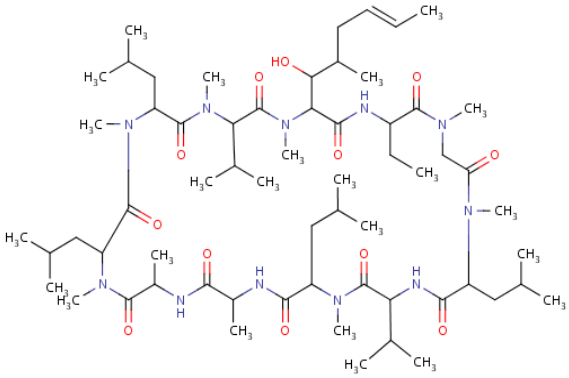
CYCLOSPORINE, USP, EP

Cyclosporine a cyclic peptide from an extract of soil fungi that selectively inhibits T cell function; used as an immunosuppressant to prevent rejection in organ transplant recipients and to treat severe psoriasis and severe rheumatoid arthritis.

Structure	
Molecular	$C_{62}H_{111}N_{11}O^{12}$
Molecular Weight	1202.61
Chemical Name	1/C62H111N11O12/c1-25-27-28-40(15)52(75)51-56(79)65-43(26-2)58(81)67(18)33-48(74)68(19)44(29-34(3)4)55(78)66-49(38(11)12)61(84)69(20)45(30-35(5)6)54(77)63-41(16)53(76)64-42(17)57(80)70(21)46(31-36(7)8)59(82)71(22)47(32-37(9)10)60(83)72(23)50(39(13)14)62(85)73(51)24/h25,27,34-47,49-52,75H,26,28-33H2,1-24H3,(H,63,77)(H,64,76)(H,65,79)(H,66,78)/b27-25+
Therapeutic Category	Immunology
CAS #	59865-13-3
AbbVie U.S. Drug Master File (DMF)	013800
Packaging	Tight, light resistant containers at controlled room temperature (15° to 30°C); desiccated
Shelf Life	4 years

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SPECIFICATIONS

TEST NAME	ACCEPTANCE CRITERIA
Appearance	Powder, some lumps may be present
Color	White to essentially white
Assay (By HPLC)	98.5 - 101.5 %, calculated on the dried basis
Impurities (by HPLC) **- Total**	≤ 1.5 %
Impurities (by HPLC) - **Any Largest Single Impurity**	≤ 0.7 %
Identification (by HPLC)	The main peak of the sample preparation shall have a similar retention time and peak response to that of the respective peak in the standard preparation
Loss on Drying	≤ 2.0 %
Appearance of Solution (Color)**, EP**	The solution is not more intensely colored than reference solution Y5, BY5 or R7
Appearance of Solution (Clarity)**, EP**	The solution is clear
Specific Optical Rotation, EP	Between -193° to -185° calculated with reference to the anhydrous substance
Identification (by IR)**, EP**	The maxima in the sample spectrum correspond in position and relative intensity to those in the spectrum obtained from a similar preparation of Cyclosporine reference standard
Heavy Metals (as Pb)**: Method II, USP**	≤ 0.002 %
Residual Solvents (by GC)**, Acetone** (%)	≤ 0.09 %
Residual Solvents (by GC)**, Hexanes** (%)	≤ 0.1 %
Residual Solvents (by GC) - **Acetone** (ppm)	≤ 1000 ppm
Residual Solvents (by GC) - **Hexanes** (ppm)	≤ 1499 ppm
Heavy Metals - Method C (EP)	≤ 20 ppm
Total Aerobic Microbial Count by Pour-Plate Method	≤ 2000 CFU/g
Total Yeast and Mold Count by Pour-Plate Method	≤ 200 CFU/g