DONGBANG FTL
동방에프티엘

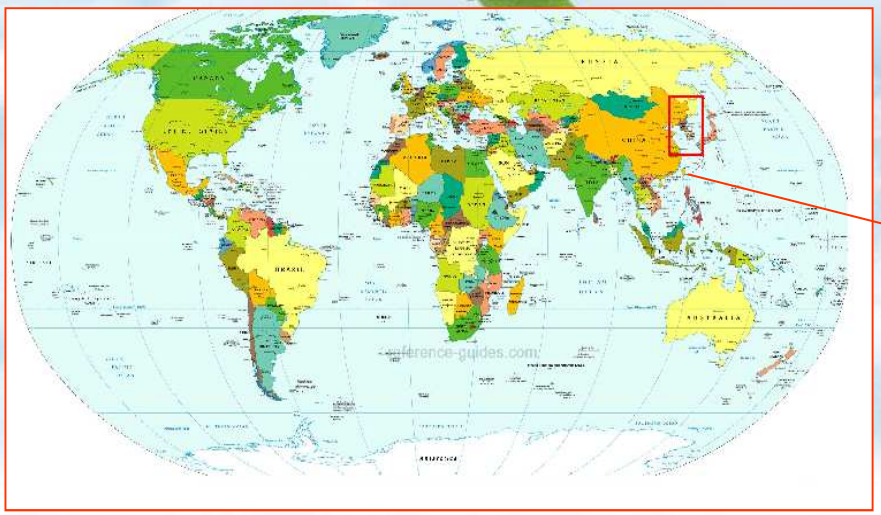
최고의 원료의약품만을 고집하는
연구중심의 기업이 되겠습니다

Dongbang FTL

for Wellbeing and Wellaging

CUSTOMER CENTER
82-2-741-7516

◆ *We are located in…*



KOREA

SEOUL OFFICE

3rd floor IL-Yang building, 9, Donhwamun-Ro 11-Gil,
Jongno-Gu, Seoul, 110-807, Korea

TEL : 82-2-741-7516~8 FAX : 82-2-741-7525

FACTORY

78, Jeyakgongdan 4-Gil, Hyangnam-Eup, Hwaseong-Si,
Gyeonggi-Do, 445-922, Korea

TEL : 82-31-354-1114 FAX : 82-31-353-4120

HOMEPAGE

www.DongbangFTL.com

◆ *History of Dongbang FTL 1/3*

1990.02	**Corporate Organization**
1991.06	**Completion of factory**
1991.08	**Acquisition of permission for pharmaceutical raw material manufacturing**
1994.01	**Finished enlargement of building for management office and factory**
1996.02	**Establishment of affiliated technique research institute**
1996.04	**Authentication of ISO 9002/EN ISO 9002/ KS A 9002**
1996.12	**Increase of pharmaceutical raw material manufacturing facilities**
1997.03	**Change company name to DONG BANG FUTURE CHEMICAL CO., LTD.**
1999.04	**Completion of Cosmetic factory (Amiesay cosmetic)**
1999.06	**Authentication of Australian GMP (TGA)**
1999.11	**Award of prize for the minister of the industry resources administration in the trade day**
1999.12	**Award of prize for the foreign frontier field of Gyeonggi-Do**
2000.05	**Authentication of BGMP by Korea Food and Drug Administration**
2000.06	**Increase of Cosmetic manufacturing facilities**
2001.11	**Selected INNO-BIZ enterprise(medium sized business office)**

◆ *History of Dongbang FTL 2/3*

2002.11	**Change company name to DongBang Future Tech & Life co., LTD**
2003.12	**Authentication of KS Q ISO 9001 :2001 / ISO 9001 : 2000**
2004.04	**Authentication of BGMP for Herbal product by Korea Food and Drug Administration**
2006.04	**Authentication of Australian GMP (TGA) following ICH guideline**
2006.10	**Acquisition of certificate of suitability for Mefenamic acid from EDQM**
2009.03	**Authentication of KGMP**
2009. 05	**Authentication of Australian GMP (TGA)**
2009. 10	**Acquisition of certificate of suitability for Ketoprofen from EDQM**
2010.10	**Inspection of KGMP by Korea Food and Drug Administration**
2010.12	**Authentication of KS Q ISO 9001 :2009 / ISO 9001 : 2008**
2011.03	**Authentication of Chemical BGMP by Korea Food and Drug Administration (Product GMP for Loperamide)**
2011.05	**Authentication of Herbal BGMP by Korea Food and Drug Administration (Product GMP for Pelargonium sidoides)**
2011.07	**Inspection of KGMP by Korea Food and Drug Administration**
2011. 11	**Authentication of Australian GMP (TGA)**

