

Saudi Drug Registration

Welcome mohammed

[Home](#) | [Logout](#)

Type of Application

Application Details

Names and ATC Code**Product Information****Legal Status****Contact Information****Manufacturers****Animal Source Material**

Scientific Advice

Application Status

Inquiries

Type of Application

Data has been saved/updated successfully

This application concerns : Herbal product Health product**Please provide the following information for the product :****Herbal product:****Product information in COO:**Is Saudi Arabia the country
of origin(COO)? : Yes No

Trade name : CAPSOL-T

Product strength : 350

Strength Unit : mg

Dosage form : Capsule

Marketing authorization
holder :

Name : STANDARD ENZYME COMPANY OF NORTH AME

Address Line1 : 106 Buchanan St. North

Address Line2 :

Address Line3 :

Postal Zip Code : 30110

City : Bremen, GA

Country : United states

Certifying Authority : N/A

Date of authorization : 3/1/2003

Certifying Country : United states

Save

Next

Saudi Drug Registration

Welcome mohammed

Home | Logout

Type of Application

Name(s) and ATC code

Application Details

Names and ATC Code

Product Information

Legal Status

Contact Information

Manufacturers

Animal Source Material

Scientific Advice

Application Status

Inquiries

Proposed trade name : CAPSOL-T

List the active substance(s) :

 Single active substanceType of the active substance(s) : Multiple active substances

Name of active substance(s) :

Quantity :

Unit : Select ▼

Reference/Monograph standard :

Add Active Substance

Substance Name	Quantity	Unit	Reference	Delete
DECAFFEINATED GREEN TEA EXTRACT	350	mg		Delete
CHILI PEPPER EXTRACT	350	mg		Delete

List the excipient(s):

Name of excipient(s) :

Quantity :

Unit : Select ▼

Reference/Monograph standard :

Add Excipient

Excipient Name	Quantity	Unit	Reference	Delete
Microcrystalline Cellulose	164.10	mg		Delete
Magnesium Stearate	10.60	mg		Delete
Silicon Dioxide	5.30	mg		Delete
Clear Veggie Capsule Size 0	100	mg		Delete

Raw plant materials :

Scientific name, family :

Traditional or common name (Arabic and/or English) :

Used parts :

Saudi Drug Registration

Welcome mohammed

[Home](#) | [Logout](#)

Type of Application

Application Details

Names and ATC Code

Product Information

Legal Status

Contact Information

Manufacturers

Animal Source Material

Scientific Advice

Application Status

Inquiries

Product Information

Manufacturer name : ARNET PHARMACEUTICAL

Manufacturing site :

City : DAVIE

Country : United states

Dosage form : Capsule

Strength : 350 Strength Unit : mg

Package size : Volume : Volume Unit :
Select

Add Package Size

Package Size	Volume	Volume Unit	Delete
180	0	mg	Delete

Available options

Selected options

Route of administration :

- Auricular use
- Beak dipping
- Buccal use
- Conjunctival use
- Cutaneous use
- Dental use
- Dipping

>
<

- Oral use

Administration device (if applicable) :

Primary packaging : Bottle

Secondary packaging : White HDPE 300cc45mm

Proposed shelf life : 36 Month(s)

Proposed shelf life after first opening container (if applicable) : Select

Proposed shelf life after reconstitution or dilution (if applicable) : Select

Available options

Selected options

Proposed storage conditions :

- Do not freeze
- Do not refrigerate
- Do not refrigerate or freeze
- Do not store above 25°C
- Do not store above 30°C
- in order to protect from light

>
<

- Store below 25°C

Available options

Selected options

Proposed storage conditions after first opening (if applicable) :

- Do not freeze
- Do not refrigerate
- Do not refrigerate or freeze
- Do not store above 25°C
- Do not store above 30°C
- in order to protect from light



Empty box for selected options.

Reference Pharmacopeia :

Empty text input field.

Previous

Save

Next

Saudi Drug Registration



Welcome mohammed

[Home](#) | [Logout](#)

Type of Application

Legal Status

Application Details

Names and ATC Code

Product Information

Legal Status

Contact Information

Manufacturers

Animal Source Material

Scientific Advice

Application Status

Inquiries

Does this product have medical claims? : Yes No

If yes, please specify :

ANTI CANCER PRODUCT

Saudi Drug Registration

Welcome mohammed

Home | Logout

Type of Application

Application Details

Names and ATC Code

Product Information

Legal Status

Contact Information

Manufacturers

Animal Source Material

Scientific Advice

Application Status

Inquiries

Contact Information

Please fill all contact sessions below before proceeding to save.

