Janssen | PHARMACEUTICAL COMPANIES OF Johnson&Johnson

CERTIFICATE OF ANALYSIS

FOR ANALYTICAL PURPOSES ONLY

REFERENCE STANDARD: **JNJ-25875382-AAA** **LOT:** **A14JS2686**
CoA NUMBER: AD-RSCoA-JNJ-25875382-AAA-A14JS2686
VERSION NUMBER: V2

TYPE OF STANDARD:	Drug Substance API	RE-EVALUATION DATE:	31-Oct-2017
INTENDED USE:	Quantitative	EFFECTIVE DATE:	08-Apr-2016
SALT FACTOR: F	1.000		
SALT FACTOR: F'	1.000		
PURITY:	0.919	STORAGE CONDITION(S):	Room temperature dry
REMARKS:	n.a.		

CHEMICAL NAME:	Carbamic acid, N-[(1S,2R)-3-[[(4-aminophenyl)sulfonyl](2-methylpropyl)amino]-2-hydroxy-1-(phenylmethyl)propyl]-, (3R,3aS,6aR)-hexahydrofuro[2,3-b]furan-3-yl ester		
OTHER COMPOUND ID:	R319064 / DARUNAVIR / TMC114		
PROJECT NAME:	R319064	MANUFACTURER DATE:	09-Oct-2014
MOLECULAR FORMULA:	$C_{27}H_{37}N_3O_7S$	MANUFACTURER LOT:	A14JS2686
MOLECULAR WEIGHT:	547.66	MANUFACTURER:	CILAG AG
MOLECULAR WEIGHT PARENT:	547.66	MANUFACTURER ADDRESS:	Hochstrasse 201, CH-8205 Schaffhausen, Switzerland

ANALYTICAL TEST RESULTS:

TESTS PERFORMED	RESULTS (UNITS)
Appearance	White powder
NMR identification	Confirms the structure
IR identification	Complies with reference spectrum
Water determination Karl Fisher	0.1 % w/w
GC residual solvent determination	998 ppm
UPLC purity	0.27 % w/w
Residue on ignition	< 0.1 % w/w
Heavy metals	< 20 ppm
Ethanol content	7.6 % w/w
Base titration	101.1 % w/w
Specific optical rotation	-1.6°

PURITY CALCULATION: P = (100 - % water content - % residual solvent - % chromatographic purity - % anorganic impurities - % ethanol content) / 100

APPROVED BY:

NAME: Anke Grootaert SIGNATURE:

DATE: 08-Apr-2016

DEPARTMENT: PDMS Analytical Development - Small Molecules Method Development

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