

TSE USDA STATEMENT

Due to the concern caused by the risk involved in using materials derived from animal and/or human source and/or cell culture products, Fermion Oy confirms that all Active Pharmaceutical Ingredients manufactured and sold by Fermion Oy are produced solely by chemical synthesis. No animal or human material and/or cell culture derived products are used in the manufacturing process. None of the raw-materials purchased by Fermion Oy contains animal or human material or cell culture products.

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

Thus it can be stated that none of the Active Pharmaceutical Ingredients sold by Fermion Oy contains or is derived from risk materials as defined in the guidance: EMEA/410/01 Rev. 3 Note for Guidance on Minimizing the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products.

Fermion Oy confirms that APIs manufactured and sold by Fermion Oy do not belong to the materials derived from any animal, including materials produced with animal products or extracts of microorganisms, that should be controlled in accordance with the regulations of U.S. Department of Agriculture (USDA) guidelines of importations #1105 (Effective April 14, 1998, Revised August 10, 2006).

Active Ingredients (APIs) concerned:

Alprazolam, Atipamezole HCl, Azathioprine, Benserazide HCl, Buspirone HCl, Cabozantinib S-malate, Carbidopa, Darolutamide, Detomidine HCl, Dexmedetomidine HCl, Diltiazem HCl, Entacapone, Fluoxetine HCl, Flutamide, Fluticasone propionate, Formoterol fumarate, Glipizide, Hydroxychloroquine sulfate, Irinotecan HCl, Levosimendan, Medetomidine HCl, 6-Mercaptopurine, Methotrexate, Methotrexate disodium, Nadolol, Nintedanib esylate, Nitrofurantoin macrocrystals, Nitrofurantoin monohydrate, Propafenone HCl, Quetiapine fumarate, Salmeterol xinafoate, Sodium Cromoglycate, Tamsulosin HCl, Tasipimidine sulfate, Tolnaftate, Toremifene citrate, Trazodone HCl

Seppo Hiltunen
Quality Assurance Manager



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Written by: Lindman Anneli

Date dd.mm.yyyy (UTC)	Justification	Electronically signed by
15.10.2021 05:12:19	Approved	Hiltunen Seppo (sephil)