◆ *History of Dongbang FTL 3/3*

2011.12	Authentication of KS Q ISO 9001 :2009 / ISO 9001 : 2008
2012.03	Authentication of BGMP by Korea Food and Drug Administration
2012.10	Authentication of KGMP for Quasi Drug by Korea Food and Drug Administration
2012.12	Authentication of KS Q ISO 9001 :2009 / ISO 9001 : 2008
2013.03	**Authentication of Japanese GMP by on-site audit of PMDA**
2013.07	Authentication of BGMP by Korea Food and Drug Administration
2014.03	**Authentication of Australian GMP (TGA)**

◆ *Major Activities of DongbangFTL*

Chemical API

Herbal API

Finished Product

Organic Synthesis

◆ The number of employees

Quality Related Systems (100)	QC	25
	QA	10
	Production	30
	R&D, Regulatory	30
	Warehouse	5
Others (30)	Sales & Marketing	5
	Administration	10
	Other support services	15

◆ *Size Idea of Dongbang FTL*

Place	Area
Total Area of Factory	16,179.32 m^2
Plant for Chemical API	5,718.23 m^2
Plant for Herbal API	262.94 m^2
Laboratory	493.23 m^2
Warehouse	636.60 m^2
Other Facilities	9,068.32 m^2

◆ *Features of Our Business*

DONGBANG FTL 동방에프티엘

Active Pharmaceutical Ingredients

'Quality-Assured API with Toll Manufacturing Service'

GMP Approved by...

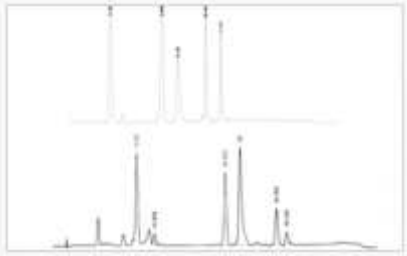
식품의약품안전처 MINISTRY OF FOOD AND DRUG SAFETY

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Pmda Pharmaceuticals and Medical Devices Agency, Japan

Natural Active Ingredients

"1st Approval of BGMP for Natural Active Pharmaceutical Ingredients in Korea and the best partner of joint research for new natural drugs. "



GMP Approved by...

식품의약품안전처 MINISTRY OF FOOD AND DRUG SAFETY

◆ *Strength of DongBang FTL*

1. Abundant experience in Japanese Pharmaceutical business
   - Business with Japanese companies over 10 years
   - MF registration of 10 products in Japan and 5 new products on the preparation
   - Close communication and rapid response with customers by regular visit to Japan (over 10 times a year including CPHI Japan, Interphex)

◆ *Strength of DongBang FTL*

2. High GMP Standard
   - Audit from Korean FDA and other country's MOH (PMDA in 2013, TGA in 2014, KFDA in 2014)
   - Audit from Japanese and foreign companies (Pfizer and Bayer) every year.
   - No "Major or critical observation"
3. Stable Product Supply
   - Multiple sources for starting materials & intermediates
   - New API plant to increase production line and New Chemical Plant under GMP control (scheduled in 2015)

◆ *Strength of DongBang FTL*

4. High Technology
   - Many patents for high quality API
   - Various analytical equipments
   - Cooperation with various organizations and universities under the mutual agreement
5. Easy Access
   - Minimization of quality problem while transporting (by air: 1day, by sea: 3days)
   - Rapid response & solution in case of problems occurring

◆ *Representative Certificates of Dongbang FTL 1/2*

Australian Government
Department of Health
Therapeutic Goods Administration

Certificate of GMP Compliance of a Manufacturer

of Active Pharmaceutical Ingredients (APIs)

Certificate Number:
MI-2013-CE-04316-1

Issued to:
Dongbang Future Tech & Life Co Ltd

Manufacturing Site Address:
78, Jeyakgongdan 4-gil, Hyangnam-eup,
Hwaseong-si, Gyeonggi-do
KOREA - REPUBLIC OF

The Therapeutic Goods Administration, the Competent Authority of Australia, confirms that this manufacturer of Active Pharmaceutical Ingredients (APIs) has been inspected following section/s 25(1)(g), 26(1)(g) and/or 26A(3) of the *Therapeutic Goods Act 1989* in connection with marketing authorisation/s listing API manufacturers located outside Australia.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 03 to 05 March 2014, it is considered that the manufacturer complies with the Good Manufacturing Practice requirements of the PIC/S Guide to Good Manufacturing Practice for Medicinal Products – 15 January 2009.

