

Innovation for Better Quality of Life

EstroG-100®

Novel Proprietary Herbal Formula for
Women's Health

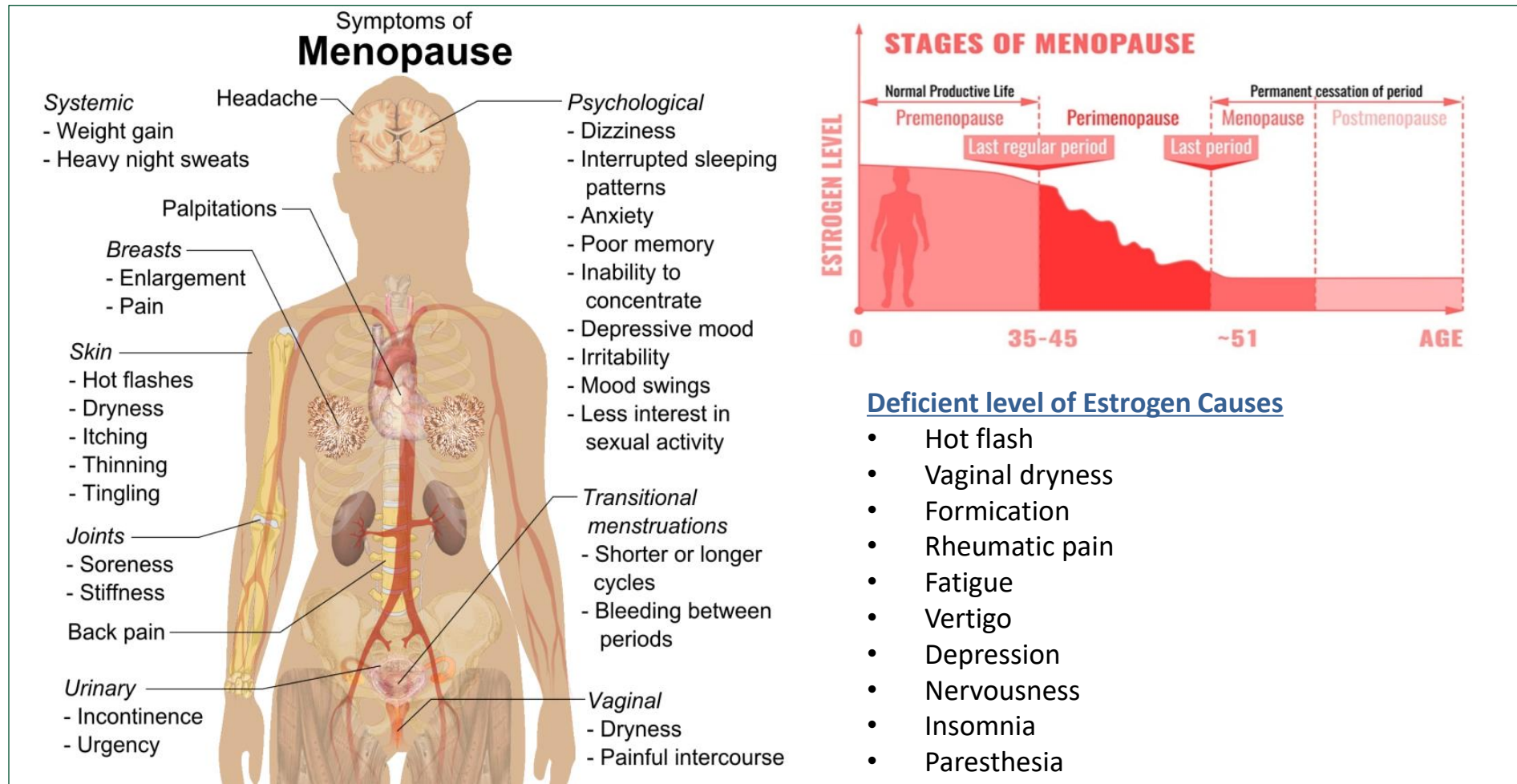
Herbal Hormone Research Institute



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01. About Menopause




- ✓ Menopause occurs when the levels of reproductive hormones (estrogen & progesterone) decline & ovaries stop producing eggs.
- ✓ Menopause is a natural process that all women go through.



02. What is EstroG-100

- **EstroG-100** is patented natural botanical blend, made from natural ingredients, there are *Cynanchum wilfordii*, *Phlomis umbrosa*, and *Angelica gigas* Nakai, which has been used for more than 400 years as a traditional medicine in Korea.
- **EstroG-100** is suitable for the market demand and has been a great spotlight as a safe and effective product for improving women's quality of life.
- **EstroG-100** has been confirmed:
 - ✓ to improve **10 menopausal symptoms without any adverse effects** through 3 clinical studies (no increase in body weight and serum hormone levels).
 - ✓ to improve some of the symptoms, **such as hot flash, bone mineral density, sleep disorders, anxiety and fatigue from animal studies.**
 - ✓ to be safe by **single oral dose, repeated oral dose, and genetic toxicity studies** and by **estrogen receptor binding study**, which makes it distinguishable from other products binding to the estrogen receptors and causing adverse effects.

EstroG-100[®]: Raw material

	C. Wilfordii	P. Umbrosa	A. Gigas
Scientific Name	Cynanchum wilfordii Hemsley	Phlomis umbrosa Turczaninow	Angelica gigas Nakai
Family Name	Asclepiadaceae	Labiatae	Umbelliferae
Common Name	白首乌, Baishouwu 隔山牛皮消, Ge Shan Niu Pi Xiao	糙苏, Cao Su 续断, Xu Duan	当归, Dong Quai
Range	East Asia	East Asia-northern China, Korea	East Asia
Official compendium	Korean Food Code, KHP	Korean Food Code, KHP	KP, CP, JP, EP
Photo			
History	<ul style="list-style-type: none"> Recorded in Dong-Eui-Bo-Gam (Heo, 1610). Used for more than 390 years in Northern China and Korea. Applications for women’s disordered symptoms related to pregnancy and birth, preventing the aging of the body, and especially strengthening the bones and muscles. Toxicologically safe. 	<ul style="list-style-type: none"> Recorded in Dong Eui Bo Gam (Heo, 1610). Used more than 390 years in Northern China and Korea. Applications for pains, skin damage, and putting together of muscles and bones as its name stands for (in Korean the name Sok dan means “connecting of the cut”). 	<ul style="list-style-type: none"> Recorded in Dong-Eui-Bo-Gam(Heo, 1610). Used more than 390 years in Korea at least. Applications for women, has effects on menstrual irregularities and menstrual pain, and is known to have some effects on forgetfulness, insomnia, mental anxiety, and anti-inflammatory effects.

