



Biofarma Pharmaceutical Ind. Co. Inc.

Location – Map



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Address: Akpınar Mah. Osmangazi Cad. No:156 SANCAKTEPE / ISTANBUL
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- **Established in 1945 Mercan /İstanbul**
- **Sancaktepe current plant set up in 1990**
- **Modern facility area 15.000 m2**
- **Acquired by joint stock company in 1998**

It was a part of Partners in Life Sciences (PILS) and Citigroup Venture Capital International (CVCI) till December 2014

Today; Biofarma is part of SBK Holding.

Production

Production Planning

Warehouse

Quality Assurance (inc. IPC)

Quality Control

Engineering Department

Human Resources Administration

Regulatory Affairs

Intellectual Property

Research & Development

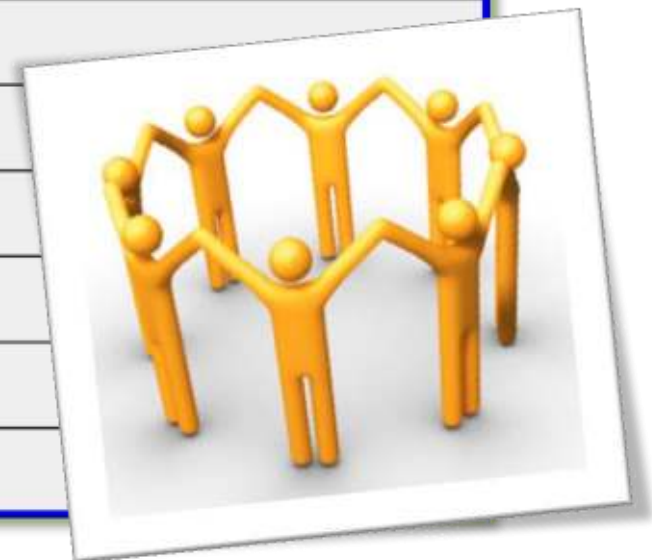
Information Technology

Budget&Account&Finance

Purchasing

Sales & Marketing

Export Department



Organization

Site Operations Area Distribution	Area (m ²)
Warehouse-206	1200 m ²
Warehouse-209	800 m ²
Warehouse-210	2200 m ²
Raw Materials Dispensing	190 m ²
Solid Production	1420 m ²
Solid Primer Packaging (Blistering ,bottling)	470 m ²
Solid Secondary Packaging	850 m ²
Liquid Production	720 m ²
Liquid Filling	110 m ²
Liquid Secondary Packaging	450 m ²
Ampoule washing ,filling	440 m ²
Ampoule Optic Control	115 m ²
Hormone Production	420 m ²
Research & Development Formulation Lab	250 m ²
Research & Development Analytical Lab	220 m ²
Quality Control Analytical Lab	430 m ²
Quality Control Microbiology Lab	200 m ²

Non sterile Products :

- Tablets ,Film Tablets
- Capsules
- Dry Powder Suspension
- Solutions
- Suspensions
- Ointments ,Cream and Gels
- Syrups
- Soft Gelatine Capsules
- Suppositories
- Sprays

Hormone Dedicated Facility:
Hormone/steroid



The manufacturing plants in İstanbul / Sancaktepe region consist of two main structures:

1. Main facility building



2. Hormone facility building



Main facility building :

- 5 operating divisions
- solid forms department
- liquid(sterile and nonsterile) forms department
- semi solid forms production department
- packaging department (2D Barcode is applied to all domestic markets products)
- warehouses



Hormones facility building :

The production of highly active products requiring specially controlled hormones in building apart from main production building.