This certificate reflects the status of the manufacturing site at the time of the inspection noted above. This certificate remains valid until the expiry date provided that re-inspections are conducted as determined by the Therapeutic Goods Administration as the issuing Authority. This certificate should not be relied upon to reflect the compliance status after the expiry date.

EXPIRY DATE: 03 September 2017
ISSUE DATE: 29 October 2014

Name and signature of an authorised person of the Competent Authority of Australia:

Signed:

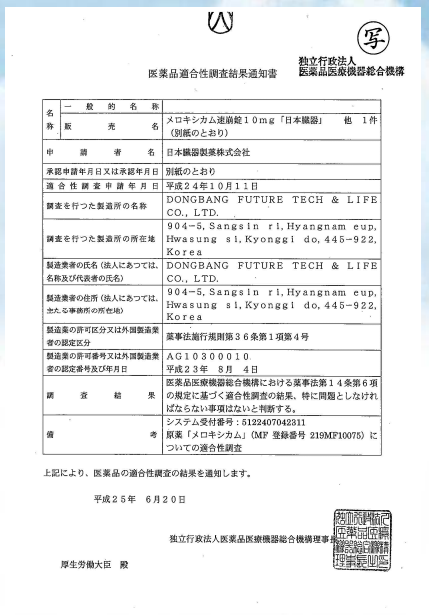
Noel Fraser
Office of Manufacturing Quality

This certificate is valid only if the security provisions (blue and grey curved dotted lines on the bottom half of each page) are visible. This certificate remains valid only if re-inspections are conducted when scheduled by the Therapeutic Goods Administration. The authenticity of this certificate may be verified with the Therapeutic Goods Administration as the issuing authority.

PO Box 100 Woden ACT 2606 ABN 40 939 406 804
Phone: 02 6232 8444 Fax: 02 6232 8605 Email: info@tga.gov.au www.tga.gov.au

TGA Health Safety Regulation

Page 1 of 2



独立行政法人
医薬品医療機器総合機構

医薬品適合性調査結果通知書

名称	一般的名称	
	販売名	メロキシカム速崩錠１０mg「日本臓器」　他　1件（別紙のとおり）
申請者名		日本臓器製薬株式会社
承認申請年月日又は承認年月日		別紙のとおり
適合性調査申請年月日		平成２４年１０月１１日
調査を行った製造所の名称		DONGBANG FUTURE TECH & LIFE CO., LTD.
調査を行った製造所の所在地		904-5, Sangsin ri, Hyangnam eup, Hwasung si, Kyonggi do, 445-922, Korea
製造業者の氏名（法人にあつては、名称及び代表者の氏名）		DONGBANG FUTURE TECH & LIFE CO., LTD.
製造業者の住所（法人にあつては、主たる事務所の所在地）		904-5, Sangsin ri, Hyangnam eup, Hwasung si, Kyonggi do, 445-922, Korea
製造業の許可区分又は外国製造業者の認定区分		薬事法施行規則第３６条第１項第４号
製造業の許可番号又は外国製造業者の認定番号及び年月日		AG1030001０ 平成２３年　８月　４日
調査結果		医薬品医療機器総合機構における薬事法第１４条第６項の規定に基づく適合性調査の結果、特に問題としなければならない事項はないと判断する。
備考		システム受付番号：512407042311 原薬「メロキシカム」（MF 登録番号 219MF10075）についての適合性調査

上記により、医薬品の適合性調査の結果を通知します。

平成２５年　６月２０日

独立行政法人医薬品医療機器総合機構理事長

厚生労働大臣　殿

Korea Food & Drug Administration

Certificate of Good Manufacturing Practice

Representative	YOUNG-JUN CHUNG	Name Of Manufacturer	DONGBANG FUTURE TECH & LIFE CO, LTD
Address(Plant)	904-5, 907-2 Sangsin-RI, Hyangnam-Eup, Hwasung-Si, Kyonggi-Do, Korea		
Registered Production Manager	SO MIN HWAN	Registered Quality Control Manager	KEON-TAEK LEE
Approved Dosage Forms		Approval Date	
Generic medicinal(final and intermediate) Chemicals		March 30, 2009	