03. Summary of EstroG-100 Clinical Studies

	Clinical Study I	Clinical Study II	Clinical Study III
Study Location	Seoul, Korea (2003~2004)	CA, USA (2010)	Suwon & Seoul, Korea (2014)
Test Period	12 weeks (Safety : 52 weeks)	12 weeks	12 weeks
Test Compound & Dosage	EstroG-100 & 514mg/day		
Study Participants	47 (23/24)	61 (29/32)	96 (48/48)
Efficacy	Climacteric Symptoms : improvement by 5 times	KMI improvement	KMI improvement
	Femoral BMD & Serum Osteocalcin improvement and Menopausal symptoms	Improvements on 10 individual Menopausal symptoms	Improvements on 9 individual Menopausal symptoms
Safety	No serious adverse event No significant statistical difference between baseline and end-time and between the two groups on weight, BMI, serum estrogen and follicular stimulating hormone(FSH)		

Clinical Study 1 : Protocol

Clinical Study I

Test Method	Randomized, double-blind, placebo-controlled study - Primary endpoint : Interview on the improvement of menopausal symptoms - Secondary endpoint : Evaluation of effectiveness (BMD, Serum Osteocalcin, Serum ALP, etc.)
Study Location	Samsung Cheil Hospital (in Seoul, Korea)
Test Period	- Primary endpoint (Climacteric syndrome) : 12 weeks - Secondary endpoint & Safety : 52 weeks (May 2003 – April 2004)
Dosage	514mg/day as EstroG-100
Study Participants	23 subjects in placebo group & 19 active group (48 enrolled and 6 drop out)
Inclusion Criteria	Age of 46 ~ 66 & Diagnosis of menopausal syndrome (average age=54)

Ref: J. Korea Society of Menopause, 11(1); 16~26 (2005)

Clinical Study 1 : Result (1)

[Primary Endpoint Evaluation : Change of Climacteric Symptoms after 3 months]

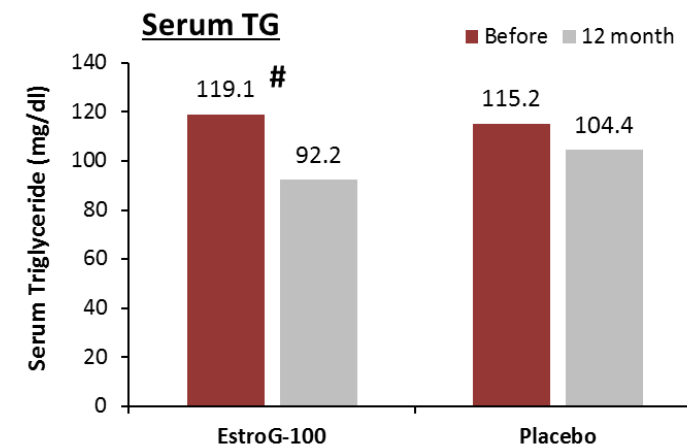
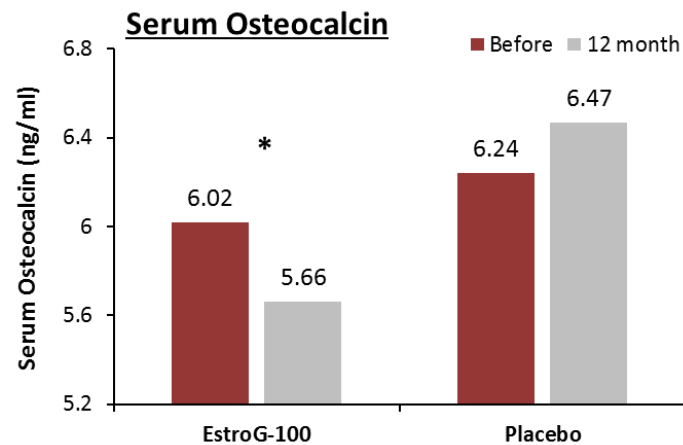
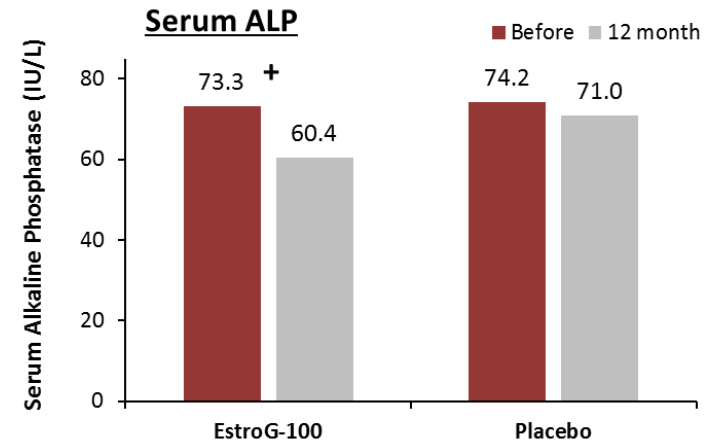
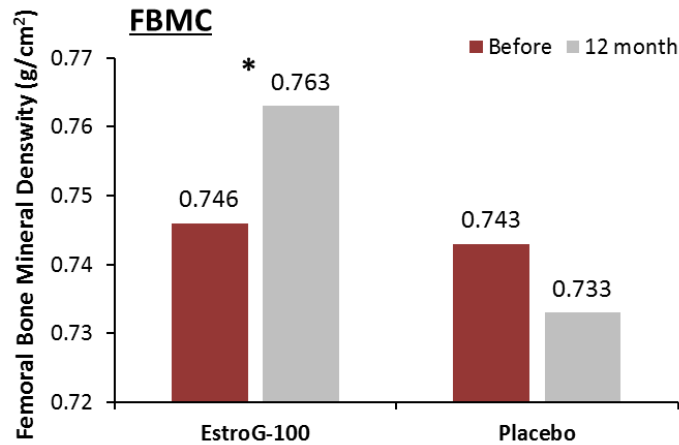
		Change of Climacteric Symptoms		Total
		No improvement	Improvement	
Placebo Group	Case	18	5	23
	(%)	78.3%	21.7%	100%
Study Group	Case	10	14	24
	(%)	41.7%	58.3%	100%
Total	Case	28	19	47
	(%)	59.6%	40.4%	100.0%

