LIST OF INSPECTIONS AT FERMION OY

Authority please see the explanations below this table	**Period of Inspection**	**Site**	**Outcome**
FIMEA	March 17-18, 2026	Oulu	Classified as acceptable
FIMEA US FDA	February 24-25, 2026	Espoo	Classified as acceptable. US FDA has reviewed and accepted the inspection conducted by FIMEA as mutual recognition agreement is in place.
CFDI (China)	September 23-27, 2024	Hanko	Classified as acceptable
FIMEA US FDA	March 12-14, 2024	Hanko	Classified as acceptable. US FDA has reviewed and accepted the inspection conducted by FIMEA as mutual recognition agreement is in place.
US FDA	November 22-24, 2023	Espoo	Classified as acceptable
US FDA	March 13-17, 2023	Hanko	Classified as acceptable
FIMEA	February 2, 2023	Espoo	Classified as acceptable
FIMEA US FDA	January 30-31, 2023	Oulu	Classified as acceptable. US FDA has reviewed and accepted the inspection conducted by FIMEA as mutual recognition agreement is in place.
FIMEA	May 4-7, 2021	Hanko	Classified as acceptable
FIMEA	February 26, 2020	Espoo	Classified as acceptable
FIMEA US FDA	February 11-12, 2020	Oulu	Classified as acceptable. US FDA has reviewed and accepted the inspection conducted by FIMEA as mutual recognition agreement is in place.
US FDA	September 10-14, 2018	Hanko	Classified as acceptable
FIMEA	March 19-20, 2018	Hanko, only new Plant IV	Classified as acceptable
US FDA	December 4-5, 2017 December 7-8, 2017	Oulu	Classified as acceptable
FIMEA	May 4-5, 2017	Hanko	Classified as acceptable
FIMEA	February 16, 2017	Espoo	Classified as acceptable
FIMEA	February 21-22, 2017	Oulu	Classified as acceptable
US FDA	May 30 – June 3, 2016	Oulu	Classified as acceptable
US FDA	June 6-10, 2016	Hanko	Classified as acceptable
ANVISA	February 1-3, 2016	Oulu	Classified as acceptable

Authority please see the explanations below this table	**Period of Inspection**	**Site**	**Outcome**
FIMEA	April 8-9, 2014	Oulu	Classified as acceptable
FIMEA	April 1-2, 2014	Hanko	Classified as acceptable
US FDA	March 10-14, 2014	Hanko	Classified as acceptable
US FDA	December 9-13, 2013	Oulu	No FDA-483 was issued
FIMEA	September 26-27, 2013	Espoo	Classified as acceptable
US FDA	June 13-16, 2011	Hanko	Classified as acceptable
US FDA	June 17, 2011	Espoo	No FDA-483 was issued
ANVISA	May 16-20, 2011	Oulu	Classified as acceptable
FIMEA	April 27-28, 2011	Hanko	Classified as acceptable
FIMEA	April 5-6, 2011	Oulu	Classified as acceptable
US FDA	September 23-24 & 27-29, 2010	Oulu	Classified as acceptable
FIMEA	September 20-21, 2010	Espoo	Classified as acceptable
KFDA	March 23-24, 2010	Oulu	Classified as acceptable
MOH	February 8-10, 2010	Oulu	Classified as acceptable
NAM	May 12-13, 2008	Oulu	Classified as acceptable
NAM	April 7-8, 2008	Hanko	Classified as acceptable
US FDA	October 15-18, 2007	Hanko	No FDA-483 was issued
NAM	August 29-30, 2007	Espoo	Classified as acceptable
US FDA	October 9-12, 2006	Oulu	Classified as acceptable
PMDA	May 30 – June 1, 2006	Hanko	Classified as acceptable
NAM	March 21-23, 2005	Hanko	Classified as acceptable
NAM	May 18-20, 2005	Oulu	Classified as acceptable
US FDA	October 4-6, 2004	Hanko	No FDA-483 was issued
NAM	March 31 – April 1, 2004	Espoo	Classified as acceptable
US FDA	January 27-28, 2003	Oulu	No FDA-483 was issued
US FDA	January 30-31, 2003	Espoo	No FDA-483 was issued
NAM	March 18-19, 2002	Espoo	Classified as acceptable
NAM	March 26-27, 2002	Hanko	Classified as acceptable

Authority please see the explanations below this table	**Period of Inspection**	**Site**	**Outcome**
NAM	April 10-11, 2002	Oulu	Classified as acceptable
US FDA	June 11-13, 2001	Oulu	Classified as acceptable
US FDA	June 18-21, 2001	Hanko	Classified as acceptable
US FDA	June 25-28, 2001	Espoo	Classified as acceptable
US FDA	May 18-29, 1998	Espoo	Classified as acceptable
US FDA	May 18-29, 1998	Hanko	Classified as acceptable
NAM	November 19-20, 1998	Espoo	Classified as acceptable
US FDA	November 3-14, 1997	Espoo	Classified as acceptable
US FDA	November 3-14, 1997	Hanko	Classified as acceptable
US FDA	November 3-14, 1997	Oulu	Classified as acceptable
US FDA	October 30 - November 1, 1995	Hanko	No FDA-483 was issued
US FDA	August 22-25, 1995	Oulu	No FDA-483 was issued
NAM	January 26-27, 1995	Espoo	Classified as acceptable
NAM	March 1-2, 1995	Hanko	Classified as acceptable
NAM	October 23-24, 1995	Oulu	Classified as acceptable
US FDA	June 7-10, 1993	Espoo	Classified as acceptable
US FDA	June 7-10, 1993	Hanko	Classified as acceptable
US FDA	November 2-6, 1992	Hanko	Classified as acceptable
US FDA	May 18-19, 1992	Oulu	Classified as acceptable
US FDA	May 26-27, 1988	Espoo	Classified as acceptable
US FDA	May 23-24, 1988	Hanko	Classified as acceptable

Explanations of abbreviations	
FIMEA	Finnish Medicines Agency (European Medicines Agency, EMA, has authorized the inspections to be carried out by national authorities of the EU Member States)
NAM	National Agency for Medicines, nowadays FIMEA
US FDA	USA Food and Drug Administration
ANVISA	Brazil National Health Surveillance Agency
KFDA	South Korea Food and Drug Administration
MOH	Mexico Ministry of Health

Authority please see the explanations below this table	**Period of Inspection**	**Site**	**Outcome**
PMDA	Japan Pharmaceuticals and Medical Devices Agency		
CFDI	Center for Food and Drug Inspection of NMPA (China)		

This document has been signed in validated Documentum application by:

Satu Vartiainen
VP, Quality Management

List of Inspections at Fermion Oy

Written by: **Lindman Anneli**

Date dd.mm.yyyy (UTC)	Justification	Electronically signed by
22.10.2026 16:22:46	Approved	Vartiainen Satu (satkat)