Solid products (tablets and film tablets) of hormone are manufactured packaged
Currently manufactured products :

-Finasteride 1mg and 5 mg Film Tablets

-Hydrocortisone 5 mg and 10 mg Tablets



Key production forms and Capacity

State-of-the-art manufacturing facilities built upon world pharmaceutical standards (cGMP, cGLP and MHRA compliant)

Production forms and key products

	Forms	Capacity ¹	Usage Capacity (%)
1	Tablets	663.750.000 units / year	% 65
2	Coated tablets	202.500.000 units / year	% 60
3	Hard gelatine capsules	1.462.500 litres / year	% 100
4	Syrup and suspensions	337.500 kilos / year	% 70
5	Powder and granules	9.562.500 units / year	% 10
6	Cream and ointments	3.712.500 blisters / year	% 20
7	Suppositories	35.437.500 units / year	% 100
8	Soft gelatine capsules		

- **All systems are compliant with the requirements of**

- GMP (Good Manufacturing Practices)

- EU GMP Guideline

which demonstrate the compliance with quality and control of production facilities and relevant organizational processes



GMP CERTIFICATE

REPUBLIC OF TURKEY
MINISTRY OF HEALTH
 Turkish Medicines and Medical Devices Agency

GMP CERTIFICATE

We hereby certify that,

BIOFARMA İLAÇ SAN. ve TİC. A.Ş.
 Akpınar Mah. Osmangazi Cad. No : 156
 Sancaktepe / İstanbul / TURKEY

is a Pharmaceutical Product Manufacturing Plant and subject to inspection at suitable intervals and that the mentioned manufacturer conforms to the requirements for current GMP as recommended by the World Health Organisation in respect of products to be sold or distributed within the country of origin or to be exported.


Ecz. Güven ARTIRAN
 Kurum Başkanı Yardımcısı

MANUFACTURING LICENCE

REPUBLIC OF TURKEY
MINISTRY OF HEALTH
 General Directorate of Pharmacological and Pharmacy

ÖRNEKTİR

= 1 NİSNE
 No - 5920
 27 Mart 2009

It is hereby announced that sterile hormone (steroidal tablet) is manufactured at the registered manufacturing plant, 05.01.2009
 Dr. Halil AKAR
 Deputy General Director
 (signature)

It is hereby approved that the number of the registered manufacturing plant in this certificate is recorded as "T17" 05.01.2009
 Dr. Halil AKAR
 Deputy General Director
 (signature)

0999 1

CERTIFICATE OF LICENSE FOR MANUFACTURING PLANT

This is the certificate of license for the manufacturing plant that authorizes the manufacture of tablet, capsule, sugar coated tablet, ampoule, vial, powder, suspension, soft gelatin capsule, granule, prodrug, suspension, cream, gel, coated tablet, solution or the manufacturing plant of Dişarınca İlaç San. ve Tic. A.Ş. residing at the address of İstanbul, Kartal, Sarıyer, Akpınar Mah. Park Cad. No:2. 10.65.2006

Dr. Mahmut TORCAÇ
 General Director
 (signature)

Specialist Dr. Orhan F. GÜMBÜKÇÜOĞLU
 Deputy Undersecretary
 (signature)

The address of the registered manufacturing plant is hereby announced as İstanbul, Sancaktepe, Sarıyer, Akpınar Mah. Park Cad. No: 2. 05.01.2009
 Dr. Halil AKAR
 Deputy General Director
 (signature)

ASLI GİBİDİR

Hırsız, Tıbbi Değerler ve Diğerleri İçin Kullanılmamalıdır.
 Kopyaları İçin Gözetim Kurumuna Başvurulmalıdır.

Apart from production of its own registered products, Biofarma has been providing support to other pharmaceutical companies for a period of more than ten years with its experience on outsourcing.

Toll Manufacturing agreements with multi-national and local companies such as;

Sanofi Aventis

CevaDif

Bilim İlaç

Basel İlaç

Casel İlaç

Münir Şahin İlaç

Recordati İlaç

Eczacıbaşı İlaç

Toll
Manufacturing

Toll Manufacturing agreements with EU Countries:

Finasteride 1mg and 5 mg Film Tablets :

Finasteride 5 mg Film Tablets :

Loratadine 10 mg Tablets :

Toll Manufacturing Partners:

BELUPO – Croatia

MYLAN – European Countries, New Zealand, Algeria

HEMOPHARM – Bosnia & Herzegovina, Albania, Serbia

CONSILINT HEALTH – UK & Ireland

Authority Inspections by:

Turkish Ministry Of Health:

- Inspected on 16-17.05.2005
- Inspected on 20.03.2007
- Inspected on 16-17-18.09.2009
- Inspected on 28.06/03.07-2012