OR=5.04 (95% C,I : 1,4-18,1), Fisher's Exact Test

**Improvements with statistical significance
on climacteric symptoms by 5 times compared to placebo**

Clinical Study 1 : Result (2)

[Secondary Endpoint Evaluation]



*: $p < 0.05$, #: $p = 0.06$, +: $p = 0.08$ compared to placebo by Mann-Whitney test

Clinical Study 2 : Protocol

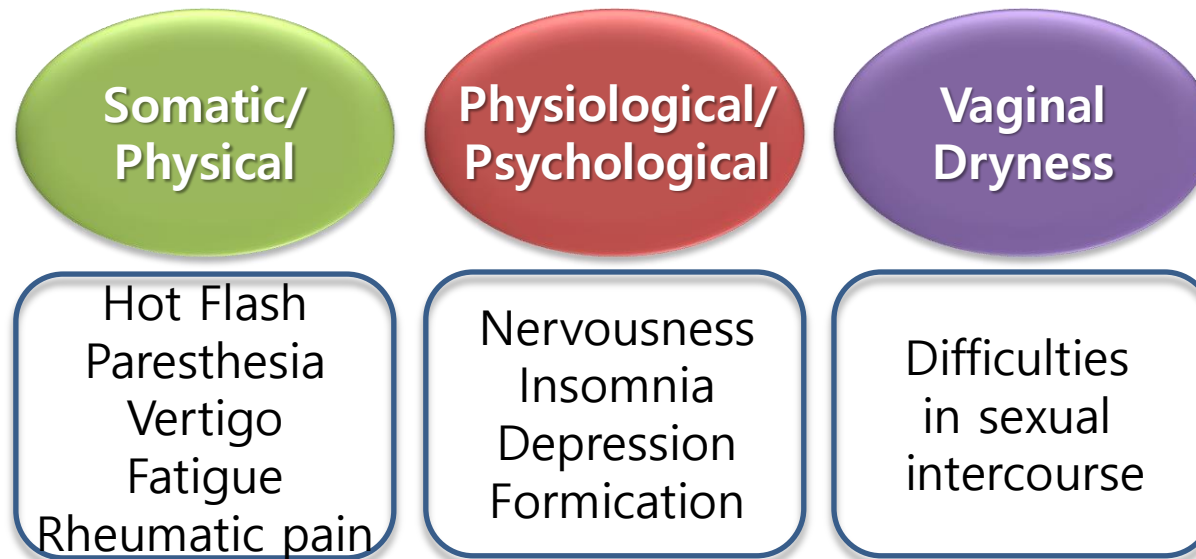
Clinical Study II

Test Method	Randomized, double-blind, placebo-controlled study - Primary endpoint : Mean change of questionnaire (Kupperman Menopausal Index) - Secondary endpoint : Mean change in scores of the 11 individual menopausal symptoms of KMI and Vaginal Dryness
Study Location	Friends Medical Group (in California, USA)
Test Period	12 weeks (May 2009 – January 2010)
Dosage	514mg/day as EstroG-100
Study Participants	32 subjects in placebo group & 29 active group (64 enrolled and 3 drop out)
Inclusion Criteria	Age of 42 ~ 70, Diagnosis of menopausal syndrome (average age = 53)

Ref: Phytother. Res. 26; 510~516 (2012)

Clinical Study 2 : Result (1)

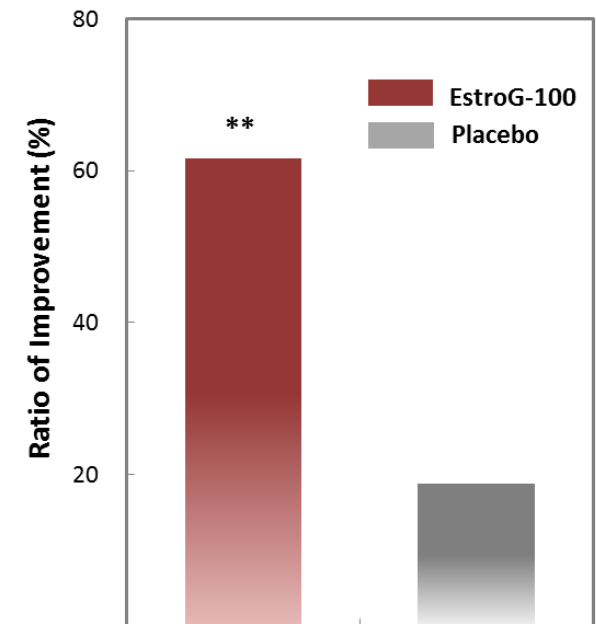
Significant improvements on total KMI & 10 individual Menopausal Symptoms



[Safety Evaluation]

No significant change in Weight, BMI, E2 and FSH, etc. in EstroG-100 groups after 12 weeks ($p > 0.05$, t-test)

