Ministry of Food and Drug Safety

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Certificate

┌ No. of Certificate : 2018-A1-1194
├ 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 : Q.E.SANGSA

o **Manufacturer**
- Manufacture's Name : Farmson Pharmaceutical Gujarat Pvt, Limited
- Manufacture's Address : Plot No 14, GIDC Industrial Estate, Nandesari City : Nandesari-391 340, Dist : Vadodara, Gujarat State, India

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

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

Issued date :JUL. 31, 2018 2018-A1-1194

Certified by Joung Keon Oh

Director
Drug Review Management Division
Drug Evaluation Department
National Institute of Food and Drug Safety Evaluation

[ ] Manufacture [V] Import Drug Substance Registration License			Registration No. 20180621-32-C-371-22	
Applicant	Name of Importer	HOIN KIM	Registration No.	680
	Address of Importer	23-10,NONHYUN-RO 12GIL, GANGNAM-GU, SEOU,KOREA	Tel No.	02-806-0078
	Name of Representative(e-mail)	HOIN KIM qe@qesangsa.com	Residence No.	781115 - *******
Manufacturer	Name of Manufacturer	Farmson Pharmaceutical Gujarat Pvt, Limited	Manufacturing Country	INDIA
			Tel No.	265-6138455
	Address of Manufacturer	Plot No 14, GIDC Industrial Estate, Nandesari City : Nandesari-391 340, Dist : Vadodara, Gujarat State		
	Name of Manufacturer's Representative	VINIT MENON (vinit@farmson.com)		

Classification No. (Final Product)	114	Route of administration (Final Product)	ORAL

Name	Generic Name	Acetaminophen	
	Chemical Name	N-(4-hydroxyphenyl)acetamide	CAS No. 103-90-2
Appearance	Physical Properties	White to off-white crystal	
	Chemical Properties	Soluble in water, slightly soluble in Ethanol, insoluble in methylen	

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	Preserve in airtight containers, Store at temperature(1-30°C), 60 months from manufacturing 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.
2018 . 06 . 21 .
The Commissioner of Ministry of Food and Drug Safety (Stamp)