the spine area and areas where there is no skin discoloration or skin damage.

(2) Test method

The subject's back is cleaned with 70% ethanol and dried then the test product 'VITAMIN SHOWER FILTER' is loaded with IQ chamber 20μℓ then fixed on the skin and applied for 24 hours.

(3) Determination of irritation

The existence of skin irritation was assessed by a dermatologist at 30 minutes and 24 hours after removal of the skin patch following determination standards. Skin reaction and skin irritation index was calculated based on the Frosch & Kligman and CTFA guidelines and the Draize method was applied to the skin irritation index to categorize the degree of skin irritation for test substances(Table 2 ~ 3).

Table 2. Skin Irritation Evaluation Criteria

Symbol	Grade	Evaluation Criteria
+	1	Slight erythema, either spotty or diffuse
++	2	Moderate uniform erythema
+++	3	Intense erythema with edema
++++	4	Intense erythema with edema & vesicles

※Skin Irritation Index Formula

Skin Irritation Index

$$= \frac{\left[\left(\frac{\sum_{i=1}^n \text{Evaluation Value}}{n(\text{Number of Test Subjects})} \right) 30\text{min} + \left(\frac{\sum_{i=1}^n \text{Evaluation Value}}{n(\text{Number of Test Subjects})} \right) 24\text{hrs} \right]}{m(\text{Number of times evaluated})}$$

Table 3. Skin Patch Test Results Determination Table

Skin Irritation Index	Irritation Evaluation
0.00 ~ 0.25	No irritation
0.26 ~ 1.00	Mild irritation
1.01 ~ 2.50	Medium irritation
2.51 ~ 4.00	Strong irritation

2) Abnormal Evaluation

At every visit, researchers conducted visual assessment of the skin around the tested area and checked for any degree of symptoms. In addition, the subjects were instructed to report immediately when they felt any adverse reaction during the test period. If a skin adverse reaction occurs, researchers must inform the research investigator immediately and the research investigator must check the symptom to determine the appropriate action and whether to continue participation of the test.



6. Test Results

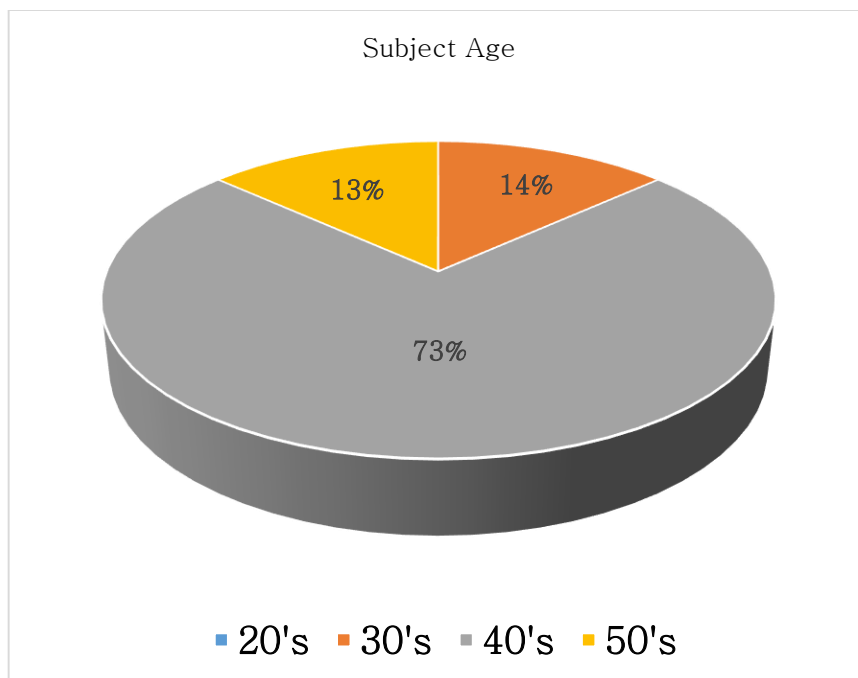
1) Subject Information

30 people completed this clinical trial and their gender and ages are as follows (Table 4, Fig. 1).

Table 4. Subject Information

Participants		30
Drop-out		0
Completed		30
Gender	Female	28
	Male	2
Average age		45.70

Fig. 1. Subject Age



2) Result Determination of Skin Patch

(1) Result determination of skin patch

The test product 'VITAMIN SHOWER FILTER' was applied for 24 hours and after removing it, they were visually evaluated, 30 minutes and 24 hours after removal, by a dermatologist and found to be non-irritating(Table 5).