Proposed marketing authorization holder/person legally responsible for placing the product on the market in KSA:

Person/Company authorized for communication in KSA on behalf of the applicant:

Person/Company authorized for communication between the marketing authorization holder and the SFDA after authorization:

First Name :

Middle Name :

Last Name :

Company Name :

Address Line1 :

Address Line2 :

Address Line3 :

Postal Zip Code :

City :

Country :

Phone :

Ext :

Fax :

E-mail :

Saudi Drug Registration

Welcome mohammed

[Home](#) | [Logout](#)

Type of Application

Application Details

Names and ATC Code

Product Information

Legal Status

Contact Information

Manufacturers

Animal Source Material

Scientific Advice

Application Status

Inquiries

Contact Information

Please fill all contact sessions below before proceeding to save.

Proposed marketing authorization holder/person legally responsible for placing the product on the market in KSA:

Person/Company authorized for communication in KSA on behalf of the applicant:

First Name :

Middle Name :

Last Name :

Company Name :

Address Line1 :

Address Line2 :

Address Line3 :

Postal Zip Code :

City :

Country :

Phone : Ext :

Fax :

E-mail :

Person/Company authorized for communication between the marketing authorization holder and the SFDA after authorization:

Saudi Drug Registration

Welcome mohammed

[Home](#) | [Logout](#)

Type of Application

Contact Information

Application Details

Please fill all contact sessions below before proceeding to save.

Names and ATC Code

Product Information

Legal Status

Contact Information

Manufacturers

Animal Source Material

Scientific Advice

Application Status

Inquiries

Proposed marketing authorization holder/person legally responsible for placing the product on the market in KSA:

Company Name : STANDARD ENZYME COMPANY OF NORTH AME

First Name : Abdel

Middle Name : Rahman

Last Name : Alkhalouf

Address Line1 : 106 Buchanan St. North

Address Line2 :

Address Line3 :

Postal Zip Code : 30110

City : Bremen, GA

Country : United states ▼

Phone : 7705374445 Ext :

Fax : 7705371747

E-mail : abdel@euromedglobal.com

Person/Company authorized for communication in KSA on behalf of the applicant:

Person/Company authorized for communication between the marketing authorization holder and the SFDA after authorization:

[Previous](#)

[Save](#)

[Next](#)

Saudi Drug Registration

Welcome mohammed

Home | Logout

Type of Application

Application Details

Names and ATC Code

Product Information

Legal Status

Contact Information

Manufacturers

Animal Source Material

Scientific Advice

Application Status

Inquiries

Manufacturers

Please fill all manufacturer sessions below before proceeding to save.

Active Ingredient manufacturer (raw material manufacturer)
Excipients manufacturer
Finished Product manufacturer

Do you have a valid inspection report from the MoH or SFDA in the past 5 years? : Yes No

Is this product under-license? : Yes No Not applicable

Name of Manufacturer :

Address Line1 :

Address Line2 :

Address Line3 :

Phone : Ext :

City :

Fax :

Postal Zip Code :

Country :

Activity :

Is it GMP certified? : Yes No

Certifying Authority :

Date :

Name of manufacturer	Valid inspection report	Address	Activity	GMP Certified	Certifying Authority	Edit	View	Delete
Arnet Pharmaceutical	Yes	2525 DAVIE ROAD, SUITE 330, DAVIE, FLORIDA 33317, DAVIE, United states	FINISHED PRODUCT MANUFACTURER	Yes	USA FDA	Edit	View	Delete

Saudi Drug Registration



Welcome mohammed

[Home](#) | [Logout](#)

- Type of Application
- Application Details
 - Names and ATC Code**
 - Product Information**
 - Legal Status**
 - Contact Information**
 - Manufacturers**
 - Animal Source Material**
- Scientific Advice
- Application Status
- Inquiries

Manufacturers

Please fill all manufacturer sessions below before proceeding to save.