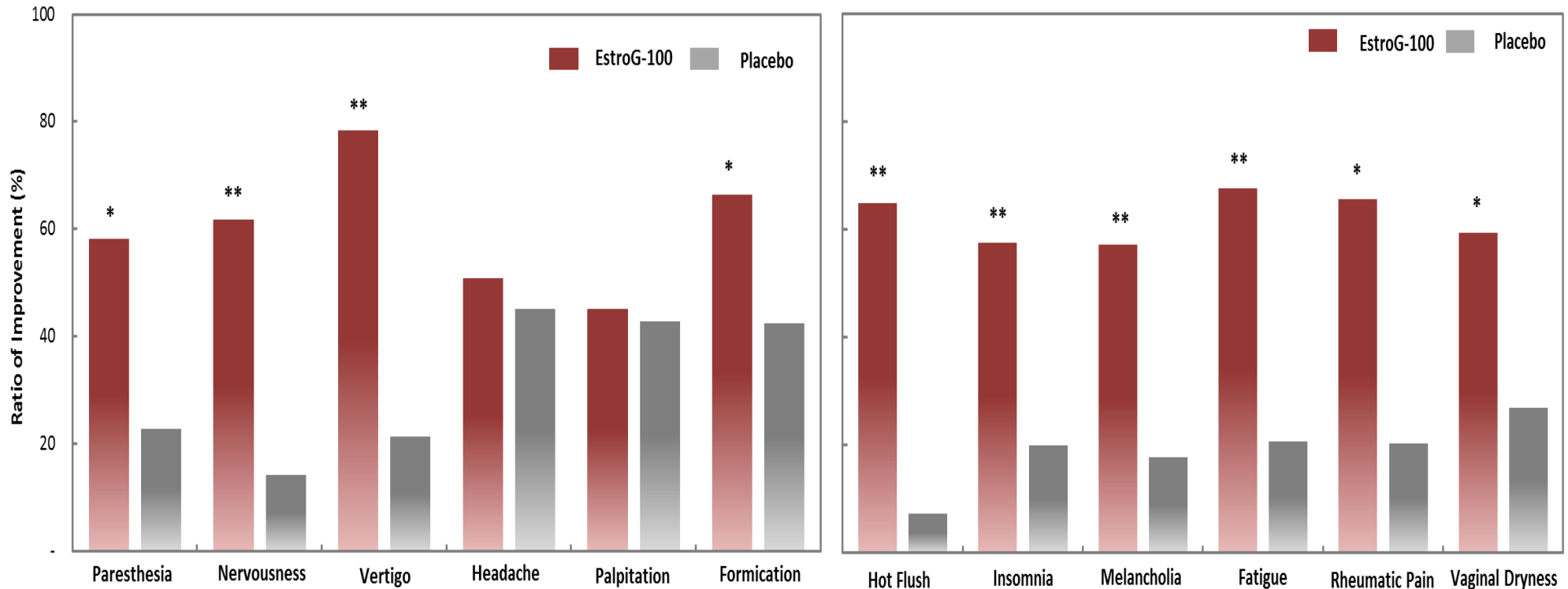
[Mean Change of KMI]



** , $p < 0.01$ compared between groups by t-test

Clinical Study 2 : Result (2)

[Change of Individual Menopausal Symptoms]



*, p<0.05; **,p<0.01 compared between groups by t-test

Clinical Study 3 : Protocol

Clinical Study III

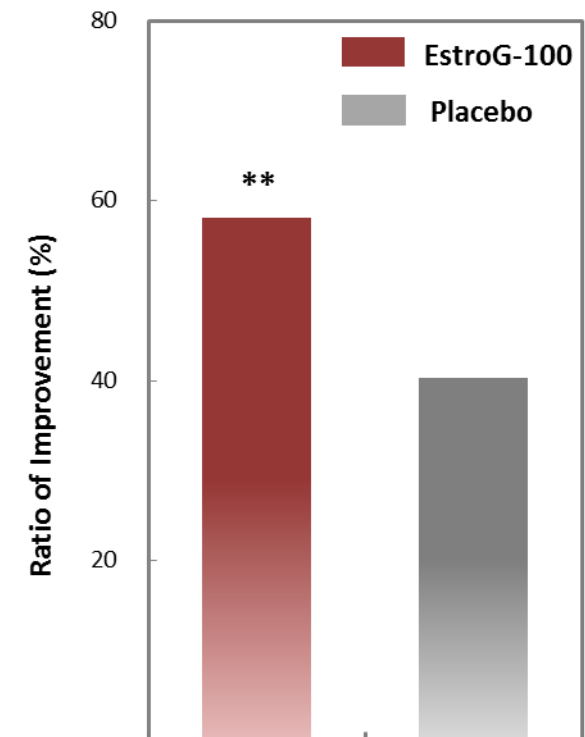
Test Method	Multicenter, randomized, double-blind, placebo-controlled study - Primary endpoint : Mean change of questionnaire (Kupperman Menopausal Index) - Secondary endpoint : Mean change in scores of the 11 individual menopausal symptoms of KMI and vaginal dryness
Study Location	i. Ajou University Medical Center, ii. Korea University Anam Hospital, iii. Yonsei University College of Medicine Severance Hospital (in Seoul & Suwon, Korea)
Test period	12 weeks (March – August 2014)
Dosage	514mg/day as EstroG-100
Study Participants	96 female participants of age of 40~70 with menopausal symptoms (105 enrolled and 9 drop out)
Inclusion Criteria	Age of 40 ~ 70 with menopausal syndromes (average age = 54)

Clinical Study 3 : Result (1)

Significant Improvements on KMI & 9 individual Menopausal Symptoms

- The result almost **duplicated in the 2nd Clinical Study (Non-Asian)** by **improving as many as 9 different symptoms (Hot flush, paresthesia, nervousness, melancholia, vertigo, fatigue, formication, rheumatic pain & vaginal dryness)**
- No significant differences or changes observed in **endometrial thickness**
- No change in weight, BMI, and the level of estrogen and FSH
- No adverse events reported during the study