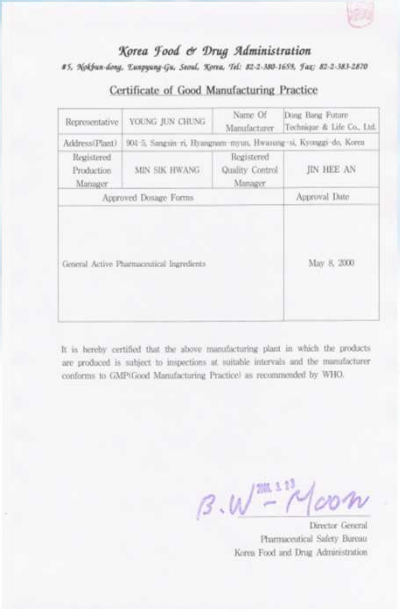
KFDA

It is hereby certified that the above manufacturing plant in which the products are produced is subject to inspections at suitable intervals and the manufacturer conforms to GMP(Good Manufacturing Practice) as recommended by WHO.

Issued date: Oct. 24, 2011 2011-A1-1709

Certified by:

Commissioner
Korea Food Drug Administration



Korea Food & Drug Administration

Certificate of Good Manufacturing Practice

Representative	YOUNG JUN CHUNG	Name Of Manufacturer	Dong Bang Future Technique & Life Co., Ltd.
Address(Plant)	904-5, Sangsin ri, Hyangnam-myun, Hwasung-si, Kyonggi-do, Korea		
Registered Production Manager	MIN SIK HWANG	Registered Quality Control Manager	JIN HEE AN
Approved Dosage Forms		Approval Date	
General Active Pharmaceutical Ingredients		May 8, 2000	

It is hereby certified that the above manufacturing plant in which the products are produced is subject to inspections at suitable intervals and the manufacturer conforms to GMP(Good Manufacturing Practice) as recommended by WHO.

B.W-Moon

Director General
Pharmaceutical Safety Bureau
Korea Food and Drug Administration

TGA Authentication **PMDA Authentication** **KGMP Authentication** **BGMP Authentication**

◆ *Representative Certificates of Dongbang FTL 2/2*

Certification of Substances Division

Certificate of suitability
No. R1-CEP 2004-296-Rev 01

Name of the substance:
MEFENAMIC ACID

Name of holder:
DONG BANG FUTURE TECH & LIFE CO., LTD.
78, Jeyakgongdan 4-Gil
Hyangnam-Eup
Korea (Republic of)-445-937 Hwaseong-Si, Gyeonggi-Do

Site(s) of production:
SEE ANNEX 1

THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE
R1-CEP 2004-296-REV 00

After examination of the information provided on the manufacturing method and subsequent processes (including purification) for this substance on the site(s) of production listed in annex, we certify that the quality of the substance is suitably controlled by the current version of the monograph **MEFENAMIC ACID** no. 1240 of the European Pharmacopoeia, current edition including supplements, only if it is supplemented by the test(s) mentioned below, based on the analytical procedure(s) given in annex.

– Test for residual solvents by gas chromatography (Annex 2)
Methanol not more than 500 ppm

In the last steps of the synthesis water is used as solvent.

The substance is packed in a polyethylene bag placed in a fibre drum.

The holder of the certificate has declared the absence of use of material of human or animal origin in the manufacture of the substance.

The submitted dossier must be updated after any significant change that may alter the quality, safety or efficacy of the substance.

Manufacture of the substance shall take place in accordance with the Good Manufacturing Practice and in accordance with the dossier submitted.

Address: 7 Allée Kastner, CS 30026
F-67081 Strasbourg (France)
Tel: +33 (0) 3 88 41 30 30 – Fax: +33 (0) 3 88 41 27 71 - e-mail: cep@edqm.eu
Internet: http://www.edqm.eu

Certification of Substances Division

Certificate of suitability
No. R1-CEP 2008-120-Rev 00

Name of the substance:
KETOPROFEN

Name of holder:
DONG BANG FUTURE TECH & LIFE CO., LTD.
78, Jeyakgongdan 4-gil
Hyangnam-eup
Korea (Republic of)-445-937 Hwaseong-si, Gyeonggi-do

Site(s) of production:
SEE ANNEX 1

THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE
RO-CEP 2008-120-REV 01

After examination of the information provided on the manufacturing method and subsequent processes (including purification) for this substance on the site(s) of production listed in annex, we certify that the quality of the substance is suitably controlled by the current version of the monograph **KETOPROFEN** no. 922 of the European Pharmacopoeia, current edition including supplements.