MHRA –UK

(Medicine and Healthcare Products Regulatory Agency)

- Inspected on 15-16.10.2006
- Inspected on 14-15.09.2009
- Inspected on 13-17.06.2012
- Inspected on 15-18.02.2014

Belarus Ministry Of Health

- Inspected on 29-30.09.2010

North of Iraq Ministry of Health

- Inspected on 08.05.2013

State Administration of Ukraine

- Inspected on 12.05.2015



Site Views Solid Production



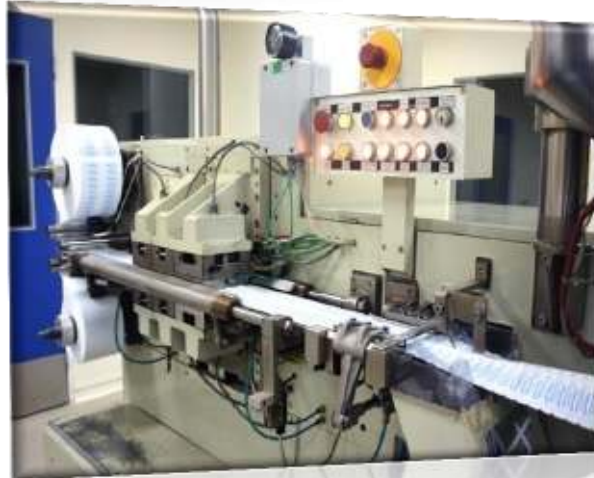
Solid Production



Syrup And Suspension Production



Semi-Solid Production



Packaging



- Anti-Infectives
- **Dermatologicals**
- Respiratory System
- **Parasitology**
- Oral Antidiabetics
- **Urologicals**
- Nervous System
- **Psychiatry**
- Cardiovascular System
- **Musculo-Skeletal System**
- Alimentary T.& Metabolism



AZELTIN (Azithromycine)

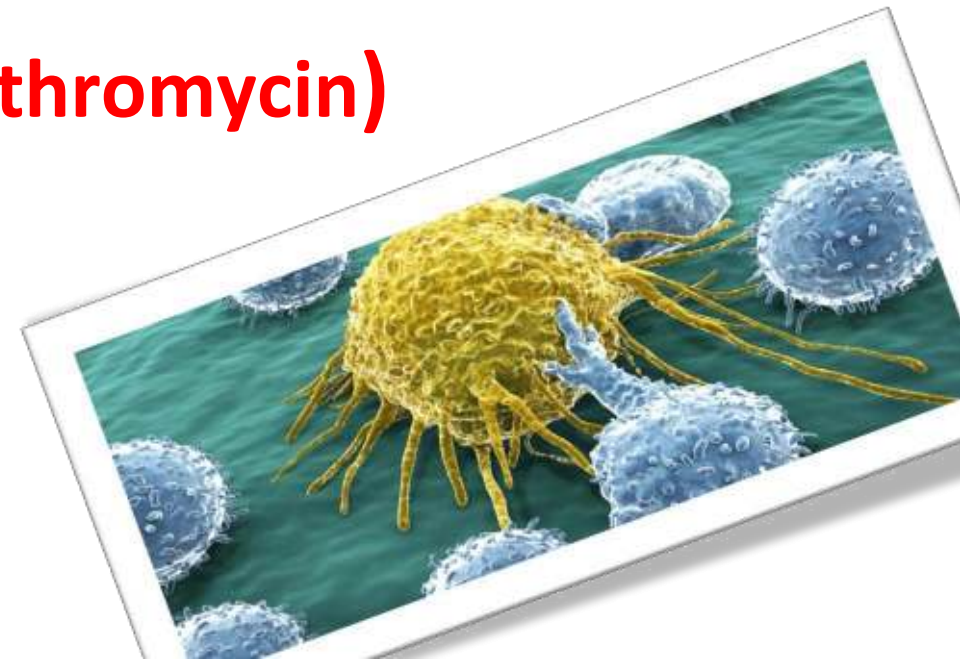
CIPRO (Ciprofloxacin)

MOXIFOR (Moxifloxacin)

NEVOTEK (Levofloxacin)

ZIZOLID (Linezolid)