Table 5. Result Determination of the Skin Patch

Test Product Name	Skin Response		Irritation index	Irritation evaluation
	After 30min.	After 24h.		
VITAMIN SHOWER FILTER	9	0	0.15	No irritation

3) Abnormal reaction evaluation

(1) Evaluation by dermatologist

Physical examination by a dermatologist did not reveal any adverse skin reactions during the study period.



7. Results and Conclusion

This clinical trial was conducted on 30 adult men and women aged 20 to 60 years old who were subjected to primary irritation test using 'VITAMIN SHOWER FILTER' skin patch requested by FILTECHKOREA CO.,LTD.

The test product 'VITAMIN SHOWER FILTER' was applied for 24 hours, and 30 minutes and 24 hours after removal, they went through visual evaluation by dermatologist and were found to be non-irritating.



8. References

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Guidelines for cosmetic clinical and efficacy examination, Ministry of Food and Drug Safty. 2012.

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CTFA Safety Testing Guideline: The Cosmetic, Toiletry and Fragrance Association, Inc. Washington, D.C. 1991:20036.

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Draize J.H. *Dermal Toxicity Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics*, Association of Food and Drug Officials of the United States, Austin, Tex, USA. 1959.

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Frosch P. J. & Kligman A.M. The soap chamber; a new method for assessing the irritancy. *J. Invest. Dermtol.* 1979;40:11-14.

Appendix 1. Subject Information

Control No.	Initial	Age	Gender
1	KYS	47	Female
2	TSM	39	Female
3	MJS	45	Female
4	KMH	44	Female
5	KHJ	46	Female
6	OYG	49	Female
7	SYH	56	Female
8	JSH	45	Female
9	JSY	47	Female
10	PKA	44	Female
11	JMN	49	Female
12	KSJ	40	Female
13	KEY	38	Female
14	KHS	52	Female
15	GJS	49	Female
16	JKR	46	Female
17	LYH	48	Female
18	LJS	49	Female
19	HSS	56	Female
20	AYS	42	Male
21	KHK	46	Female
22	LKS	43	Female
23	PSH	47	Female
24	LJH1	34	Female
25	LSM	46	Female
26	KMS	42	Female
27	KJS	38	Male
28	YHJ	44	Female
29	PCY	54	Female
30	LJH2	46	Female

Appendix 2. Test Product Ingredients

VITAMIN SHOWER FILTER

Corn Starch, Lactose, Gellangum, Ascorbic acid, Glycerin, Gollagen, Aroma Oil



Appendix 3. Results of Determination

1) Skin patch test results determination

VITAMIN SHOWER FILTER		
Control No.	After 30 min of patch removal	After 24 hour of patch removal
1	0	0
2	0	0
3	0	0
4	0	0
5	1	0
6	0	0
7	0	0
8	1	0
9	0	0
10	0	0
11	0	0
12	0	0
13	0	0
14	1	0
15	0	0
16	0	0
17	0	0
18	1	0
19	1	0
20	1	0
21	0	0
22	1	0
23	0	0
24	0	0
25	0	0
26	0	0
27	1	0
28	0	0
29	1	0
30	0	0

Main Equipment of the Testing Institute

1. Skin Visiometer SV700 USB
2. Vacuum pump VP45 4 1 Calibration slide
3. Visioscan(VC98)
4. Skin glossmeter
5. Moisturemeter D
6. VISIA CR-2.3
7. Primos-lite
8. F-ray (research) 2230megapixel general picture / F-ray / UV
9. Antera 3D CS
10. Epsilon (Model: E100)
11. FLIR 530
12. Chromameter(CR400)
13. Cannon EOS 5D MARK4
14. JANUS-1
15. High Performance Skin Ultrasound System(DermaScan C USB)
16. DermaLab Combo Series Specification
 - Moisture / Hydration Probe
 - Sebum sensor
 - TEWL Probe
 - Elasticity Probe
 - Color meter Probe
 - Skin PH Meter
 - Skin Thermometer
17. FOLLISCOPE 5.0
18. KONG (MULTI-FUNCTIONAL SCOPE)
19. Cellulite Inspection System
20. Termohydrostat
21. Operation PC (24V360-LA35K)
21. Korea plus Statistics for Data Analysis Embedded on SPSS Statistics Premium
22. Image Analysis Application for windows - Image-Pro 10

23. Clean bench
24. Constant temperature incubator
25. FACS (Fluorescence activated cell sorter)
26. JULI stage
27. Chemidoc
28. Western blot
29. A bacteria incubator
30. Centrifuge
31. ELISA reader
32. LC-MS/MS
33. HPLC
34. ICP-MS
35. ICP-OES
36. AAS
37. Automatic mercury analyzer
38. IC
39. UV-VIS
40. GC-FID
41. GC-MS
42. Head space



