

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

**A randomized, open label, two treatments, single dose, crossover, bioequivalence study of Dapoxetine 30mg tablet of Alborz Darou Pharm Co., IRAN in comparison of Priligy 30mg tablet of Menarini in 24 healthy adult subjects under fasting condition**

### Protocol summary

#### Study aim

A randomized, crossover bioequivalence study of single dose of test formulation (two tablets of Dapoxetine 30mg produced by Alborz Darou Pharm. Co.) in comparison of reference product (two tablets of Priligy 30mg) by means of AUC<sub>0-t</sub> and C<sub>max</sub> in healthy, adult human subjects under fasting conditions.

#### Design

A randomized, open label, single dose, crossover, bioequivalence study in 24 healthy subjects under fasting condition with wash out period of at least one week

#### Settings and conduct

This study is carried out in Core Research Center of Zahedan University of Medical Sciences located in Imam Ali Hospital in Zahedan. There is a separate space for sampling and forecasting emergency situations in order to accommodate and rest the volunteers. This crossover and open label study was performed on 24 healthy volunteers with wash out period of at least one week. The volunteers' health is verified by the project physician prior to entry into the study, and the volunteers' status is regularly monitored by the project physician on the day of drug administration. This study will be covered by insurance in order to compensate for any adverse effects.

#### Participants/Inclusion and exclusion criteria

Main Inclusion criteria: Healthy subjects aged between 18 -50 years old and weighted between 50 - 100 kg\\  
Main exclusion criteria: Donation a unit of blood or participated in another clinical trial within the last three months; History of drug or alcohol abuse; Used any medication within 7- 14 days before the first treatment;

#### Intervention groups

Intervention: Single dose of two Dapoxetine 30mg tablets of Alborz darou Pharm Co., IRAN Control: Single

dose of two Priligy 30mg tablets of Menarini

#### Main outcome variables

Plasma concentration of dapoxetine

### General information

#### Reason for update

#### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20190706044111N18**

Registration date: **2020-05-21, 1399/03/01**

Registration timing: **prospective**

Last update: **2020-05-21, 1399/03/01**

Update count: **0**

#### Registration date

2020-05-21, 1399/03/01

#### Registrant information

##### Name

Ladan Tayebi

##### Name of organization / entity

Pars Biopharmacy Research Co.

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8895 6061

##### Email address

l.tayebi@parsbiopharmacy.com

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2020-06-21, 1399/04/01

#### Expected recruitment end date

2021-03-19, 1399/12/29  
**Actual recruitment start date**  
empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

**Scientific title**  
A randomized, open label, two treatments, single dose, crossover, bioequivalence study of Dapoxetine 30mg tablet of Alborz Darou Pharm Co., IRAN in comparison of Priligy 30mg tablet of Menarini in 24 healthy adult subjects under fasting condition

**Public title**  
Bioequivalence study of Dapoxetine 30mg tablet of Alborz Darou Pharm Co., IRAN

**Purpose**  
Other

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
- Aged between 18 - 50 years - Body weight between 50 - 100 kg - Having good health on the basis of medical history and physical & clinical examination - Understand the procedures and give written informed consent  
**Exclusion criteria:**  
Subject had undergone surgery of the gastro-intestinal tract Subject had donated a unit of blood or participated in another clinical trial, within the last two months before the first treatment. Subject had a history of drug or alcohol abuse. Subject who smokes more than 10 cigarettes per day. Subject had used any prescription medication within 14 days, or any non-prescription medication within 7 days, before the first treatment.

**Age**  
From **18 years** old to **50 years** old

**Gender**  
Both

**Phase**  
Bioequivalence

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **24**  
More than 1 sample in each individual  
Number of samples in each individual: **2**  
Each volunteer, 2 times take medicine in the study. One-time test product and the other time reference product with at least one week wash-out period.

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Using Excel software, each subject will be randomly assigned to one of the two sequence AB or BA in a balanced manner.

**Blinding (investigator's opinion)**  
Not blinded

**Blinding description**

**Placebo**  
Not used

**Assignment**

Crossover  
**Other design features**

## Secondary Ids

empty

## Ethics committees

1

### Ethics committee

#### Name of ethics committee

Ethics committee of Zahedan University of medical Sciences

#### Street address

Dr. Hessabi square Zahedan University of Medical Sciences

#### City

Zahedan

#### Province

Sistan-va-Balouchestan

#### Postal code

9816743463

### Approval date

2020-04-26, 1399/02/07

### Ethics committee reference number

IR.ZAUMS.REC.1399.040

## Health conditions studied

1

### Description of health condition studied

Premature ejaculation

### ICD-10 code

F52.4

### ICD-10 code description

Premature ejaculation

## Primary outcomes

1

### Description

Plasma concentration of dapoxetine

### Timepoint

At 0 (before dosing), 0.5, 1.0, 1.5, 2.0, 2.5, 3.0, 4.0, 6.0, 8.0, 10.0, 24.0 & 48.0 hr. after drug administration

### Method of measurement

High Performance Liquid Chromatography (HPLC)

## Secondary outcomes

empty

## Intervention groups

1

### Description

Intervention group: Single dose of two Dapoxetine 30mg

tablets of Alborz Darou Pharm Co., IRAN

**Category**

Other

**2**

**Description**

Control group: Single dose of two Priligy 30mg tablets of Menarini

**Category**

Other

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Core Research Lab. of ZAUMS

**Full name of responsible person**

Gholamreza Komeili

**Street address**

Emam Ali Hospital, Salamat Blv., Khalij-e-Fars Highway

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Sistan-va-Balouchestan

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crl@zaums.ac.ir

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<http://crl.zaums.ac.ir/>

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Alborzdarou Pharm. Co.

**Full name of responsible person**

Ali Mortazavi

**Street address**

8th Hekmat street, Alborz Industrial City, Ghazvin

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3431957693

**Phone**

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**Fax**

+98 28 3222 1001

**Email**

info@alborzdarouco.com

**Web page address**

<http://www.alborzdarouco.com>

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Alborzdarou Pharm. Co.

**Proportion provided by this source**

100

**Public or private sector**

Private

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

Industry

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Pars Biopharmacy Research Co.

**Full name of responsible person**

Ladan Tayebi

**Position**

Managing Director

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Medical Pharmacy

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## Person responsible for updating data

### Contact

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Pars Biopharmacy Research Co.  
**Full name of responsible person**  
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**Position**  
Managing Director  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

### Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

### Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

### Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

### Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

### Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

### Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available