Active Ingredient manufacturer (raw material manufacturer)
Excipients manufacturer

Name of Manufacturer :

Name of Excipient :

Address Line1 :

Address Line2 :

Address Line3 :

Phone : Ext :

City :

Fax :

Postal Zip Code :

Country :

Activity :

Is it GMP certified? : Yes No

Certifying Authority :

Date :

Name of manufacturer	Name of excipient	Address	Phone	Fax	Activity	GMP Certified	Certifying Authority	Certifying Date	Edit	Delete
Blanver	Microcrystalline Cellulose	1515 South Federal Highway Suite 105, Boca Raton, FL 33432 USA, Boca Raton, United states	5614165513			Yes			Edit	Delete
American International Chemical	Magnesium Stearate	135 Newnury St, Farmingham, MA 01701, USA, Farmingham, United states	8002380001			Yes			Edit	Delete
Bell Chem Corp	Silicon Dioxide	1340 Bennett Drive, Longwood, FL 32750, USA, Longwood, United states	4073392355			Yes			Edit	Delete
ACG North America LLC	Clear Veggie Capsule Size 0	229 Durham Ave, South Plainfield, NJ 07080, USA, South Plainfield, United states	8776183344			Yes			Edit	Delete

Finished Product manufacturer

Saudi Drug Registration

Welcome mohammed

Home | Logout

- Type of Application
- Application Details
- Names and ATC Code**
- Product Information**
- Legal Status**
- Contact Information**
- Manufacturers**
- Animal Source Material**
- Scientific Advice
- Application Status
- Inquiries

Manufacturers

Please fill all manufacturer sessions below before proceeding to save.

Active Ingredient manufacturer (raw material manufacturer)

Name of Manufacturer :

Name of Ingredient :

Address Line1 :

Address Line2 :

Address Line3 :

Phone : Ext :

Fax :

City :

Postal Zip Code :

Country :

Activity :

Is it GMP certified? : Yes No

Certifying Authority :

Date :

Name of manufacturer	Name of ingredient	Address	Phone	Fax	Activity	GMP Certified	Certifying Authority	Certifying Date	Edit	Delete
Mor-NuTech, Inc	Green Tea Extract	1112 Cherry Lane, West Lafayette, IN 47906, West Lafayette, United states	7654914876	7654914876	Active ingredients manufacturer	Yes	USA FDA		Edit	Delete
Mor-NuTech, Inc.	Guajillo Pepper Powder	1113 Cherry Lane, West Lafayette, IN 47906, West Lafayette, United states	7654914877	7654914876	Active ingredients manufacturer	Yes	USA FDA		Edit	Delete

Excipients manufacturer

Finished Product manufacturer

Saudi Drug Registration

Welcome mohammed

[Home](#) | [Logout](#)

Type of Application

Animal Source Material

Application Details

Names and ATC Code

Any material of animal source contained in any component of the product :

Product Information

Legal Status

Contact Information

Manufacturers

Animal Source Material

Scientific Advice

Application Status

Inquiries

Saudi Drug Registration

Welcome mohammed

[Home](#) | [Logout](#)

Type of Application

Application Details

Names and ATC Code

Product Information

Legal Status

Contact Information

Manufacturers

Animal Source Material

Scientific Advice

Application Status

Inquiries

Scientific Advice

Was there any formal scientific advice given by the SFDA for this medicinal product? : Yes No

Previous

Save

Next

Saudi Drug Registration

Welcome mohammed

[Home](#) | [Logout](#)

Type of Application

Application Details

Names and ATC Code

Product Information

Legal Status

Contact Information

Manufacturers

Animal Source Material

Scientific Advice

Application Status

Inquiries

Application Status

Status of the application in other regulatory agencies:

Tick the appropriate box and fill the information.

Authorized

Country :

Trade name :

Product strength :

Dosage form :

Marketing authorization holder :

Date of marketing authorization :

Country	Trade name	Product strength	Dosage form	Marketing authorization holder	Date of marketing authorization	Edit/Delete
United states	Capsol-T	350 mg	Capsule	Standard Enzyme		Edit Delete

Pending

Refused

Withdrawn (by applicant after authorization)

Suspended/revoked (by competent authority)

Saudi Drug Registration



Welcome mohammed

[Home](#) | [Logout](#)

Type of Application

Application Details

Names and ATC Code

Product Information

Legal Status

Contact Information

Manufacturers

Animal Source Material

Scientific Advice

Application Status

Inquiries

Fees

Data has been saved/updated successfully

Application Type :

Fee Amount (SAR) : 20000

Invoice Number : 2284759

Transaction Date : 9/27/2016

Status : New

Please the payment sholud be paid before proceeding