In the last steps of the synthesis acetic acid and water are used as solvents. Their residual content is limited by the test for loss on drying described in the monograph with a limit of not more than 0.5%.

The substance is packed in a double polyethylene bag placed in a fibre drum.

The holder of the certificate has declared the absence of use of material of human or animal origin in the manufacture of the substance.

The submitted dossier must be updated after any significant change that may alter the quality, safety or efficacy of the substance.

Manufacture of the substance shall take place in accordance with the Good Manufacturing Practice and in accordance with the dossier submitted.

Failure to comply with these provisions will render this certificate void.

Address: 7 Allée Kastner, CS 30026
F-67081 Strasbourg (France)
Tel: +33 (0) 3 88 41 30 30 – Fax: +33 (0) 3 88 41 27 71 - e-mail: cep@edqm.eu
Internet: http://www.edqm.eu

Mefenamic acid COS

Ketoprofen COS

Number of Lab & RA People

LAB	
Male	Female
14	7

Degree	People
PhD. degree	5
MSc. degree	6
BSc. degree	10

Director (1)		
Synthetic team	Analysis team	Pilot team
12	3	6

RA
9

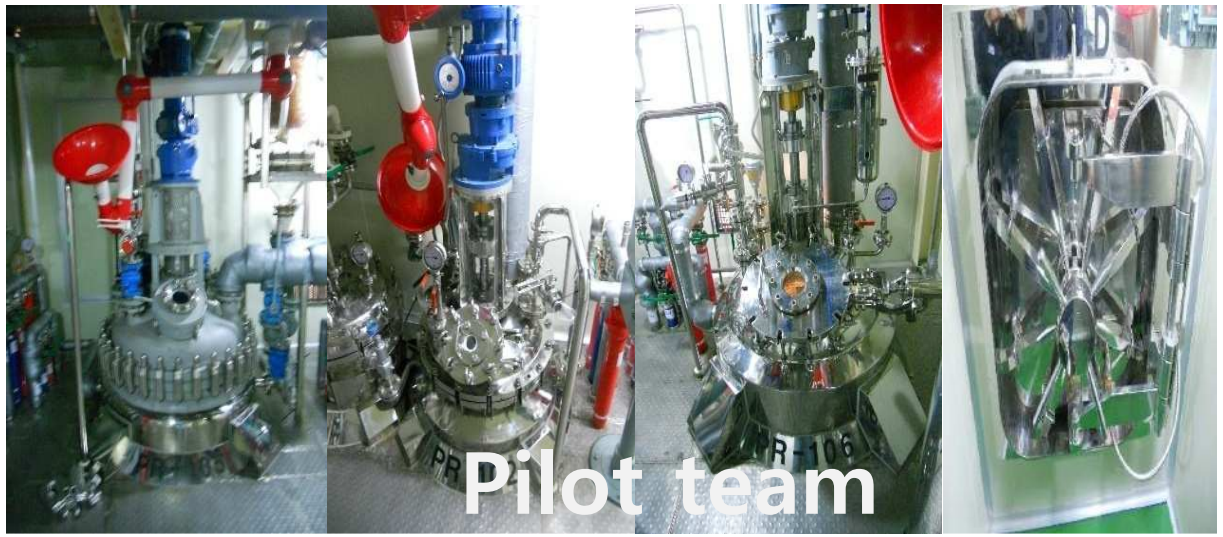
- Total : 30

Laboratory

Entrance

Synthesis analysis team

Lab



Pilot team

Status of Major Patent 1/2

2003

- (Process for preparation of 5-substituted Indole Derivatives)
- 1004115990000

2004

- (Process for preparation of Gugulsterons)
- 1004460680000
- (Process for preparation of the Propiverine Hydrochloride)
- 1005007600000

2005

- (Process for preparation of the Propiverine Hydrochloride from O-n-Propylbenzylic Acid)
- 1005107880000
- (The method of manufacturing of the extract from the Platycodon Grandiflorum A. DC)
- 1005131620000

