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정부시점확인센터

Ministry of Food and Drug Safety

Osong Health Technololgy Administration Complex, 187, Osongsaengmyeong 2-ro,
Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28159, Republic of Korea,
Tel: +82-43-719-1010, Fax: +82-43-719-1000

Certificate of DMF Registration

No. of Certificate : 2023-A1-0326
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**
- Name : Hwail Pharm. Co., Ltd

o **Manufacturer**
- Name : Smruthi Organics Limited
- Address : A-27, M.I.D.C. Chincholi, Tal-Mohol, Solapur 413255, Maharashtra state, India

o **The Generic Name of Drug Substance** : Telmisartan

Attachment
Attached form #17 of the Regulation on Safety of Pharmaceuticals, etc. (Ordinance of the Prime Minister)

Issued date :FEB. 20, 2023 (Certificate No.2023-A1-0326)
Certified by **Lee Sujung**

이 수정

Director
Director for Approval Management
Ministry of Food and Drug Safety

You can verify the Certificate through VERIFICATION NO. on the webpage(https://nedrug.mfds.go.kr/pbp/CCBSC03/certificate)
or by checking the barcode with the mobile scanner App (MaSmartDetector).

Drug Substance Registration License

DMF Registration No.20230209-209-J-1310

Applicant	Name of Representative Cho, Kyoung Sook	Date of Birth 1960.02.21.
	Name Hwail Pharm. Co., Ltd	Registered No. 331
	Address 45, Barangongdan-ro 1-gil, Hyangnam-eup, Hwaseong-si, Gyeonggi-do, Republic of Korea	
Manufacturer	Name Smruthi Organics Limited	Manufacturing Country India
		Tel No. +91-217-2357492
	Address A-27, M.I.D.C. Chincholi, Tal-Mohol, Solapur 413255, Maharashtra state, India	
	Manufacturer's Representative (e-mail) Mr.Eaga(eaga@smruthiorganics.com)	
Route of administration(Final Product) Oral		[ ] Manufacture [V] Import
Name	Generic Name Telmisartan	
	Chemical Name 4'[[4-Methyl-6-(1-methyl-2-benzimidazolyl)-2-propyl-1-benzimidazolyl] methyl]-2-biphenylcarboxylic acid	CAS No. 144701-48-4
Appearance	Physical Properties White or Slightly yellowish, crystalline powder	
	Chemical Properties Soluble in 1M Sodium hydroxide, Sparingly soluble methylene chloride, slightly soluble Methanol, Practically insoluble in water	

Data Requirements	Items	page number
	1. Data for each of the following items on the manufacturing site of the drug substance	
	a. Data on the facilities pursuant to Article 31 (1) of the Pharmaceutical Affairs Act	
	b. Data demonstrating that implementation status of each product meets or exceeds Good Manufacturing Practice for Drug Substances in Annex 1-2 of the Regulation on Safety of Pharmaceuticals, etc., or a certificate of manufacture pursuant to Article 4 (1) 4 A	
	2. Data for each of the following items on the ingredients, name and manufacturing method of the drug substance	
	a. Data on physicochemical properties and stability	
	b. Data on the manufacturing methods, packaging, containers, cautions in handling, etc.	
	c. Data on certificate of analysis of drug substances, analytical procedures, the solvents used, etc.	
	d. Drug substances for investigational use (as applicable only when deemed necessary for quality test by the Minister of Food and Drug Safety)	

Storage Condition and Shelf Life Store in a light-resistant and well-closed container at room temperature (1~30℃) / 60 months from the date of manufacture

Other Remarks General, Synthesis

This certifies that the drug substance is registered or the registration is updated as above pursuant to the provisions of Article 31-2 (2) and (3) and Article 42 (4) of the Pharmaceutical Affairs Act and Article 16 (1) and 17 (3) of the Regulation on Safety of Pharmaceuticals, etc.

2023. 02. 09.

The Minister of Food and Drug Safety

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