열 람 용

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-A1-1618
├ 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 : Dongjin Pharmaceutical Co.,Ltd.

o Manufacturer
- Manufacture's Name : Mangalam Drugs and Organics Ltd.(Unit-2)
- Manufacture's Address : Plot No.1203, Phase-III, G.I.D.C..City: Vapi-396 195, Dist: Valsad, Gujarat State, India

o The Generic Name of Drug Substance : Tenofovir Disoproxil Orotate(micronized)

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

Issued date :DEC. 24, 2019 (Certificate No.2019-A1-1618)
Certified by Kim Myengho

김 명 호

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

열 람 용

[ ] Manufacture [√] Import Drug Substance Registration License			Registration No. 수247-15-ND(1)	
Applicant	Name of Importer	Dongjin Pharmaceutical Co.,Ltd.	Registration No.	289
	Address of Importer	41, Dongsan-ro, 8-gil, Seocho-gu, Seoul, Republic of Korea	Tel No.	+82-2-579-1056
	Name of Representative(e-mail)	Min, Byung Gyu	Residence No.	630401 - *******
Manufacturer	Name of Manufacturer	Mangalam Drugs and Organics Ltd.(Unit-2)	Manufacturing Country	India
			Tel No.	919374107111
	Address of Manufacturer	Plot No.1203, Phase-III, G.I.D.C..City: Vapi-396 195, Dist: Valsad, Gujarat State, India		
	Name of Manufacturer's Representative	Dr. Bhanvesh Naik (bhanvesh@mangalamdrugs.com)		
Route of administration (Final Product)		-		
Name	Generic Name	Tenofovir Disoproxil Orotate(micronized)		
	Chemical Name	2,4,3,8-Tetraoxa-5-phosphanonanedioic acid, 5-[[(1R)-2-(6-amino-9H-purin-9-yl)-1-methylethoxy]methyl]-,19-bis(1-methylethyl)ester, 5-oxide, 1,2,3,6-tetrahydro-2,6-dioxo-4-pyrimidinecalboxylate(1:1)	CAS No.	1636180-90-9
Appearance	Physical Properties	White to gray white powder		
	Chemical Properties	Freely soluble in N,N-dimethyl formamide and N-methyl-2-pyrrolidone		
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		Store in a light-resistant and tight container at refrigerated temperature (2℃-8℃) / Retest period: 18 months from the date of manufacture		
Other Remark	General, Synthesis, Micronized			

I hereby certify that the drug substance is registered or the registration is updated as above under 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.

2019. 1. 24.

The Minister of Food and Drug Safety