

FAGRON IBÉRICA, S.A.U
Corresponde al lote de Fagron:

15629-805

Director Técnico

A member of Infra Group



Derivados Químicos
FINE CHEMICALS

CERTIFICATE OF ANALYSIS

FLUTAMIDE

2-METHYL-N-(4-NITRO-3-TRIFLUOROMETHYLPHENYL)PROPANAMIDE

(C₁₁H₁₁F₃N₂O₃)

Complies with: PhEur / USP

Edition date: 10/12/2014 Quantity: 340,0 kg Mol Weight: 276,22 g/mol Retest date: nov-19

Register n.: 616/14 Batch n.: 670001T02N Analysis date: 10/12/2014 Manuf. date: nov-14

SOLUBILITY: Practically insoluble in mineral oil, in ether of petroleum and in water. Soluble in chloroform and in ether. Very soluble in acetone, in ethyl acetate, in ethanol and in methanol. Practically insoluble in heptane

TEST	RESULTS	SPECIFICATIONS
DESCRIPTION	Complies	Pale yellow crystalline powder, odorless
IDENTIFICATION	Complies Complies	A): IR spectrum: according to standard B): HPLC: RT according to standard
LOSS ON DRYING	0.02%	Not more than 0.50%
SULPHATED ASH	0.08%	Not more than 0.10%
HEAVY METALS	Complies	Not more than 10 ppm
ASSAY (HPLC)	100.1%	Between 98.0 and 101.0% with reference to the dried substance.
RELATED SUBSTANCES (HPLC)	0.05% not detected 0.01% not detected not detected not detected	A) Known impurities: Not more than 0.10% Imp. A Imp. B Imp. C Imp. D Imp. E Imp. F B): Unknown impurities > 0.05% : 0. Main unknown impurity C): Sum of unknown impurities: Not more than 0.10%. D): Sum of all impurities: Not more than 0.40%.
RESIDUAL SOLVENTS (GC)		
Toluene	16 ppm	Not more than 60 ppm
Ethanol	398 ppm	Not more than 2000 ppm

"This batch has been produced following current Good Manufacturing Practice (GMP)".

Quality Control

[Signature]
10.12.2014

Quality Assurance

[Signature]
11/12/2014

Qualified Person

[Signature]
11/12/2014

REVISION N°: 12

3 kg

24/02/2015

Manufacturing Site: Camino Viejo de Pliego, S/N - 30820 Alcantarilla - Murcia (Spain)

Tel. +34 968 892512 - Fax +34 968 892656 - e-mail: derivados@infagroup.com