LARICID (Clarithromycin)



ANTI - INFECTIVES



DERMATOLOGY

Corbinal	Terbinafine Hydrochloride	0.01 g / 1 ml	30 ml Spray / Bottle / Box
Corbinal	Terbinafine Hydrochloride	10 mg / g	15 g Cream / Tube / Box
Corbinal	Terbinafine	250 mg	14 Tablet / Box
Corbinal	Terbinafine	250 mg	28 Tablet / Box
Troderm	Izokonazole Nitrate Diflocortolone Valerate	%1 %01	15 g Cream / Tube / Box
Clobesol	Clobetasole Propionate	%0.05	50 g Cream / Tube / Box
Clobesol	Clobetasole Propionate	%0.05	50 g Ointment / Tube / Box

DERMATOLOGICALS



AIRLAST (Montelukast)

ALARIN (Loratadine)

DESRINAL (Desloratadine)

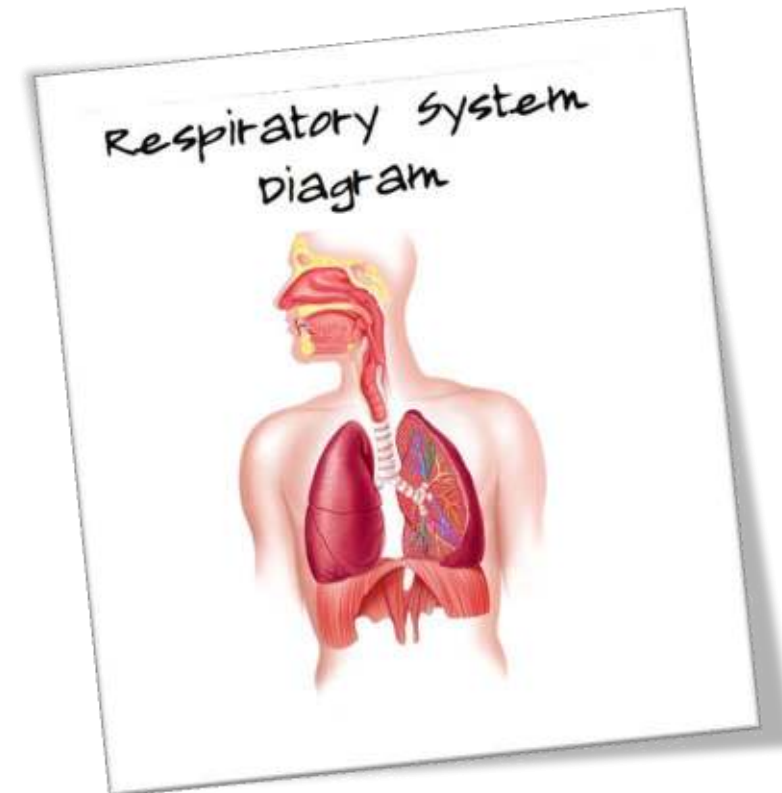
KATARIN

(Paracetamol, Oxolamine Citrate,
Chlorpheniramine Maleate)

Fort

MUKORAL

(Ambroxol Hydrochloride)



RESPIRATORY SYSTEM



ANDAZOL (Albendazole)



PIYELOSEPTYL
(Nitrofurantoin)

DILAPROST
(Finasteride)

TOLDIN
(Tolderodine Tartrate)

SOLIFENACIN
(Solifenacin Succinate)

UROLOGICALS



ARYPEZ (Donezepil Hydrochloride)

EBITEX (Memantine)

RISTART (Rivastigmine)

RICUS (Risperidone)

ZYZAPIN (Olanzapine)

EPSILE (Oxcarbazepine)

GABASET (Gabapentin)

LYPRE (Pregabalin)

OPEMIN (Piracetam)

NÖROMAT (Topiramate)

VETRIA (Levetiracetam)



NERVOUS SYSTEM



NERVOUS SYSTEM



FULSAC (Fluoxetine)

