



Ministry of Food and Drug Safety

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Certificate

- ┌ No. of Certificate : 2019-A1-0182
- ├ Exporting (certifying) country : Republic of Korea
- └ Importing (requesting) country : India

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 : Sungwoo Chemical Co., Ltd.

o **Manufacturer**

- Manufacture's Name : Exemed pharmaceuticals
- Manufacture's Address : Block No. 628 (A & B) ECP Canal Road, Vill : Luna,
Taluka: Padra, District: Vadodara - 391440, Gujarat, India

o **The Generic Name of Drug Substance** : Metformin Hydrochloride

Attachment

(the attached form #17 to the Enforcement Rule)

Issued date : MAR. 06, 2019 (Certificate No.2019-A1-0182)

Certified by **Kim Sang-bong**

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



<input type="checkbox"/> Manufacture <input checked="" type="checkbox"/> Import Drug Substance Registration License			Registration No. 20181217-37-C-377-27	
Applicant	Name of Importer	Sungwoo Chemical Co., Ltd.	Registration No.	473
	Address of Importer	32, Barangongdan-ro 1-gil, Hyangnam-eup, Hwaseong-si, Gyeonggi-do, Republic of Korea	Tel No.	031-359-8616
	Name of Representative(e-mail)	Young-bong Yoon (ojs@sungwoochem.co.kr)	Residence No.	501105 - *****
Manufacturer	Name of Manufacturer	Exemed pharmaceuticals	Manufacturing Country	India
	Address of Manufacturer	Block No. 628 (A & B) ECP Canal Road, Vill : Luna, Taluka: Padra, District Vadodara - 391440, Gujarat, India		
	Name of Manufacturer's Representative	Mr. Sanjoy Saha (ssaha@exemedpharma.com)		
Classification No. (Final Product)	03960	Route of administration (Final Product)	Oral	
Name	Generic Name	Metformin Hydrochloride		
	Chemical Name	1,1-Dimethylbiguanide hydrochloride	CAS No. 1115-70-4	
Appearance	Physical Properties	White or almost white crystals		
	Chemical Properties	Freely soluble in water, slightly soluble in ethanol (95%), practically insoluble in acetone and in methylene chloride		
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		Storage Condition : Well-closed container, room temperature(1-30℃) Retest period : 60 months from the date of manufacture		
Other Remark	General, Synthetic			
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. 2018. 12. 17. The Minister of Food and Drug Safety (Stamp)				

