Ministry of Food and Drug Safety

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Certificate of DMF Registration

┌ No. of Certificate : 2020-A1-0237
├ 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 : Pharmapia co., Ltd

o **Manufacturer**
- Manufacture's Name : Emmennar Pharma Pvt Ltd
- Manufacture's Address : Unit-II, Plot No. 15, Jawaharlal Nehru Pharma City, Tadi (Village), Parawada Mandal, Visakhapatnam, District Andhra Pradesh, India.

o **The Generic Name of Drug Substance** : Sodium Bicarbonate

Attachment

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

Issued date :JAN. 30, 2020 (Certificate No.2020-A1-0237)

Certified by **Kim Myengho**

김 명 호

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

[ ] Manufacture [√] Import Drug Substance Registration License			Registration No. 20200113-211-J-530	
Applicant	Name of Importer	Pharmapia co., Ltd	Registration No.	258
	Address of Importer	Pharmapia Bldg, 12, Songi-ro 32-gil, Songpa-gu, Seoul, Republic of Korea	Tel No.	+82-2-425-0870
	Name of Representative(e-mail)	Yong hee, Shin	Residence No.	560819 - *******
Manufacturer	Name of Manufacturer	Emmennar Pharma Pvt Ltd	Manufacturing Country	India
			Tel No.	+91-91000 33243
	Address of Manufacturer	Unit-II, Plot No. 15, Jawaharlal Nehru Pharma City, Tadi (Village), Parawada Mandal, Visakhapatnam, District Andhra Pradesh, India.		
	Name of Manufacturer's Representative	Mr. B. Venkata Rami Reddy (qa@emmennar.com)		
Route of administration (Final Product)		Oral		
Name	Generic Name	Sodium Bicarbonate		
	Chemical Name	Carbonic acid monosodium salt; Monosodium carbonate;	CAS No. 144-55-8	
Appearance	Physical Properties	White or almost white crystalline powder		
	Chemical Properties	Soluble in water; and insoluble in ethanol		
Data Requirements	Items			
	1. Data on the facilities pursuant to Article 31 (1) of the Pharmaceutical Affairs Act			
	2. 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			
	3. Data on physicochemical properties and stability			
	4. Data on the manufacturing methods, packaging, containers, cautions in handling, etc.			
	5. Data on certificate of analysis of drug substances, analytical procedures, the solvents used, etc.			
	6. 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 well-closed container at room temperature (1~30℃) / 30 months from the date of manufacture		
Other Remarks	General, Synthetic			

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.

2020. 1. 13.

The Minister of Food and Drug Safety