

CERTIFICATE OF ANALYSIS

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

Generated Date:
09-2017

Item: I1000200569
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

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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: 7/28/17