

Certificate of Analysis

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Bicalutamide API

Lot Number : 19BL000456
Item Number : 125225 Date of Manufacture : 03-Jul-2019
Retest Date : 03-Jul-2022
Manufacturing Site : Synthon, s.r.o.

Tests	Results	Acceptance Criteria
Appearance	Complies	White or almost white powder
Identification IR spectrum	Complies	The same as Ref. Standard
Identification HPLC retention time	Complies	The same as Ref. St. Prep.
Clarity of solution	Complies	≤ Ref. Susp. I
Colour of solution	Complies	≤ Reference Solution B7
Optical rotation	0.0 °	-0.1 - 0.1 °
Loss on drying	0.2 %	≤ 0.5 %
Sulphated ash	0.1 %	≤ 0.1 %
Residue of catalyst (for CF Pharma drug subst.) Palladium	Not Performed	≤ 0.0005 %
Heavy metals	Complies	≤ 0.002 %
Residual solvents (GC) (for Synthon drug subst.) Acetonitrile	0.009 %	≤ 0.041 %
Ethanol	≤ 0.05 %	≤ 0.5 %
2-Propanol	≤ 0.05 %	≤ 0.5 %
Residual solvents (GC) (for CF Pharma drug subst.) N,N-dimethylformamide	Not Performed	≤ 0.088 %
Dichloromethane	Not Performed	≤ 0.060 %
Toluene	Not Performed	≤ 0.089 %
Dimethylacetamide	Not Performed	≤ 0.109 %
Impurities (HPLC) (for Synthon drug subst.) A/509	≤ 0.05 %	≤ 0.1 %
Largest unidentified impurity	≤ 0.05 %	≤ 0.1 %
Total impurities	≤ 0.05 %	≤ 1.0 %

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Tests	Results	Acceptance Criteria
Impurities (HPLC) (for CF Pharma drug subst.)		
Diol (A/509)	Not Performed	$\leq 0.1 \%$
Sulfinate (A/507)	Not Performed	$\leq 0.1 \%$
Acid (A/510)	Not Performed	$\leq 0.1 \%$
Anilide (A#520)	Not Performed	$\leq 0.1 \%$
Aniline (A/502)	Not Performed	$\leq 0.1 \%$
Sulfon (A#514)	Not Performed	$\leq 0.1 \%$
2-F-Bica (A#518)	Not Performed	$\leq 0.1 \%$
iso-Bica (A#519)	Not Performed	$\leq 0.1 \%$
Largest unidentified impurity	Not Performed	$\leq 0.1 \%$
Total impurities	Not Performed	$\leq 1.0 \%$
Assay (HPLC, dry basis)	100.0 %	98.0 - 102.0 %
Microbial contamination		
Total aerobic microbial count (TAMC)	<10 CFU/g	≤ 1000 CFU/g
Total combined yeasts/moulds count (TYMC)	<10 CFU/g	≤ 100 CFU/g
Escherichia coli	Complies	Not present/g
Particle size distribution		
d(0.9)	13 μm	< 50 μm

This batch complies with the specification set in CASS.NUS.BCM.002.01.

Issued by : Michaela Matejková
QA manager

Date of Issue : 06/Sep/2019
This is an electronic signature