

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: : 050759

CHEMISTRY REVIEW(S)

**DIVISION OF SPECIAL PATHOGENS AND
IMMUNOLOGIC DRUG PRODUCTS—HFD-590**
Review of Chemistry, Manufacturing and Controls Section

NDA #: 50-759

CHEMISTRY REVIEW #: 1

REVIEW COMPLETED: September 28, 1998

SUBMISSION TYPE	DOCUMENT DATE	CDER DATE	ASSIGNED DATE
Original NDA	September 30, 1997	October 1, 1997	October 6, 1997
BC	January 6, 1998	January 7, 1998	January 13, 1998
NC	January 22, 1998	January 26, 1998	February 3, 1998
BC	February 13, 1998	February 17, 1998	February 25, 1998
BC (stability update)	March 6, 1998	March 9, 1998	March 17, 1998
BC	May 12, 1998	May 13, 1998	May 20, 1998
BC (MV)	May 29, 1998	June 1, 1998	June 6, 1998
BC	September 9, 1998	September 10, 1998	September 16, 1998
BC	September 17, 1998	September 21, 1998	September 24, 1998

NAME/ADDRESS OF SPONSOR:

Syntex (U.S.A.) Inc.
3401 Hillview Avenue
Palo Alto, California 94303

DRUG PRODUCT NAME:

Proprietary:

CellCept Oral Suspension

Established Name:

mycophenolate mofetil for oral suspension

CHEM. TYPE/THER. CLASS:

3S

DRUG CLASS:

5010400

PHARMACOLOGICAL CATEGORY:

Immunosuppressant

INDICATION:

For the prophylaxis of organ rejection in patients receiving allogeneic renal transplants and in patients receiving allogeneic cardiac transplants.

DOSAGE FORM/STRENGTH:

Powder for oral suspension, 200 mg/mL

ROUTE OF ADMINISTRATION:

Oral

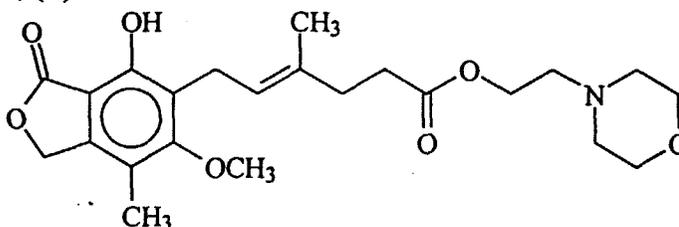
CHEMICAL NAME/STRUCTURAL FORMULA:

4-Hexenoic acid, 6-(1,3-dihydro-4-hydroxy-6-methoxy-7-methyl-3-oxo-5-isobenzofuranyl)-4-methyl)-, 2-(4-morpholinyl)ethyl ester, (E)-

CAS Registry: 115007-34-6

Molecular Formula: C₂₃H₃₁NO₇

Molecular Weight: 433.50



Other chemical names for the drug substance:

- 1) 2-Morpholinoethyl (E)-6-(4-hydroxy-6-methoxy-7-methyl-3-oxo-5-phthalanyl)-4-methyl-hexenoate
- 2) 2-Morpholinoethyl (E)-6-(1,3-dihydro-4-hydroxy-6-methoxy-7-methyl-3-oxo-5-isobenzofuranyl)-4-methyl-4-hexenoate

SUPPORTING DOCUMENTS:

INDs and NDAs Associated with Mycophenolate Mofetil

IND

IND

IND

IND

NDA 50-722 CellCept (mycophenolate mofetil capsules), 250 mg; AP 5/3/95
(formerly 20-513)

N50-722/SCS-001 Drug substance manufacturing supplement, AP 6/12/97

N50-722/SE1-002 Cardiac supplement, AP 2/11/98

NDA 50-723 CellCept (mycophenolate mofetil tablets), 500 mg; AP 6/19/97
(formerly 20-514)

NDA 50-723/SLR-001 Cardiac supplement, AP 2/11/98

NDA 50-758 CellCept Intravenous (mycophenolate mofetil hydrochloride for
injection); AP 8/12/98

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RELATED DOCUMENTS:

Memorandum of Telephone Conversation: June 2, 1998; August 28, 1998
17, 1998

; September

2 pages

TRADE SECRET

Confidential

Commercial