Researcher CV

1. Center Head

1) Personal details

Name: Ih Seup Chang

2) Education

1977~1981: Seoul National University, Industrial Chemical Engineering

1981~1983: Seoul National University, Industrial Chemical Engineering, Masters in Biotechnology

1985~1992: Seoul National University, Industrial Chemical Engineering, PhD in Biotechnology

2001~2003: Aju University, MBA

3) Career

1983~2007: AmorePacific Skn Technology Research

2000~2005: National Research Lab (NRL) Business, Researcher in-charge, Nanotech research

2003 ~2005: Jungang University Industrial Graduate School Adjunct Professor (Nano bio area)

2005~2006: Ministry of Health and Welfare, Committee member senior service promotion business

2006: World Cosmetic Scientist Society committee member (Korean representative of review board)

2008~2014: Bioland medical device business unit

2014~2017: Chungnam Technopark Biocenter Head

2015~: Committee member of Korea Polytech, Bio area committee member

2015~2017: Committee member of Chungnam Marine New Business Development Association

2018~: OATC Skin Clinical Trial Center Head

4) Academic Activities

Life time member of the Korean Society for Biotechnology and Bioengineering

Member of the Korean Journal of Chemical Engineering

Member of the Polymer Society of Korea

Member of the Korean Society of Industrial and Engineering Chemistry

Chief editor of the Society of Cosmetic Scientists of Korea

Director of the Korean Society for Skin Barrier Research

5) Awards

1984 Presidential citation (Science technology development expansion meeting)

2001 Precision technology development competition, Minister's Award, (Skin friendly seramide)

2002 Ministry of Science and ICT, Minister Award (Science day)

2002 Korea Health Industry Development Institute Grand Award (Health & welfare technology competition)

2003 Ministry of Health and Welfare, Minister Award (Stabilizing technology for cosmetic substances)

2004 Ministry of Science and ICT, IR52 Jangyoungsil Award (Developing nanocomposite UV blocker)

2004 Ministry of Health & Welfare, Minister Award (Cosmetic substance detecting technology)

2005 Ministry of Health & Welfare, Minister Award (Wrinkle improvement technology and Elastinate development)

2007 Awarded Korea new technology (NET) Award (Enzyme to organism conversion technology development)



2. Research Investigator

1) Personal Details

Name: Won Kyu Hong

2) Education

2004: Inha University, Medical school, Bachelor

2004~2005: Inha University Hospital intern

2005~2009: Inha University Hospital resident

2007: Inha University, Medical school, Master

3) Career

2004: Acquired medical license (license no.: 83931)

2009: Acquired license for dermatology (license no.: 1771)

2009~2012: Korean Hansen Welfare Association, Chunbuk branch, Head of Annex center

2013~2015: Pyungtaek Human Dermatology, Chief Director

2013~: Inha University, Adjunct professor of Skin Science Class

2016~: Chungra Human Dermatology, Chief Director

2018~: Human Cosmetic, Research Director

2018~: International St. Mary's Hospital, Adjunct Professor

2018~: OATC Skin Clinical Trial Center, Research Director

4) Academic Activities

Member of the Korean Dermatological Association

Member of the Korean Society for Acne Research

Member of the Korean Hair Research Society

Member of the Korean Association of Dermatologists

2018~: Information committee member of Korean Association of Dermatologists

2018~: Planning & policy committee member of Korean Association of Dermatologists

3. Quality Assurance Officer

1) Personal Details

Name: Eun Ji Lim

2) Education

2008~2011: Youngnam University, Bachelor in Food and Nutrition

2011~2013: Youngnam University, Master in Food and Nutrition

3) Career

2018~: OATC Skin Clinical Trial Center, Assistant Manager

4. Researcher

1) Personal Details

Name: Jong Seon Lee

2) Education

2009~2013: Mokpo University, Bachelor in Oriental Medicine Resources

3) Career

2018~: OATC Skin Clinical Trial Center, Assistant Manager

1) Personal Details

Name: Ji Sun Han

2) Education

2006~2010: Sungkyul University, Bachelor in Beauty Design

2010~2012: Sungkyul University, Master in Beauty Education

3) Career

2018~: OATC Skin Clinical Trial Center, Assistant Manager

1) Personal Details

Name: Bo Ram Kim

2) Education

2010~2013: Suwon Science College, Bachelor in Tourism Chinese

3) Career

2018~: OATC Skin Clinical Trial Center, Associate

1) Personal Details

Name: Ju Seon Lee

2) Education

2010~2014: Chungju National University, Department of Biotechnology, bachelor of engineering (science)

2014~2016: Incheon National University, Department of Cosmetic Science & Management, Master of Science

