
RE: Sterility_tests

Saatja Väisänen Elina <Elina.Vaisanen@fimea.fi>

Kuupäev E, 07.09.2026 13:04

Adressaat Aune Ahman - RA <aune.ahman@ravimiamet.ee>

Koopia Signe Leito - RA <signe.leito@ravimiamet.ee>; Eveli Holst - RA <eveli.holst@ravimiamet.ee>

Tähelepanu! Tegemist on välisvõrgust saabunud kirjaga.

Tundmatu saatja korral palume linke ja faile mitte avada.

Dear Aune,

thank you for the SOPs. I reviewed the documents and we can carry out the testing.

You can send the samples this week.

And we will plan the testing so that we have the results for you in the beginning of December. That is suitable for us.

Kind regards,
Elina

Elina Väisänen, PhD
Senior researcher (microbiology)

Tel. +358 29 522 3203

elina.vaisanen@fimea.fi

fimea

Finnish Medicines Agency Fimea

P.O.Box 55, FI-00034 FIMEA, FINLAND | Tel. +358 29 522 3341 | registry@fimea.fi

www.fimea.fi | [LinkedIn](#) | [Instagram](#)

The information contained in this message may be legally privileged and confidential and protected from disclosure. Any unauthorized use, distribution or copying of this communication is strictly prohibited. If you have received this communication in error, please notify us immediately by replying to the message and deleting it from your computer.

From: Aune Ahman - RA <aune.ahman@ravimiamet.ee>

Sent: perjantai 4. syyskuuta 2026 13.52

To: Väisänen Elina <Elina.Vaisanen@fimea.fi>

Cc: Signe Leito - RA <signe.leito@ravimiamet.ee>; Eveli Holst - RA <eveli.holst@ravimiamet.ee>

Subject: Vs: Sterility_tests

Dear Elina,

Thank you for your response and for willingness to provide subcontracting services for us.

You can download the Imipenem/Cilastatin Venus Pharma manufacturer's Standard Operating Procedure (SOP) for sterility testing from the following link (access is 60 calendar days):  [Sterility_2026](#)

We would like to send the samples to you next week. Given your current queue, we would be very grateful if we could receive the results by the beginning of December, if possible.

Please let us know if this timeframe works for you.

Best regards,

Aune Ahman

Head of Quality Control Laboratory

State Agency of Medicines

Email: aune.ahman@ravimiamet.ee

1 Nooruse Street

50411 Tartu

Estonia

Phone : +3727374140

www.ravimiamet.ee

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: Väisänen Elina <Elina.Vaisanen@fimea.fi>

Saadetud: neljapäev, 3. september 2026 13:29

Adressaat: Aune Ahman - RA <aune.ahman@ravimiamet.ee>

Teema: RE: Sterility_tests

Tähelepanu! Tegemist on välisvõrgust saabunud kirjaga.

Tundmatu saatja korral palume linke ja faile mitte avada.

Dear Aune,

Thank you for your email.

We are able to carry out sterility testing for Adrenaline Auxilia and Adrenaline Demo and the 4 ampoules are sufficient for the testing.

Regarding Imipenem/Cilastatin Venus Pharma, I would need manufacturer's SOP for sterility testing. The product is a broad-spectrum antibiotic, and usually the manufacturer has specific instructions for sterility testing (such as using tween in washing fluid, or using B-lactamase or something else to remove the antibiotic affecting the microbial growth, etc). Would it be possible to receive the SOP for sterility testing?

Otherwise, 1 package containing 5 vials is sufficient amount for the testing.

We have currently quite many samples waiting for sterility testing. Are you in a hurry with the results?

Kind regards,

Elina

Elina Väisänen, PhD
Senior researcher (microbiology)

Tel. +358 29 522 3203

elina.vaisanen@fimea.fi

fimea

Finnish Medicines Agency Fimea

P.O.Box 55, FI-00034 FIMEA, FINLAND | Tel. +358 29 522 3341 | registry@fimea.fi

www.fimea.fi | [LinkedIn](#) | [Instagram](#)

The information contained in this message may be legally privileged and confidential and protected from disclosure. Any unauthorized use, distribution or copying of this communication is strictly prohibited. If you have received this communication in error, please notify us immediately by replying to the message and deleting it from your computer.

From: Aune Ahman - RA <aune.ahman@ravimiamet.ee>

Sent: keskiviikko 2. syyskuuta 2026 15.55

To: Väisänen Elina <Elina.Vaisanen@fimea.fi>

Subject: Sterility_tests

Dear Elina,

I hope this email find you well.

We would like to send the following medicinal products with a marketing authorisation to you for sterility testing:

- Agency's ID: M-8/2026 IMIPENEM/CILASTATIN VENUS PHARMA 500 mg + 500 mg powder for solution for infusion N5 – for sterility testing, 1 package containing 5 vials
- Agency's ID: M-10/2026 ADRENALINE AUXILIA 1 mg/ml epinefrine solution for injection/infusion 1 ml N50 – for sterility testing, 4 ampoules
- Agency's ID: M-11/2026 ADRENALINE DEMO 1 mg/ml epinephrine solution for injection/infusion 1 ml N20 – for sterility testing, 4 ampoules

Could you please confirm if the sample quantities listed above are sufficient?

Regarding adrenaline's, we are unable to send the full packages; therefore, we would take the required number of ampoules from the packages for sterility testing and send those to you.

Would it be suitable for you if we send the samples next week? Also, could you please let us know if you require the manufacturer's specifications

Best regards

Aune Ahman

Head of Quality Control Laboratory

State Agency of Medicines

Email: aune.ahman@ravimiamet.ee

1 Nooruse Street

50411 Tartu

Estonia

Phone : +3727374140

www.ravimiamet.ee

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.