

## CERTIFICATE OF ANALYSIS

FOR ANALYTICAL PURPOSES ONLY

**REFERENCE STANDARD:** JNJ-25875382-AAA      **LOT:** A14JS2686  
**CoA NUMBER:** AD-RSCoA-JNJ-25875382-AAA-A14JS2686  
**VERSION NUMBER:** V3

TYPE OF STANDARD:	Drug Substance API	RE-EVALUATION DATE:	31-Oct-2020
INTENDED USE:	Quantitative	EFFECTIVE DATE:	01-Nov-2017
SALT FACTOR: F	1.000		
SALT FACTOR: F'	1.000		
PURITY:	0.918	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

<b>MOLECULAR FORMULA:</b> C <sub>27</sub> H <sub>37</sub> N <sub>3</sub> O <sub>7</sub> S <b>MOLECULAR WEIGHT:</b> 547.66 <b>MOLECULAR WEIGHT PARENT:</b> 547.66	<b>MANUFACTURER DATE:</b> 09-Oct-2014 <b>MANUFACTURER LOT:</b> A14JS2686 <b>MANUFACTURER:</b> CILAG AG <b>MANUFACTURER ADDRESS:</b> Hochstrasse 201, CH-8205 Schaffhausen, Switzerland
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### ANALYTICAL TEST RESULTS:

#### TESTS PERFORMED

Appearance  
 NMR identification  
 IR identification  
 Water content vaporisation  
 GC residual solvent determination  
 UPLC impurity  
 Residue on ignition  
 Heavy metals  
 Ethanol content  
 Base titration  
 Specific optical rotation

#### RESULTS (UNITS)

White powder  
 Confirms the structure  
 Complies with reference spectrum  
 0.1 % w/w  
 998 ppm  
 0.39 % w/w  
 < 0.1 % w/w  
 < 20 ppm  
 7.6 % w/w  
 101.1 % w/w  
 -1.6°

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

#### APPROVED BY:

**NAME:** Tine Sommen

**SIGNATURE:**

**DATE:** 26-Oct-2017

**DEPARTMENT:** PDMS Analytical Development – Clinical Release & Stability