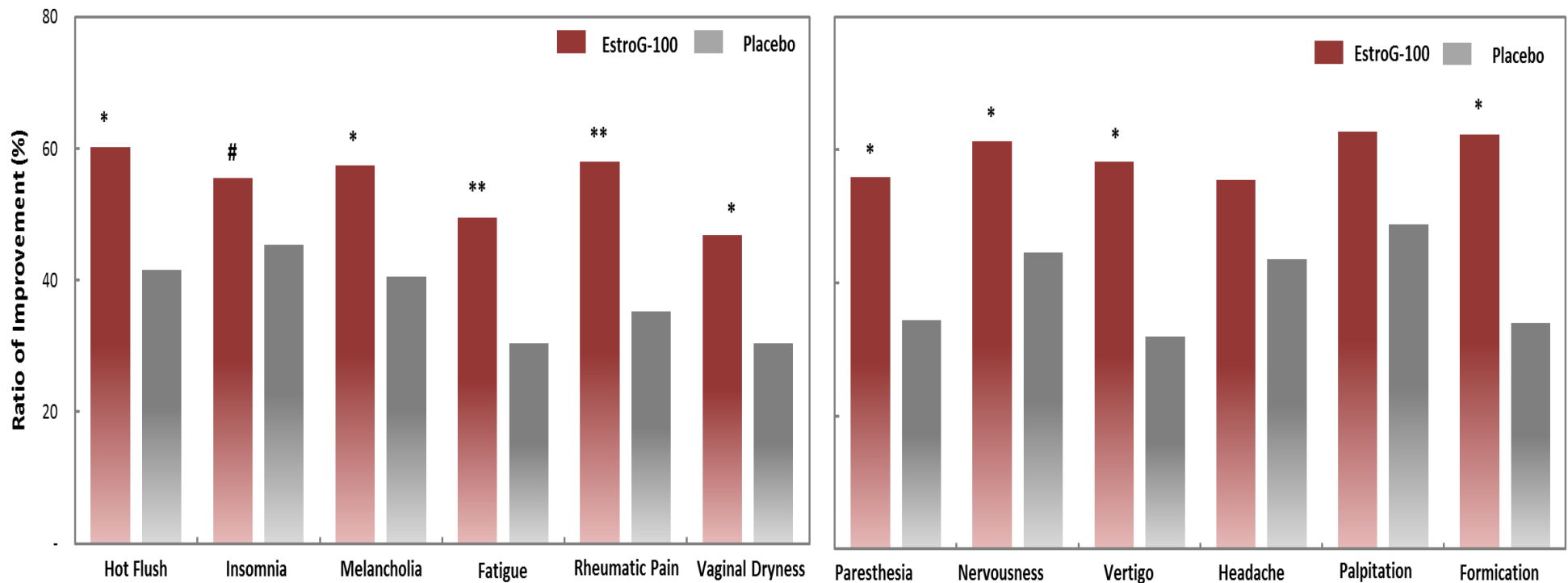
[Mean Change of KMI]



** , p<0.01 compared between groups by t-test

Clinical Study 3 : Result (2)

[Change of Individual Menopausal Symptoms]



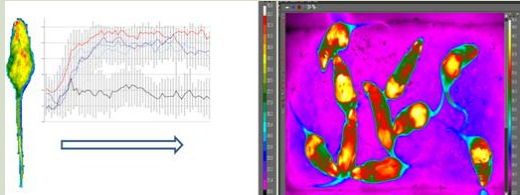
*, $p < 0.05$; **, $p < 0.01$; #, $p = 0.084$ compared between groups by t-test

04. Summary of EstroG-100 MOA(1)

Menopausal Symptoms




Hot Flash

Method	Result
<ul style="list-style-type: none"> Evaluation of Tail skin temperature in OVX rat model (<i>in vivo</i>) 	<ul style="list-style-type: none"> Reduction of tail skin temperature induced by Yohimbine or artificial Stress J. Food and Nutrition Research, 6, 116-123, 2018 <p>Improve Hot flush in clinical study (Kupperman Index)</p>



Joint Pain

Method	Result
<ul style="list-style-type: none"> Evaluation of Osteoarthritis in paw edema model or MIA model (<i>in vivo</i>) <p>1% Carrageenan</p>  <p>Not treated Normal Celecoxib</p>	<ul style="list-style-type: none"> Reduction of paw edema and increase motility →via Anabolic factor increase and Catabolic factor decrease Prev. Nutr. Food Sci., 21, 310-316, 2016 <p>Improve joint pain in clinical study (Kupperman Index)</p>



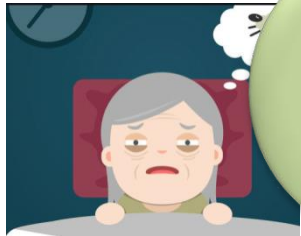
Decrease of Bone Density

Method	Result												
<ul style="list-style-type: none"> Evaluation of osteoporosis in OVX rat model (<i>in vivo</i>) TRAP assay (<i>in vitro</i>) <table border="1"> <thead> <tr> <th>RANKL</th> <th>-</th> <th>+</th> <th>+</th> </tr> <tr> <th>Sample</th> <th>-</th> <th>-</th> <th>ALN 10uM</th> </tr> </thead> <tbody> <tr> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table>	RANKL	-	+	+	Sample	-	-	ALN 10uM					<ul style="list-style-type: none"> Increase effects of bone mineral density in OVX rats →via suppression of osteoclast differentiation Korean J. Food SCI. TECHNOL., 40; 316~320, 2008
RANKL	-	+	+										
Sample	-	-	ALN 10uM										

04. Summary of EstroG-100 MOA(2)

Menopausal Symptoms

Sleep Disorder



- Evaluation of pentobarbital induced model (*in vivo*)
- Evaluation of GPCR assay (*in vitro*)



- Improve of sleep latency and duration time → **via adenosine A1 receptor agonist effect**
- *unpublished*; ongoing, confidential.

