

A76-1

A76-1



CERTIFICATE OF ANALYSIS

PHARMACIA & UPJOHN COMPANY LLC
(A SUBSIDIARY OF PFIZER INC)
7000 PORTAGE RD
KALAMAZOO, MI 49001-0199 USA

Page: 1 of 2

Generated Date:
09-2017

Item: H000200569
Title: ANIDULAFUNGIN
Retest Date: 19-MAY-2018
Expiration Date: N/A
Date Of Manufacture: 19-MAY-2017
Specification: 200569 COA EXTENDED
LOT NUMBER: T03710

TEST NAME	SPECIFICATION	UNITS	RESULTS
APPEARANCE	MEETS TEST	NONE	MEETS TEST
IDENTIFICATION IR	MEETS TEST	NONE	MEETS TEST
IDENTIFICATION-HPLC	MEETS TEST	NONE	MEETS TEST
ASSAY ANHYDROUS FRUCTOSE FREE	94.0-102.0	wt%	99.1
PEAK B	<=1.5	Area %	0.2
DESMETHYL 1	<=2.0	Area %	0.6
DESMETHYL 2	<=1.0	Area %	0.3
DESOXY	<=1.0	Area %	0.6
IMPURITIES UNSPECIFIED	<=0.4	Area %	<0.1
IMPURITIES TOTAL UNSPECIFIED	<=1.0	Area %	<0.1
IMPURITIES TOTAL	<=5.0	Area %	1.6
FRUCTOSE CONTENT	7.0-17	% wt/wt	12.3
WATER CONTENT	<=7.0	%	4.1
RESIDUAL SOLVENTS METHANOL	<=0.5	% wt/wt	0.2
RESIDUE ON IGNITION	<=0.2	%	<0.1

Documentation is considered PROPRIETARY and is made available for business operations and review by employees and regulatory agencies. Distribution to third parties without prior permission is prohibited.





CERTIFICATE OF ANALYSIS

Page: 2 of 2

PHARMACIA & UPJOHN COMPANY LLC
(A SUBSIDIARY OF PFIZER INC)
7000 PORTAGE RD
KALAMAZOO, MI 49001-0199 USA

Generated Date:
09-2017


Item: H000200569
Title: ANIDULAFUNGIN
Retest Date: 19-MAY-2018
Expiration Date: N/A
Date Of Manufacture: 19-MAY-2017
Specification: 200569 COA EXTENDED

LOT NUMBER: T03710

<u>TEST NAME</u>	<u>SPECIFICATION</u>	<u>UNITS</u>	<u>RESULTS</u>
HEAVY METALS	≤ 20	ppm	≤ 20
MICROBIAL LIMITS AEROBIC BACTERIA	≤ 1000	CFU/g	< 100
MICROBIAL LIMITS YEAST AND MOLD	≤ 100	CFU/g	< 10
BACTERIAL ENDOTOXIN	≤ 4.0	EU/mg	< 1.0

This lot/batch was manufactured and tested according to the standard operating procedures, material specification, and batch records under cGMP's and applicable regulatory guidelines of Pharmacia & Upjohn Company, 7000 Portage Road, Kalamazoo, Michigan, 49001. Telephone: 269-833-4000.

Electronic Signature: Michael C. LaDuke Lot Release Local Timestamp: 12-JUL-2017 11:11:54

Full
Name: Michael C. LaDuke
Signature: 
Date: 9/28/17