

Eveli Holst

Saatja: Eveli Holst
Saatmisaeg: kolmapäev, 4. veebruar 2026 16:55
Adressaat: BAUTZ Ketty
Koopia: Signe Leito
Teema: Vs: Request of information - Aripiprazole Generics Programme-

Hello

Yes, we still have samples left. The scans are made for the outer packages of the following four samples:

Aripiprazole Zentiva – IT _ Sample J
Aripiprazole Sandoz – SE _ sample G
Aripiprazole Sandoz – EL _ sample I
Aripiprazole Mylan pharma – HR _ Sample E

The scans are uploaded to ACT as you requested. Please follow up.

If you have any more questions or request, we are pleased to help you if we can.

On behalf of Signe Leito.

With best regards,

Eveli Holst
State Agency of Medicines
Laboratory
laboratory specialist

Phone 737 4140
Eveli.Holst@ravimiamet.ee

1 Nooruse Str
50411 Tartu
www.ravimiamet.ee

Selles e-kirjas sisalduv teave (kaasa arvatud manused) on mõeldud ametialaseks kasutamiseks ning seda võivad kasutada vaid e-kirja adressaadid. E-kirjas sisalduvat teavet ei tohi ilma saatja selgelt väljendatud loata edasi saata ega mis tahes viisil kolmandatele isikutele avaldada. Juhul, kui Te olete saanud käesoleva e-kirja eksituse tõttu, teavitage sellest kohe saatjat ning kustutage e-kiri.

This e-mail and any attachments transmitted may contain confidential and privileged information. If you are not the intended recipient, please notify the sender immediately by returning the e-mail and permanently deleting what you have received. Any dissemination or use of this information by a third person without permission is prohibited and may be illegal.

Saatja: BAUTZ Ketty <Ketty.BAUTZ@edqm.eu>
Saatmisaeg: esmaspäev, 2. veebruar 2026 16:21

Adressaat: Ravimiamet <info@ravimiamet.ee>; Signe Leito <Signe.Leito@ravimiamet.ee>

Teema: Request of information - Aripiprazole Generics Programme-

Tähelepanu! Tegemist on väljastpoolt asutust saabunud kirjaga. Tundmatu saatja korral palume linke ja faile mitte avada.

Dear Colleagues,

I hope you are doing well!

I'm coming back to you following a request from EMA regarding the label check questionnaires that have been filled in by the samplers for Aripiprazole.

I know it's a long time now that you received the samples, but I wanted to know if you would still have samples left to get scans of the outer packages.

If yes, we would like to receive pictures of the following samples:

Aripiprazole Zentiva – IT _ Sample J

Aripiprazole Sandoz – SE _ sample G

Aripiprazole Sandoz – EL _ sample I

Aripiprazole Mylan pharma – HR _ Sample E

These can be uploaded here: <https://act.edqm.eu/s/SRkjRyfw5pxWDwf>

Many thanks in advance!

Ketty

De : BAUTZ Ketty

Envoyé : mercredi 27 juillet 2022 12:00

À : info@ravimiamet.ee

Objet : FW: Aripiprazole Generics Programme- Shipment and current status

Dear Colleagues,

In the absence of Signe, please find below the email that was addressed to her.

Please note that the shipment of samples was moved from the 02/08/22 to the 09/08/22 – hope someone will be in the office to take care of the parcel.

Kind regards;

Ketty

From: BAUTZ Ketty
Sent: mercredi 27 juillet 2022 11:51
To: 'Signe Leito' <Signe.Leito@ravimiamet.ee>
Subject: Aripiprazole Generics Programme- Shipment and current status

Dear Signe,

I hope you are doing well.

I come back to you regarding the sampling status of the Aripiprazole generics programme.

The following reference substances – that were requested for the feasibility study – are still not yet available:

NAME
Impurity-1: 7-hydroxy-3, 4-dihydroquinolin-2(1H)-one
Impurity-2: 1-(2, 3-dichlorophenyl) Piperazine Hydrochloride
Impurity-3: 7-[4-(4-(2, 3-dichlorophenyl)-1-oxy-piperazin-1-yl)butoxy]-3, 4-dihydro-2-(1H)-quinolin impurity)
Aripiprazole Working standard
Placebo
Aripiprazole Zentiva, 5 mg, Tablet

Despite several reminders/emails sent to the MAH, nothing was received until now.

The same for the ARIPIPRAZOLE ACCORD, 15 mg, Tablet sample – CTS from Accord – despite several requests, the samples still haven't been received. The MAH says it's ongoing, but this is the status that is given since months...

I would suggest to start the analysis without these samples, if this is feasible for you (especially regarding the missing substances from Zentiva).

I would like to send you the samples as of next week, if this is fine for you. We can start the clock later on – but at least samples would be in your premises. Hope this is fine for you.

In order to prepare the RDS, I would need the testing protocol.

