TSE/BSE USDA STATEMENT

Due to concerns regarding the potential risk associated with materials derived from animal or human sources and/or cell culture products, Fermion Oy confirms that all Active Pharmaceutical Ingredients (APIs) manufactured and sold by Fermion Oy are produced exclusively by chemical synthesis. No animal- or human-derived materials or cell culture products are used in the manufacturing process. Additionally, none of the raw materials purchased by Fermion Oy contains animal or human material or cell culture products. Primary packaging materials used by Fermion are in compliance with the Note for Guidance EMEA/410/01 Rev. 3.

Fermion Oy further confirms that all the Active Pharmaceutical Ingredients are pure synthetic molecules and no excipients or ingredients have been added.

Accordingly, it can be stated that none of the APIs sold by Fermion Oy contain or are derived from risk materials as defined in the applicable guidance. The APIs fully meet the requirements outlined in EMEA/410/01 Rev. 3, the *Note for Guidance on Minimizing the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products*.

Fermion Oy confirms that the APIs it manufactures and sells are not materials derived from any animals, including materials produced with animal products or extracts of microorganisms. Therefore they are not subject to controls under the U.S. Department of Agriculture (USDA) importation guidelines #1105 (Effective April 14, 1998, Revised January 11, 2026).

Active Ingredients (APIs) concerned:

Alprazolam, Atipamezole HCl, Azathioprine, Benserazide HCl, Budesonide, Buspirone HCl, Cannabidiol, Carbidopa, Darolutamide, Detomidine HCl, Dexmedetomidine HCl, Diltiazem HCl, Entacapone, Flutamide, Formoterol fumarate, Glipizide, Hydroxychloroquine sulfate, Irinotecan HCl, Lerociclib dihydrochloride dihydrate, Levosimendan, Lisdexamphetamine dimesylate, Medetomidine HCl, Mercaptopurine, Methotrexate, Methotrexate disodium, Nadolol, Nintedanib esylate, Pralatrexate, Ospemifene, Quetiapine fumarate, Salmeterol xinafoate, Sodium Cromoglycate, Tasipimidine sulfate, Tolnaftate, Toremifene citrate, Treosulfan, Trilaciclib dihydrochloride dihydrate

This document has been signed in validated Documentum application by:

Satu Vartiainen
Vice President, Quality Management

TSE USDA Statement

Written by: Lindman Anneli

Date dd.mm.yyyy (UTC)	Justification	Electronically signed by
02.02.2026 14:23:35	Approved	Vartiainen Satu (satkat)