Ministry of Food and Drug Safety

Osong Health Technology Administration Complex, 187 Osongsaengmyeong2(i)-ro, Osong-eup, heungdoek-gu cheongju-si, Chungcheongbuk-do, 363-951, Korea Tel : 82-43-719-1010, Fax : 82-43-719-1000

Certificate

┌ No. of Certificate : 2019-A1-0425
├ Exporting (certifying) country : Republic of Korea
└ Importing (requesting) country : Germany

The Ministry of Food and Drug Safety certifies that following drug substance has been registered to be imported under the Pharmaceutical Affairs Act. Attached is the registration license that has been issued to the applicant of the drug substance.

o **Applicant**
- Importer's Name : Esther Corporation Co., Ltd.

o **Manufacturer**
- Manufacture's Name : Anklam Extrakt GmbH
- Manufacture's Address : Johann-Friedrich-Bottger Strasse 4 & 10 D-17389 Anklam Germany

o **The Generic Name of Drug Substance** : Ivy Leaf 30% Ethanol Dried Extract (5 ~ 7.5 → 1)

Attachment
(the attached form #17 to the Enforcement Rule)

Issued date :APR. 30, 2019 (Certificate No.2019-A1-0425)

Certified by **Kim Sang-bong**

김 상 봉

Director
Pharmaceutical Policy Division
Pharmaceutical Safety Bureau
Ministry of Food and Drug Safety

[ ] Manufacture [√] Import Drug Substance Registration License			Registration No. 20190412-5-K-46-05	
Applicant	Name of Importer	Esther Corporation Co., Ltd.	Registration No.	143
	Address of Importer	Myungsung Plaza Room No. 701-3, 256, Godeok-ro, Gangdong-gu, Seoul, Republic of Korea	Tel No.	82-2-481-3650
	Name of Representative(e-mail)	Lee Won Hee (whlee@esthercorp.com)	Residence No.	670107 - *******
Manufacturer	Name of Manufacturer	Anklam Extrakt GmbH	Manufacturing Country	Germany
			Tel No.	49-3971-24 110-0
	Address of Manufacturer	Johann-Friedrich-Bottger Strasse 4 & 10 D-17389 Anklam Germany		
	Name of Manufacturer's Representative	Mr. Klaus Schekahn (klaus.schekahn@anklam-extrakt.com)		

Classification No. (Final Product)	-	Route of administration (Final Product)	Oral

Name	Generic Name	Ivy Leaf 30% Ethanol Dried Extract (5~7.5 → 1)	
	Chemical Name	Ivy, Hedera helix, ext	CAS No. 84082-54-2
Appearance	Physical Properties	Brown powder	
	Chemical Properties	-	

Data Requirements	Items
	1. Data on the facilities as necessary for production and quality control under the provisions of paragraph 1 of Article 31 of the Act
	2. Data on physicochemical properties and stability
	3. Data on the manufacturing process, packaging, containers, cautions in handling, etc.
	4. Data evidencing that production of each drug substance is in conformity with the Korea Good Manufacturing Practice(KGMP), Annex 2 of the Enforcement Rule or anything equivalent there to or higher.
	5. Data on batch analysis for drug substances, analytical procedures, the solvents used, etc.
	6. Sample drug substances as necessary for the quality test

Storage Condition and Shelf Life	Tight container and room temperature (1~30℃) / 36 months from manufacturing date
Other Remark	OTC, Extract CTD

I hereby certify that the drug substance is registered or the registration is updated as above under the provisions of Article 31 and Article 42 of Pharmaceutical Affairs Act and Paragraph 2 of Article 39 of Enforcement Rule of PAA.

2019. 04. 12.

The Minister of Food and Drug Safety