3) Career

2018~: OATC Skin Clinical Trial Center, Employee

1) Personal Details

Name: Hae Na Lee

2) Education

2011~2016: Sooncheonhyang University, Bachelor in Bio Medical Laboratory Science, Cosmetical Science

3) Career

2018~: OATC Skin Clinical Trial Center, Employee

1) Personal Details

Name: Hong Bi Kim

2) Education

2013~2016: Silla University, Bachelor in Pharmaceutical Engineering

2015~2018: Silla University, Master in Pharmaceutical Engineering

3) Career

2018~: OATC Skin Clinical Trial Center, Employee



Research Performance

1. Center Head

No.	Thesis
1	Hye Won Kang, Kwang Won Yu, Woo Jin Jun, Ih Seop Chang, Sang Bae Han, Hee Yun Kim, Hong Yon Cho. Isolation and characterization of alkyl peroxy radical scavenging compound from leaves of <i>Laurus nobilis</i> . <i>Biol. Pharm. Bull.</i> . 2002;25(1):102-108
2	Jin-Woong Kim, Ji-Young Ko, Jin-Gyu Park, Jung-Bae Jun, Ih-Seop Chang, Kyung-Do Suh. Fine polystyrene latexes with reactive poly(ethylene oxide)-poly(propylene oxide)-poly(ethylene oxide) triblock macrosurfactants in modified miniemulsion polymerization. <i>J. Applied Polymer Science</i> . 2002;85(2):328-332
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8	Bae-Hwan Kim, Seong-Joon Moon, Ih-Seop Chang, Young-Chul Sim, Jin-Cheon Hong, Ki-Moon Kim, Moon-Uk Park, Chang-Seok Rhoo, Min-Seok Jeong, Kyung-Sun Kang, Yong-Soon Lee. Validation study in Korea for HET-CAM test and NRU assay as alternatives to the Draize eye irritation test. <i>Altern. Animal test. Experiment</i> . 2002;8(3-4):78-90
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10	Chunja Nam, Sujong Kim, Youngchul Sim, Ihseop Chang. Anti-Acne Effects of Oriental Herb Extracts: A Novel Screening Method to Select Anti-Acne Agents. <i>Skin Pharmacology and Applied Skin Physiology</i> . 2003;16(2):84-90
11	Sun Sang Kwon, Yoon Sung Nam, Jong Suk Lee, Bong Seok Ku, Sang Hoon Han, Jang Young Lee, Ih Seop Chang. Preparation and characterization of coenzyme Q10-loaded PMMA nanoparticles by a new emulsification process based on microfluidization. <i>Colloids and Surfaces A: Physicochemical and Engineering Aspects</i> . 2002;210:95-104
12	Hee-Kyung Ju, Jin-Woong Kim, Sang-Hoon Han, Ih-Seop Chang, Han-Kon Kim, Hak-Hee Kang, Ok-Sub Lee, Kyung-Do Suh. Thermotropic liquid-crystal/polymer microcapsules prepared by in situ suspension polymerization. <i>Colloid Polym. Sci.</i> . 2002;280:879-885
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14	Yoon Sung Nam, Ju Young Park, Sang-Hoon Han, Ih-Seop Chang. Intracellular drug delivery using poly(D,L-lactide-co-glycolide) nanoparticles derivatized with a peptide from a transcriptional activator protein of HIV-1. <i>Biotech. Letters.</i> . 2002;24:2093-2098
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16	Hyung Seok Kang, Sun-Sang Kwon, Yoon-Sung Nam, Sang-Hoon Han, Ih-Seop Chang. Determination of Zeta Potentials of Polymeric Nanoparticles by the Conductivity Variation Method. <i>J. of Colloid and Interface Science</i> . 2002;255:352-355

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18	Duck Hee Kim, Jae-Sung Hwang, Heung Soo Baek, Kil-Joong Kim, Byeong Gon Lee, Ihseop Chang, Hak Hee Kang, Ok Sub Lee. Development of 5-[(3-Aminopropyl)phosphinoxy]-2-(hydroxymethyl)-4H-pyran-4-one as a Novel Whitening Agent. <i>Chem. Pharm. Bull.</i> 2003;51(2):113-116
19	Yoon Sung Nam, Hyung Seok Kang, Ju Young Park, Tae Gwan Park, Sang-Hoon Han, Ih-Seop Chang. New micelle-like polymer aggregates made from PEI-PLGA diblock copolymers: micellar characteristics and cellular uptake. <i>Biomaterials.</i> 2003;24:2053-2059
20	Y.C.Sim, Y.S.Nam, Y.H.Shin, E.Shin, S.Kim, I.S.Chang, J.S.Rhee. Proteolytic enzyme conjugated to SC-glucan as an enzymatic transdermal drug penetration enhancer. <i>Pharmazie.</i> 2003;58:252-256
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