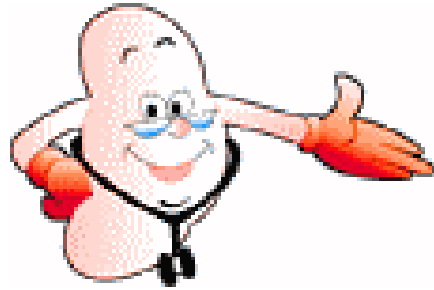
TIOPRAM (Escitalopram)

CYTERAS (Citalopram)

LUSTEC (Sertraline)







DIAFREE (Repaglinide)

TEGLIX (Nateglinide)

PIOFORCE (Pioglitazone)

ORAL ANTIDIABETICS



MEKSUN (Meloxicam)



SYNAX (Naproxen sodium)



KOLEZ (Ezetimibe)

LOXIBIN (Losartan)

LOXIBIN PLUS

(Losartan Hydrochlorothiazide)

CHOLVAST (Atorvastatine)

ATERVIX (Clopidogrel)

NIPIDOL (Amlodipe)



CARDIOVASCULAR SYSTEM



GISMOTAL (Tribumetine Maleate)

FAMOSER (Famotidine)

OSMOLAK (Lactulose)

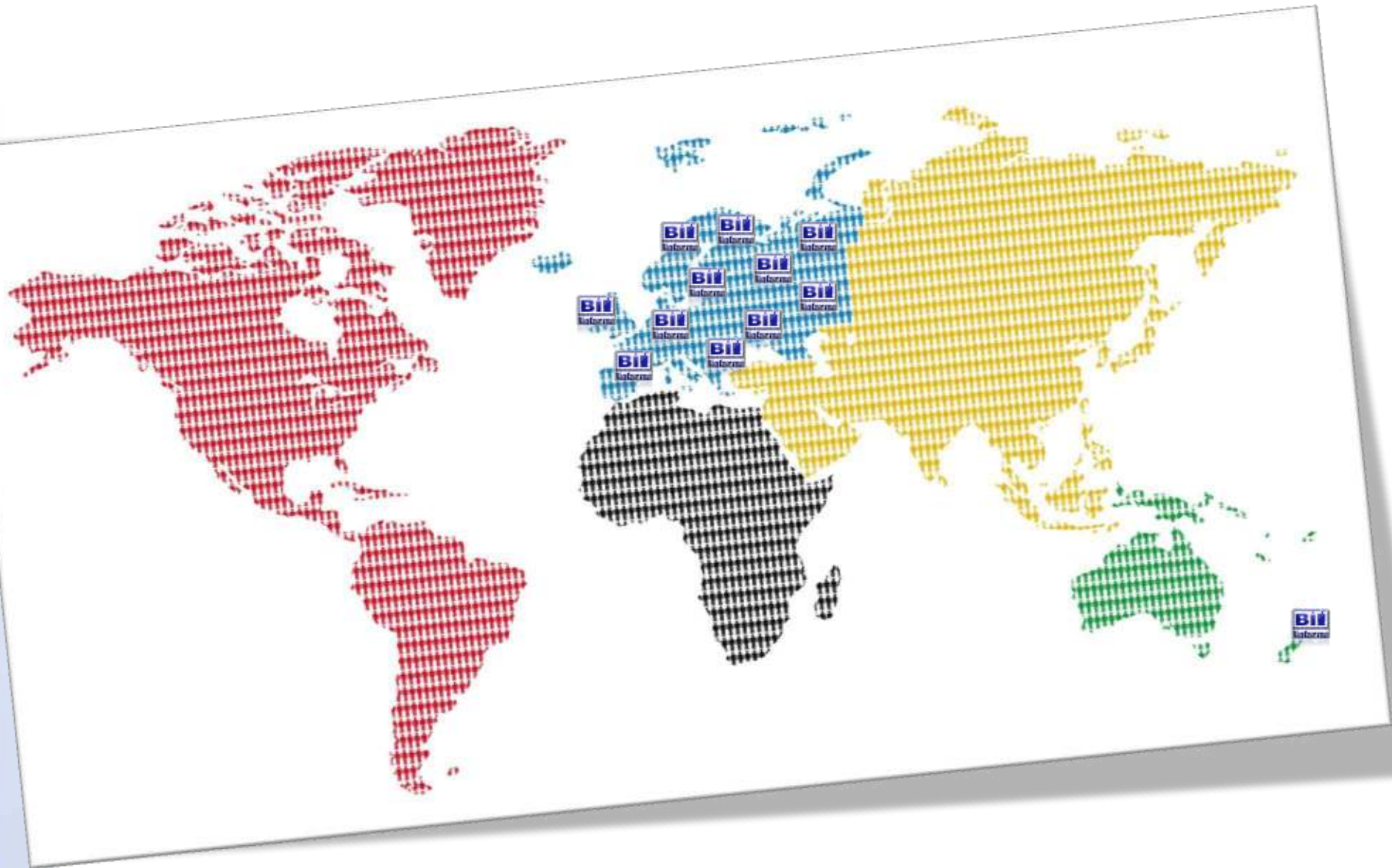
LANZEDIN (Lansoprazole)