Improve sleep disorder in clinical study (Kupperman Index)

Symptom of Depression



- Evaluation of chronic resistance stress induced model (*in vivo*)
- Evaluation of 5-HT₆ receptor activity assay (*in vitro*)



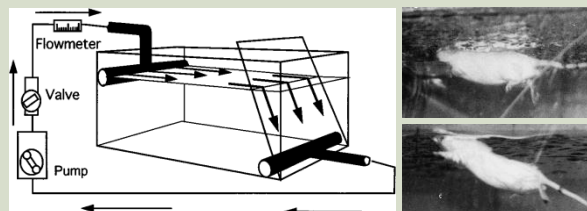
- Decrease immobility, increase swimming, decrease corticosterone in serum → **via increase neurotransmitter and agonist effects of 5-HT₆ receptor**
- J. Physiol & Pathol Korean Med. 32, 247 ~ 254, 2018

Improve depressive mood in clinical study (Kupperman Index)

Fatigue



- Evaluation of adjustable-current swimming test (*in vivo*)



- Increase muscular motility (swimming time) → **via increase fatigue regulation factor in muscle and improve anti-oxidant factor in liver**
- *unpublished*; ongoing, confidential.

Improve fatigue in clinical study (Kupperman Index)

05. Summary of EstroG-100 Safety Studies

Safety & Other proven features

- **Safety from 3 clinical studies**
 - ✓ No adverse event at all subjects
 - ✓ No change in serum biochemical and hematological parameters
- **Acute toxicity study in rat**
 - ✓ No toxic event at all dose range
 - ✓ NOAEL 4,000 mg/kg
- **26 weeks sub-acute toxicity study in rat**
 - ✓ No toxic event at all dose range
 - ✓ NOAEL 1,500 mg/kg/day
- **Genotoxicity study**
 - ✓ No genotoxicity
- **Estrogen receptor binding assay**
 - ✓ No estrogenic activity

Toxicology test

Acute toxicity Study in SD rat

- Oral administration of EstroG-100 in rat at 4,000mg/kg
- **No toxicity event at 4,000mg/kg**

26 weeks sub-chronic toxicity study in SD rat

- Oral administration of EstroG-100 in SD rat at 750, 1000, 1500 mg/kg
- No toxicity event at all dose range
- **NOAEL 1500 mg/kg/day**

AMES test

- Administration of EstroG-100 in *Salmonella typhimurium* (TA98, TA100, TA1535 and TA1537) and *E. coli* (WP2uvrA (pKM101)), at 8.19, 20.5, 51.2, 128, 320, 800, and 2000 µg/plate concentration
- **No mutagenicity at all test concentrations**

Chromosomal aberration assay

- Administration of EstroG-100 in Chinese Hamster Lung (CHL/IU) cells at 1000, 2500 and 5000 µg/ml
- **No metabolic activation to the chromosome aberrations at all test concentrations**

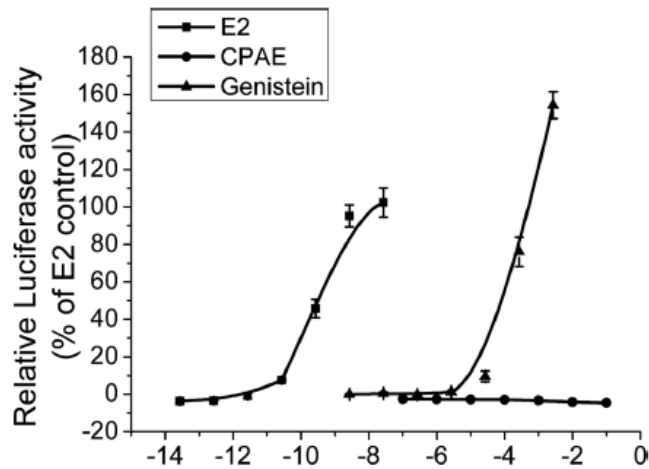
Micronucleus test in mice

- Oral administration of EstroG-100 in mice at 30, 100, 300, 1000, 2000 mg/kg
- No mortality and clinical signs in any animals
- **No mutagenicity on micronucleus formation and cytotoxicity in bone marrow cells of mice at all concentrations**

Estrogenic activity

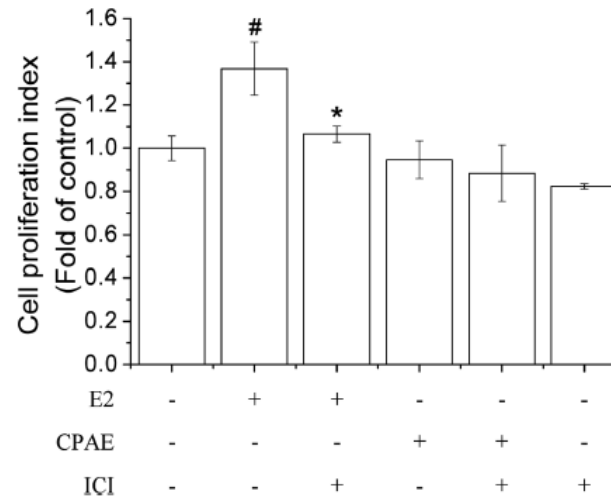
EstroG-100 can be used as beneficial herbal ingredients for menopausal women

Estrogenic activity in STTA assay

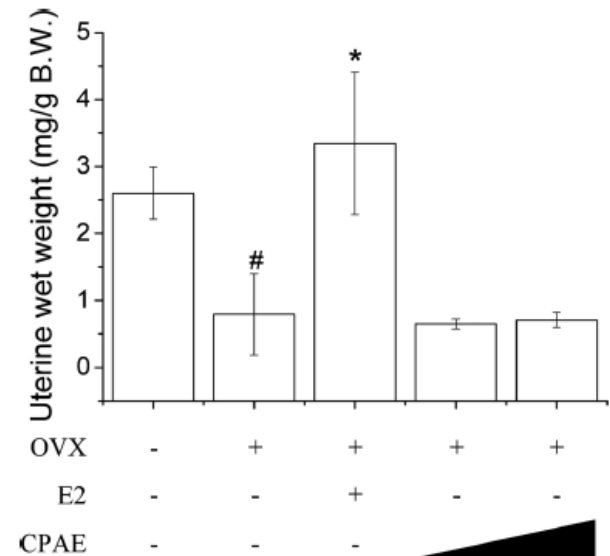


Test method: OECD Guideline TG 455

Effect on growth of MCF-7 cells



In vivo effect in uterotrophic assay



※ CPAE: EstroG-100, ICI: ER antagonist

Ref: Toxicol. Res. 33(1), 71~77 (2017)

EstroG-100 COMMERCIAL HIGHLIGHTS_Korea

Korea Brand "Estrition"



정제로 한번
빛을 쬐양송이 버섯을 오뎀이 갈아넣은
비타민D로 간편하게 뼈 건강 케어!