Status of Major Patent 2/2

2010
- (Composition of Skin cream for acnes)
- 1009830760000

2011
- (Industrial process of high purity Olmesartan Medoxomil)
- 1010903250000

2012
- (Industrial process of high purity Olmesartan Medoxomil)
- 1011345050000
- (Process for preparing crystalline polymorphic form A of high purity Pitavastatin Calcium salt)
- 1011585170000

2013
- (Efficient process of Solifenacin and it's salt)
- 1012980460000

2014
- (On the registration for process patents of Silodosin, Entecavir and Sitagliptin)

Japanese MF Status of Major Products

Products	Specification	Category	Remarks
Entecavir	IHS	Anti-Viral	- KDMF, JDMF®
Felbinac	JP, BP, EP	Anti-Inflammatory	-EDMF, JDMF, KDMF
Irsogladine Maleate	JP	Anti-Ulcerative	- KDMF, JDMF
Ketoprofen	USP, BP, EP	Anti-Inflammatory	- COS, JDMF
Levofloxacin	JP	Anti-Bacterial	- KDMF, JDMF
Loxoprofen	JP	Anti-Inflammatory	- KDMF, JDMF
Meloxicam	BP	Anti-Inflammatory	-EDMF, JDMF, KDMF
Olmesartan Medoxomil	EP	Anti-Hypertensive	-COS®, JDMF, KDMF
Silodosin	IHS	Anti-Prostatic Hyperplasia	-EDMF®, JDMF®, KDMF
Solifenacin Succinate	IHS	Anti-Spasmodic	- KDMF, JDMF®
Tamsulosin Hydrochloride	BP, EP, JP	Anti-Spasmodic	-JDMF®
Telmisartan	BP, EP	Anti-Hypertensive	- JDMF

Number of Quality People

	Task	People
QC	Chemical API	14
	Herbal API	2
	Finished Product	6
	Microorganism	3
QA	APQR/Complain/Release	10
	Deviation/OOS/Change Control	
	Self inspection/Returns/Training	
	Document SOP/Vendor audit	

- Total : 35

Q.C

Instrumental Analysis Lab.

Weighing Room

Reagents Storage

Samples Storage

Microorganism Lab.

Quality Equipment


Infrared spetroscopy


UV-VIS
spectrophotomether


Gas chromatography

Muffle Furnace


High Perfomance
Liquid Chromatography


Particle size analyzer


Convection Oven


Total Organic carbon
Analyzer

Quality Equipment

Q.C

Equipment	EA
HPLC	14
GC	3
Infrared Spectroscopy	1
UV-VIS Spectrophotometer	1
Muffle Furnace	1
Particle Size Analyzer	1
Karl-Fisher	1
Total Organic Carbon Analyzer	1
Atomic Absorption Spectrophotometer	1

Lab

Equipment	EA
HPLC	5
GC	1
Polarimeter	1
Melting point meter	1

◆ *Introduction of New API plant*

◆ *Introduction of New API plant*

◆ ***Actual photos of new plant 1/2***

<Outside of the plant>

◆ *Actual photos of new plant 2/2*

DONGBANG FTL
동방에프티엘

<Tray Dryer>

<API Reactor>

<Absorption tower>

◆ *Equipment list of new plant*

DONGBANG FTL 동방에프티엘

New API Equipment List			
Equipment name	Capacity	Number	Note
STS Reactor	$3M^3$	3	
G/L Reactor	$3M^3$	2	
STS Reactor	$6M^3$	1	
G/L Reactor	$5M^3$	1	
Tray Dryer	$1M^3$	2	
Rotary Dryer	$2M^3$	1	
Rotary Dryer	$1.5M^3$	1	
Centrifuge	40"	2	Install soon

Thank you

T G A	Authentication
B G M P	Authentication
K G M P	Authentication
P M D A	Authentication

DONGBANG FUTURE TECH & LIFE CO., LTD.
SEOUL, KOREA

- HEAD OFFICE
3FL ILYANG BLDG., 9, DONHWAMUN-RO 11-GIL, JONGNO-GU, SEOUL, 110-807, KOREA
TEL : 82-2-741-7516~8 FAX : 82-2-741-7525
e-mail : expo1 @ dongbangchem.co.kr

- FACTORY
78, JEYAKGONGDAN 4-GIL, HYANGNAM-EUP, HWASEONG-SI, GYEONGGI-DO, 445-922, KOREA
TEL : 82-31-354-1114 FAX : 82-31-353-4120
e-mail : qc1 @ dongbangchem.co.kr

CUSTOMER CENTER
82-2-741-7516