

FLUTAMIDE
USP, Ph.Eur.
METAPHARMACEUTICAL

Product Number: 133194
Batch Number: 2085736

Date of Manufacture: 18.01.2022
Retest Date: 17.01.2027
Manufacturing site: Fermion Oy, Hanko plant
Specification: EDQM Certificate of Suitability (133194) 10.02.2020

12 DEC. 2022

N DE LOTE:

0101222

2-Methyl-N(4-nitro-3-(trifluoromethyl)phenyl)propanamide. CAS-13311-84-7. Characters: A pale yellow, crystalline powder. It melts at about 112 degrees. Solubility: freely soluble in ethanol (96 per cent) and acetone, practically insoluble in water and in heptane

TESTS	METHOD	REQUIREMENTS	RESULTS	QLTY CTRL SITE
Identification, IR, USP, EP	M111126	positive	positive	Turku
Loss on drying, USP, EP	M111141	nmt 0,5 %	0,0 %	Turku
Sulphated ash	M111151	nmt 0,1 %	0,0 %	Turku
Related substances, impurity C N-[4-nitro-3-(trifluoromethyl)phenyl]propanamide	M111133	nmt 0,2 %	<0,1 %	Turku
Related substances, impurity A 4-nitro-3-trifluoromethylaniline	M111133	nmt 0,2 %	0,1 %	Turku
Related substances, impurity B N-(4-nitro-3-(trifluoromethyl)phenyl)acetamide	M111133	nmt 0,2 %	<0,1 %	Turku
Related substances, any unspecified	M111133	nmt 0,10 %	<0,05 %	Turku
Related substances, total impurities	M111133	nmt 0,5 %	0,1 %	Turku
Assay, calculated on dried basis, EP	M111133	97,5 % - 102,0 %	99,8 %	Turku
Residual solvents, methanol	M111156	nmt 0,1 %	<0,1 %	Turku

Fermion Oy

Keivus-Mankkaan tie 6 A, 02200 ESPOO
 P.O. Box 28, FI-02101 ESPOO, FINLAND
 Tel. +358 10 4261
 Fax +358 10 426 4328
 www.fermion.fi

Orioninkatu 2, 10700 HANKO
 P.O. Box 50, FI-10901 HANKO, FINLAND
 Tel. +358 10 4261
 Fax +358 10 426 8223

Lääketehtaan tie 2
 FI-90600 OULU, FINLAND
 Tel. +358 10 4261
 Fax +358 10 426 8422

Fermion Oy. Registered office and domicile: Keivus-Mankkaan tie 6 A, FI-02200 Espoo. VAT Reg. No. FI11855212-9

FLUTAMIDE**USP, Ph.Eur.**

Product Number: 133194
Batch Number: 2085736

TESTS	METHOD	REQUIREMENTS	RESULTS	QTY CTRL SITE
-------	--------	--------------	---------	---------------

ICHQ7 Compliance

This batch has been manufactured, packed and tested in accordance with EU GMP Guideline Volume 4 Part II (ICHQ7).

Electronically approved 14.02.2022 13:36:01 by Kirsi Mikkola

Fermion Oy

Koivu-Mankkaan tie 6 A, 02200 ESPOO
P.O.Box 28, FI-02101 ESPOO, FINLAND
Tel. +358 10 4261
Fax +358 10 426 4328
www.fermion.fi

Orioninkatu 2, 10900 HANKO
P.O.Box 50, FI-10901 HANKO, FINLAND
Tel. +358 10 4261
Fax +358 10 426 8223

Läskeläntie 2
FI-90660 OULU, FINLAND
Tel. +358 10 4261
Fax +358 10 426 8429

Fermion Oy, Registered office and domicile: Koivu-Mankkaan tie 6 A, FI-02200 Espoo. VAT Reg No. FI11855212-9