액상으로 또 한번
10년의 연구가 담겨있는 타르체리 및
백수오 앰플로 맛있게 갠년기 케어!



**1일 2포면 충분한
백수오 등 복합추출물
함량**

1통에 30포가 들어있으며
1포 개별포장으로 언제 어디서나
간편하게 드실 수 있습니다.



EstroG-100 COMMERCIAL HIGHLIGHTS

dm & Rossmann & Pharmacy (EU)



Walgreens & CVS & Whole Foods (U.S)



Rexall, Shopper's Drug Mart & Loblaws (Canada)



USA-Now Foods



USA-Life Extension



USA-Doctors Best



Canada-Profemin



USA -Meijer



Canada -Swiss Naturals



Canada -Menomend



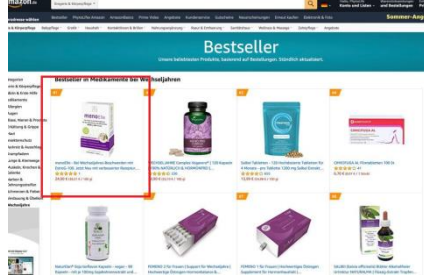
Philippines - Angel E



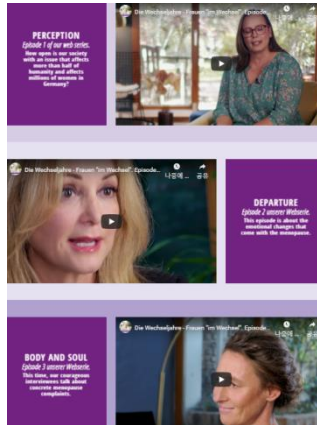
EU- Menoelle

EstroG-100 COMMERCIAL HIGHLIGHTS_EU

HSE 24



Best menopause supplement seller in category in dm



★★★★★ Petrak7 · 2 months ago
Finally no more hot flashes.

After my gynaecologist advised me about the product menoElle, I am now really excited after 3 months. My hot flashes are virtually non-existent and my restless, sleepless nights are a thing of the past. Overall, I feel more balanced and positive. It is great that there is finally an alternative to the previous plant products with the vegetable hormones, which can only be taken for a short time anyway. After trying a lot over the last few years, I have now found real help with menoElle. Have already seen it in the pharmacy. I can only recommend anyone who also suffers greatly from the menopause.

★★★★★ Marel · 2 months ago
Only to be recommended

Hello I wouldn't have thought in life that these tablets help I have tried so much that you can not imagine because of the hot flashes that were not to bear then I became aware of these tablets in the internet everywhere stood they help I am then to dm and I got them I took these tablets on 7 day was already an improvement and after 4 weeks everything is gone between it still comes through the heat but very little easy I have been taking the tablets for three months now and can only recommend this to the women who are desperate as I was it was incredible but it really helps

★★★★★ TAOB · 4 year ago
Finally something that helps to absolutely recommend !!

I was critical and was taught something to the contrary. After only 1 week I have already noticed slight improvements. In the meantime, I can say with certainty that Menoelle definitely helps me. I feel more comfortable, feel like myself again, don't sweat as much at night, and especially have no other "side effects". I will definitely continue to take Menoelle and recommend it to my girlfriends. In the past I have tried other things, actually mostly without any change, here it is different. TOP, thank you DM

★★★★★ Sus54 · 1 year ago
after four weeks without complaints

Since many women are looking for herbal products for menopause, I would like to give a very positive feedback on the menoelle product. I'll take it now for four weeks and I'm thrilled. I am almost free of complaints and right now, when it is so warm, I no longer suffer from the hot flashes that I had particularly strong. There are now many positive reports on the active substance on the internet. Apparently, there is finally a product that works and that also without hormones and soy estrogens. Since I had cancer, these products are out of the question for me anyway. Thanks to DM for an affordable and over-the-counter product for my menopause.



06. Summary EstroG-100



EstroG-100[®]
Quality of Life

- ✓ **Natural Botanical Menopause Solution**
- ✓ **Clinically Proven to be effective and safe**
- ✓ **Significantly improves 10 menopausal symptoms**
- ✓ **No side effects**
- ✓ **No estrogenic activity**
- ✓ **International Approvals(US, Canada, Europe)**
- ✓ **Manufacture at GMP facility**

EstroG-100 is a powerful combination of three botanical root extracts proven to relieve the toughest symptoms of menopause whether you're 40 or 60. Inspired by traditional Korean herbs used for centuries, this revolutionary formula is standardized, consumer tested and clinically proven to be safe and work fast on the most common effects of menopause. So just because "the change" is part of your life, it doesn't mean symptoms have to be.

Paper published in Healthcare sector of MDPI

Safety Assessment of Endocrine Disruption by Menopausal



Review

Safety Assessment of Endocrine Disruption by Menopausal Health Functional Ingredients

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Abstract: During menopause, women experience various symptoms including hot flashes, mood changes, insomnia, and sweating. Hormone replacement therapy (HRT) has been used as the main treatment for menopausal symptoms; however, other options are required for women with medical contraindications or without preference for HRT. Functional health foods are easily available options for relieving menopausal symptoms. There are growing concerns regarding menopausal functional health foods because the majority of them include phytoestrogens which have the effect of endocrine disruption. Phytoestrogens may cause not only hormonal imbalance or disruption of the normal biological function of the organ systems, but also uterine cancer or breast cancer if absorbed and accumulated in the body for a long period of time, depending on the estrogen receptor binding capacity. Therefore, we aimed to determine the effects and safety of menopausal functional health ingredients and medicines on the human body as endocrine disruptors under review in the literature and the OECD guidelines.