PANREF (Pantoprazole)



ALIMENTARY T.& METABOLISM





BIOFARMA REGISTERED PRODUCT LIST



COUNTRY		BIOFARMA LICENCES		TOTAL
		Number of Licences	on Application	
1	ALBANIA	7	1	8
2	AFGHANISTAN	13		13
3	AZERBAIJAN	11	8	18
4	BOSNIA HERZEGOVINA	8	1	9
5	GEORGIA	7		7
6	KAZAKHSTAN	19		19
7	KYRGYZSTAN	3	3	6
8	KOSOVO	4		4
9	MACEDONIA	14		14
10	MOLDOVA	2		2
11	TURKMENISTAN	18	2	20
TOTAL		106	15	121

CONTRACT MANUFACTURING



COUNTRY		CONTRACT MANUFACTURING		TOTAL
		Number of Licences	on Application	
1	ALBANIA	1		1
2	ALGERIA	1		1
3	AZERBAIJAN	10		10
4	BELARUS	5		5
5	BOSNIA HERZEGOVINA	1		1
6	BELGIUM	1		1
7	CROATIA	2		2
8	CZECH REPUBLIC	1		1
9	FRANCE	1		1
10	GEORGIA	10		10
11	GERMANY	1		1
12	GREECE	1		1
13	HOLLAND	2		2
14	IRAQ		15	15
15	IRELAND		1	1
16	ITALY	2		2
17	KAZAKHSTAN	15		15
18	KYRGYZSTAN	18		18
19	MOLDOVA	18		18
20	UZBEKISTAN	17		17
21	TAJIKISTAN	18		18
22	TURKMENISTAN	15		15
23	POLAND	1		1
24	PORTUGAL	1		1
25	RUSSIA	2		2
26	SERBIA	1		1
27	SPAIN	1		1
28	SWEDEN	1		1
29	UKRAINE	12		12
30	UNITED KINGDOM	5	1	6
31	NEW ZEALAND	1		1
TOTAL		165	17	184

OUR TARGET EXPORT COUNTRIES

1. SAUDI ARABIA

2. UKRAINE

3. IRAN

4. AFRICA

– WEST AFRICA

BENIN, BURKINA FASO, GANA, NIGER, TOGO

- EAST AFRICA

SUDAN, KENYA, ETHIYOPIA, TANZANIA, DJIBUTI

TARGET MOLECULES IN EUROPE FOR REGISTRATION

- Dutasteride + Tamsulosin Capsules (Finasteride next generation treatment)
- **Levonorgestrel 1.5 mg 1 Tablet (Oral Contraceptive)**
- Estradiol 2 mg + Norethol 1 mg 28 Tablet
(Human Replacement Product)

BIOFARMA PHARMACEUTICAL INDUSTRY CO. INC.

CONTACT

**PHONE: 00 90 216 398 10 63 (4 LINE)
00 90 216 398 00 15 (3 LINE)**

**ADDRESS : Akpınar Mah. Osmangazi Cad. No: 156
Sancaktepe/İSTANBUL**

THANKS FOR YOUR ATTENTIONS



THANK YOU

GRACIAS
ARIGATO
SHUKURIA
JUSPAXAR
DANKSCHEEN
TASHAKKUR ATU
SUKSAMA
EKGHMET
GRAZIE
MEHRBANI
PALDIES
BOLZIN
MERCICI
BIYAN
SHUKRIA
TINGKI