CERTIFICATE OF ANALYSIS

FOR ANALYTICAL PURPOSES ONLY

REFERENCE STANDARD: **JNJ-212082-AAA** **LOT:** **ZR102164PUA151**
CoA NUMBER: AD-RSCoA-JNJ-212082-AAA-ZR102164PUA151
VERSION NUMBER: V5

TYPE OF STANDARD:	Drug Substance API	RE-EVALUATION DATE:	28-Feb-2023
INTENDED USE:	Quantitative	EFFECTIVE DATE:	01-May-2020
SALT FACTOR: F	1.000		
SALT FACTOR: F'	1.000		
PURITY:	0.999	STORAGE CONDITION(S):	Room temperature
REMARKS:	n.a.		

CHEMICAL NAME:	17-(3-pyridyl)androsta-5,16-dien-3-beta-ol acetate(ester)		
OTHER COMPOUND ID:	R102164 / ABIRATERONE ACETATE		
		MANUFACTURING DATE:	22-Oct-2010
MOLECULAR FORMULA:	$C_{26}H_{33}NO_2$	MANUFACTURER LOT:	ZR102164PUA151
MOLECULAR WEIGHT:	391.56	MANUFACTURER:	Janssen Pharmaceutica NV
MOLECULAR WEIGHT PARENT:	391.56	MANUFACTURER ADDRESS:	Turnhoutseweg 30, B-2340 Beerse

ANALYTICAL TEST RESULTS:

TESTS PERFORMED	RESULTS (UNITS)
Appearance	White powder
IR identification	Complies with reference spectrum
NMR identification	Confirms the structure and/or enantiomer
Water content vaporisation	< 0.1 % w/w
GC residual solvent determination	< 500 ppm
HPLC impurity	0.09 % w/w
Base titration	100.6 % w/w
Residue on ignition	< 0.1 % w/w
Heavy metals	< 20 ppm
Pd: induced coupled plasma	< 5 ppm

PURITY CALCULATION: P = (100 - % water content - % residual solvent - % chromatographic impurity - % inorganic impurities) / 100

APPROVED BY:
NAME: Tine Sommen

MARTINE SOMMEN

Digitally signed by MARTINE SOMMEN
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DEPARTMENT: DPDS Analytical Development – Clinical Release & Stability

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