



Ministry of Food and Drug Safety

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Certificate

- ▣ No. of Certificate : 2014-A1-1762
- ┆ 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 manufactured(*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 : Yoo & Yoo Generic Co., Ltd

o Manufacturer

- Manufacture's Name : Mac-Chem Products(India) Pvt. Ltd.
- Manufacture's Address : N-211/2/10, M.I.D.C. Boisar, District - Thane 401 506, Maharashtra State, India

o The Generic Name of Drug Substance : Imatinib Mesylate

Attachment

(the attached form #17 to the Enforcement Rule)

Issued date : Oct. 14, 2014 2014-A1-1762

Certified by

Kyoung Min Myoung

Director

Drug Review Management Division

Drug Evaluation Department

National Institute of Food and Drug Safety Evaluation

<input type="checkbox"/> Manufacture <input checked="" type="checkbox"/> Import Drug Substance Registration License			Registration No.	
			수6321-4-ND	
Applicant	Name of Importer	Yoo & Yoo Generic Co., Ltd.	Registration No.	6321
	Address of Importer	3F Shinyoo B/D, 6, Gaepo-ro 26gil, Gangnam-gu, Seoul, Republic of Korea	Tel No.	+82-2-571-2713
	Name of Representative(e-mail)	Yoo Tae aun	Residence No.	주민등록번호 630313 - *****
Manufacturer	Name of Manufacturer	Mac-Chem Products(India) Pvt.Ltd.	Manufacturing Country	India
	Address of Manufacturer	N-211/2/10, M.I.D.C. Boisar, District - Thane 401 506, Maharashtra State, India		
	Name of Manufacturer's Representative	Mr. Manish Jain		
Classification No. (Final Product)	04210	Route of administration (Final Product)	Oral	
Name	Generic Name	Imatinib Mesylate		
	Chemical Name	4-[(4-methyl-1-piperazinyl)methyl]-N-[4-methyl-3-[[4-(3-pyridinyl)-2-pyrimidinyl]amino]phenyl]benzamide methanesulfonate]	CAS No. 220127-57-1	
Appearance	Physical Properties	White to off white powder		
	Chemical Properties	Freely soluble in water, Sparingly soluble in Methanol, Practically insoluble in ether		
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.			
Storage Condition and Shelf Life		Light-resistant tight containers, room temperature(1~30℃), 36 months from manufacture date.		
Other Remark	General, Synthesis			

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.

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The Commissioner of Ministry of Food and Drug Safety

(Stamp)

