

Euticals S.P.A
Viale Europa, 5
I-21040 Origgio - Varese
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Fax +39 2 96730456



LOTE ACOFARMA: 151404

Certificate of Analysis

Date: 04.06.2014

Page: 1 of 3

Material : FLUTAMIDE USP-EP MILLED
Material No. : 17204724721
Batch No. : IF1401246A

On the batch, of which the consignment is a part, the following values have been determined. They comply with product specifications in force.

Inspection characteristic Method	Limits	Result	Unit
Pale yellow crystalline powder	Pass	Pass	
IDENTIFICATION	Pass	Pass	
IDENTIFICATION: HPLC	Pass	Pass	
LOSS ON DRYING	not more than 0.5	0.0	%
RESIDUE ON IGNITION	not more than 0.1	0.0	%
HEAVY METALS	not more than 10	< 10	ppm
FREE ACIDITY	< = 0.25	0.06	ml/g
Related Substance Impurity A EP (HPLC)	not more than 0.2	0.0	%
Related Substance Impurity B EP (HPLC)	not more than 0.2	0.0	%
Related Substance Impurity C EP (HPLC)	not more than 0.2	0.0	%
Any other unspecified impurity	not more than 0.10	0.00	%
Total Impurities	not more than 0.5	0.0	%
ASSAY (HPLC) EP d.b.	98.0 - 101.0	100.7	%
Related Compound B	not more than 0.2	0.0	%
Related Compound A	not more than 0.15	0.01	%

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3-Trifluoromethyl-aniline	not more than 0.2	0.0	%
Propionyl Analog	not more than 0.3	0.0	%
Desnitroflutamide	not more than 0.2	0.0	%
o-Flutamide	not more than 0.2	0.0	%
ANY UNKNOWN	not more than 0.05	0.02	%
Total unknown	not more than 0.1	0.0	%
Total impurities	not more than 0.4	0.0	%
ANILINE A ISOMER	not more than 0.10	0.00	%
ANILINE B ISOMER	not more than 0.10	0.00	%
FLUTAMIDE A ISOMER	not more than 0.10	0.00	%
FLUTAMIDE B ISOMER	not more than 0.10	0.00	%
RESIDUAL SOLVENTS: ACETONE	< = 1000	30	ppm
RESIDUAL SOLVENTS: TOLUENE	< = 890	35	ppm
PARTICLE SIZE: LESS THAN 200 MICRON	> = 99	100	%
PARTICLE SIZE: LESS THAN 120 MICRON	> = 90	97	%

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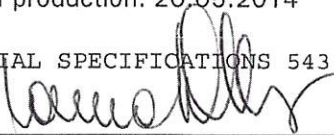
Inspection characteristic Method	Limits	Result	Unit
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Retest date: 19.05.2019

Date of Inspection: 28.05.2014

Date of production: 20.05.2014

MATERIAL SPECIFICATIONS 543-09



Laura Da Ros
Local responsible Quality control

Date: 04/06/14