

Certificate of Analysis: Androtiv (TS040S)

Substances
Synonymes : trans-Testosterone
17β-Hydroxy-3-oxo-4-androstene
17β-Hydroxy-4-androsten-3-one
4-Androsten-17β-ol-3-one

Formule : C₁₉H₂₈O₂
Poids moléculaire : 288,42 g/mol
No.-CAS : 58-22-0
No.-CE : 200-370-5

Testosterone			
No.-CAS	58-22-0	Carc. 1B; Repr. 2; H350, H361	<= 100 %
No.-CE	200-370-5		

Composants dangereux selon Directive 1999/45/EC

Testosterone			
No.-CAS	58-22-0	T, R45 - R63	<= 100 %
No.-CE	200-370-5		

QUALITY CONTROL DEPARTMENT			
CERTIFICATE OF ANALYSIS			
Product	: TESTOSTERONE Ph. Eur.	QC AR No.	: MHN-1502001
Batch No.	: 4018TS1RNJB	Release Date	: 11/03/2015
Mfg. Date	: October - 2014	Batch size	: 14.61 Kg.
Expiry Date	: September - 2018	Specification No.	: TS/BPC/TS1/PS/EP
Sr. No.	TEST	RESULTS	SPECIFICATIONS
01.	Appearance	White crystalline powder	White or almost white crystalline powder or colourless or yellowish-white crystals.
02.	Solubility	Practically insoluble in water, freely soluble in alcohol and in methylene chloride, practically insoluble in fatty oils.	Practically insoluble in water, freely soluble in alcohol and in methylene chloride, practically insoluble in fatty oils.
03.	Melting Point	155.2 °C	About 155 °C
04.	Identification	Infrared absorption spectra of sample and standard are concordant.	Infrared absorption spectra of sample and standard are concordant.
05.	Specific Optical Rotation at 20°C	+112.3°	+106° to +114° (dried substances)
06.	Impurities D and F (By TLC)	Less than 0.2% Less than 0.1%	Impurity D : Not more than 0.2% Impurity F : Not more than 0.1%
07.	Related substances by HPLC		
	Impurity C	Below Disregard Limit	Not more than 0.50 %
	Impurity I	Below Disregard Limit	Not more than 0.20 %
	Impurity A	0.07 %	Not more than 0.10 %
	Impurity B	Below Disregard Limit	Not more than 0.10 %
	Impurity E	Not detected	Not more than 0.10 %
	Impurity G	Not detected	Not more than 0.10 %
	Impurity H	Not detected	Not more than 0.10 %
	Impurity J	Not detected	Not more than 0.10 %
	Any other impurity	Below Disregard Limit	Not more than 0.10 %
	Total impurities	0.07 %	Not more than 0.60 %
08.	Loss on drying (at 105 °C for 2 hrs)	0.66 % w/w	Not more than 1.0 %
09.	Assay (By UV)	99.6 %	97.0% to 103.0% of C ₁₉ H ₂₈ O ₂ on dried basis
10.	Additional Test: Particle size distribution (Number basis)	Complies	D _n (99%): ≤20µm

Remarks: The above sample conforms as per above specifications.

K.S.Shah,

Prepared by
Date 22/04/2015

for - 102
Assistant Manager QC
Date of Print