For information, this is the list of samples that are going to be sent to you:

EDQM N°1	DATE OF ARRIVAL	EDQM NUMBER	NAME
SFE415040	14/03/2022	DBO415171	Abilify, 15 mg, Tablet - CTS A
SFE415337	24/03/2022	DBO415401	Abilify, 5 mg, Tablet - Sample A
SFE415250	18/03/2022	DBO415264	Abilify, 15 mg, Tablet - Sample B
SFE415373	30/03/2022	DBO415448	Abilify, 30 mg, Tablet - Sample C
SFE415327	25/03/2022	DBO415396	ARIPIPRAZOLE MYLAN PHARMA, 15 mg, Tablet - CTS B
SFE415263	22/03/2022	DBO415402	ARIPIPRAZOLE MYLAN PHARMA, 5 mg, Tablet - Sample D
SFE415619	13/04/2022	DBO415706	ARIPIPRAZOLE MYLAN PHARMA, 15 mg, Tablet - Sample E
SFE415017	10/03/2022	DBO415098	ARIPIPRAZOLE MYLAN PHARMA, 30 mg, Tablet - Sample F
SFE415522	08/04/2022	DBO415637	ARIPIPRAZOLE SANDOZ, 15 mg, Tablet - CTS C
SFE416373	10/06/2022	DBO416530	ARIPIPRAZOLE SANDOZ, 5 mg, Tablet - Sample G
N/A	N/A	N/A	ARIPIPRAZOLE SANDOZ, 15 mg, Tablet - Sample H
SFE416091	23/05/2022	DBO416155	ARIPIPRAZOLE SANDOZ, 30 mg, Tablet - Sample I
SFE415470	06/04/2022	DBO415555	ARIPIPRAZOLE ZENTIVA, 15 mg, Tablet - CTS D

SFE415177	18/03/2022	DBO415253	ARIPIRAZOLE ZENTIVA, 5 mg, Tablet - Sample J
SFE415486	07/04/2022	DBO415639	ARIPIRAZOLE ZENTIVA, 15 mg, Tablet - Sample K
			ARIPIRAZOLE ACCORD, 15 mg, Tablet - CTS E
SFE416396	13/06/2022	DBO416531	ARIPIRAZOLE ACCORD, 5 mg, Tablet - Sample M
-	-	-	ARIPIRAZOLE ACCORD, 15 mg, Tablet - Sample N
SFE414900	04/03/2022	DBO415097	ARIPIRAZOLE ACCORD, 30 mg, Tablet - Sample O

Kind regards,
Ketty

From: Signe Leito <Signe.Leito@ravimiamet.ee>

Sent: mercredi 18 mai 2022 16:06

To: EDQM Dispatch <dispatch@edqm.eu>

Cc: BAUTZ Ketty <Ketty.BAUTZ@edqm.eu>

Subject: Shipment # 0080508780 received

Dear Dispatch Unit,

This is to inform you, that we received the parcel today.

Please find attached the Acknowledgment of Receipt and the report of the temperature recorder Libero CB.

With best regards,

Signe Leito
Leading Specialist of Quality Control Laboratory
State Agency of Medicines
Signe.Leito@ravimiamet.ee

1 Nooruse Street
50411 Tartu
Estonia
Phone: +372 737 4140
www.ravimiamet.ee

Selles e-kirjas sisalduv teave (kaasa arvatud manused) on mõeldud ametialaseks kasutamiseks ning seda võivad kasutada vaid e-kirja adressaadid. E-kirjas sisalduvat teavet ei tohi ilma saatja selgelt väljendatud loata edasi saata ega mis tahes viisil kolmandatele isikutele avaldada. Juhul, kui Te olete saanud käesoleva e-kirja eksituse tõttu, teavitage sellest kohe saatjat ning kustutage e-kiri.

This e-mail and any attachments transmitted may contain confidential and privileged information. If you are not the intended recipient, please notify the sender immediately by returning the e-mail and permanently deleting what you have received. Any dissemination or use of this information by a third person without permission is prohibited and may be illegal.

Saatja: EDQM Dispatch <dispatch@edqm.eu>

Saatmisaeg: esmaspäev, 16. mai 2022 17:14

Adressaat: Signe Leito <Signe.Leito@ravimiamet.ee>; dispatch@edqm.eu; ketty.bautz@edqm.eu

Teema: ECH: Prior to Dispatch Notif # 0080508780

Tähelepanu! Tegemist on väljastpoolt asutust saabunud kirjaga. Tundmatu saatja korral palume linke ja faile mitte avada.

Dear Sir/Madame,

Please note we are going to send the samples related to the request of Ketty BAUTZ about Aripiprazole Generics programme.

You will find enclosed all the details of the parcel and the Acknowledgment of Receipt that will have to be completed at receipt of the parcel. A hard copy will also be attached to the parcel.

As soon as the parcel will be sent, you will receive a dispatch notification with the tracking number or AWB to follow the parcel.

P.S.: Please let us know asap if your premises are closed in the next few days so we will reschedule the shipment.

Kind regards,

Dispatching Section

Council of Europe, European Directorate for the Quality of Medicines & HealthCare (EDQM)

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

www.edqm.eu and www.edqm.eu/hd (helpdesk)