Keywords: menopause; functional food; gynecology; phytoestrogens; estrogen receptor alpha; estrogen receptor beta; endocrine disruptors; safety



Citation: Kang, S.; Jo, H.; Kim, M.-R. Safety Assessment of Endocrine Disruption by Menopausal Health Functional Ingredients. *Healthcare* **2021**, *9*, 1376. <https://doi.org/10.3390/healthcare9101376>

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1. Introduction

The average life expectancy of human beings is increasing with improvements in standards of living, economic level, scientific advances, and medical technology. The mean age of menopause is reported as 49.9 years [1], and menopausal women live an average of 30 years or more after menopause [2]. In addition, as women's education and living standards improve, personal and social interests in the treatment of menopausal symptoms and health care after menopause are increasing. Menopausal transition begins when the function of the ovaries begins to weaken, and it ends when ovarian function disappears completely with loss of female fertility [3,4]. During the period of menopausal transition, which usually begins a few years in advance and typically ends one year after the final menstrual period [3,5], women experience physical symptoms including hot flashes, sweating, muscle pain, and genitourinary symptoms, as well as psychological symptoms such as irritability, nervousness, anxiety, insomnia, and depression [3,6,7]. For these reasons, health management is considered very important for middle-aged women experiencing menopause. Hormone replacement therapy (HRT) has been used as the main treatment for menopausal symptoms, although other options are required for whom HRT is not available because of personal preference or medical contraindications such as hormonally dependent cancers [8]. Prescription therapies such as selective serotonin reuptake inhibitors (SSRIs), serotonin-norepinephrine uptake inhibitors (SNRIs), gabapentin, and clonidine have shown some degree of efficacy as nonhormonal treatment options in women with

Healthcare 2021, 9, 1376

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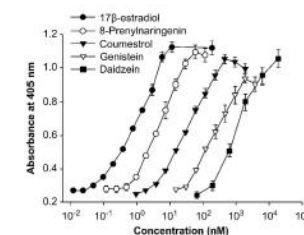


Figure 15. Estrogenic activity of 8-prnylnaringenin and phytoestrogens in human endometrial adenocarcinoma (Ishikawa Var I) cells. Reprinted from Milligan, S.R.; Kalita, J.C.; Heyerick, A.; Rong, H.; De Cooman, L.; De Keukeleire, D. Identification of a Potent Phytoestrogen in Hops (*Humulus lupulus* L.) and Beer. *J. Clin. Endocrinol. Metab.* **1999**, *84*, 2249–2252, with permission. © 1999, Oxford University Press [67].

4.2.10. Complex of *Cynanchum wilfordii* Hemsley, *Phlomis umbrosa* Turczaninow, and *Angelica gigas* Nakai extracts (CPAE)

CPAE is a complex extract composed of *Cynanchum wilfordii* Hemsley, *Phlomis umbrosa* Turczaninow, and *Angelica gigas* Nakai. It does not bind to the estrogen receptor, but exhibits an effect similar to that of estrogen. This estrogenic activity without binding to ER was demonstrated in experiments using both HeLa-9003 cells according to OECD test guideline 455 and MCF-7 cells (Figure 16) [68].

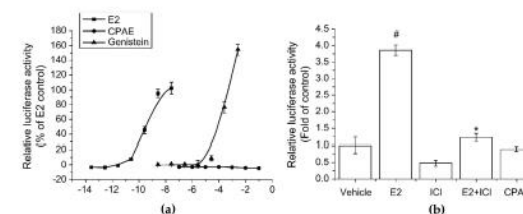


Figure 16. Estrogenic activity of CPAE using luciferase promoter activity in (a) HeLa-9003 cells and (b) MCF-7 cells, respectively. Bars represent mean \pm SD. # $p < 0.05$ vs. control; and * $p < 0.005$ vs. E2. Reprinted from Kim, S.J.; Jiri, S.W.; Lee, G.H.; Kim, Y.A.; Jeong, H.G. Evaluation of Estrogenic Activity of Extract from the Herbal Mixture *Cynanchum wilfordii* Hemsley, *Phlomis umbrosa* Turczaninow, and *Angelica gigas* Nakai. *Taiwan. Res.* **2017**, *33*, 71–77, under the terms of the Creative Commons Attribution Non-Commercial License (<http://creativecommons.org/licenses/by-nc/3.0/>), accessed on 8 August 2021 [68].

Improvement of BMD was shown in several *in vivo* studies with CPAE, and improvement of the Kupperman index, as well as alleviation of menopausal symptoms, were also confirmed in three clinical trials in Korea and the United States [111,112].

4.3. Safety Study and Side Effects of Functional Ingredients

Black cohosh extract, which is used as a medicine to treat menopausal symptoms in Korea, contains various bioactive substances. As it has pharmacological efficacy, many

Thank you for your attention

Naturalendo Tech Co., Ltd.
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Kupperman Index Questionnaire

Kupperman's index Questionnaire

Assignment Number: _____

Date of Visit: Date _____ Month _____ Year _____ (_____ visit)

Volunteer No. : _____, Name _____

Please mark on proper condition

< 0 - None S- Slight M- Moderate +- Marked (Severe) >

Symptoms	Severity			
	0	S	M	+
Hot flush or cold sweat (=vasomotor)				
Numbness and tingling (=paresthesia)				
Trouble sleeping (=insomnia)				
Nervousness				
Feeling blue or depressed (=melancholia)				
Dizzy spells (=vertigo)				
Tired feelings (=fatigue)				
Rheumatic pain (=arthralgia and myalgia))				
Headaches				
Pounding of the heart (=palpitation)				
Sensation of crawling on the skin (=formication)				
Menopausal Index (Sum)----- _____				
Sensation of dryness or burning in the vagina, difficulty with sexual intercourse (=vaginal dryness)				