

**Product Name: : Caspofungin acetate for Injection 50 mg
(Lyophilized)**



Summary of product information:

Non-proprietary name of the finished pharmaceutical product (FPP)	Caspofungin Acetate for Injection 50 mg
Proprietary name of the finished pharmaceutical product (FPP)	BIFUNGIN-50
International non-proprietary name(s) of the active pharmaceutical ingredient(s) (API(s), including form (salt, hydrate, polymorph)	Caspofungin Acetate
Applicant name and address	INDASI LIFESCIENCE PVT. LTD. (Formerly known as Bliss Indasi Lifescience Pvt. Ltd.) Plot No.: 73-76, Silver Industrial Estate, Bhimpore, Daman (UT). INDIA Phone: +91 8000590111; 8000492233 Fax: --- E-mail id: info@blissindasi.com Post code: 396210 Town: Daman Country: India
Dosage form	Lyophilized Injection
Strength(s)	50 mg/vial
Route of administration	Intravenous Infusion
Proposed indication(s)	Antifungal
Contact information	Name: Indasi Lifescience Pvt. Ltd. (Formerly known as Bliss Indasi Lifescience Pvt. Ltd.) Address: Plot No.: 73-76, Silver Industrial Estate, Bhimpore, Daman (UT). 396210 Phone: +91 8000590111; 8000492233 Fax: --- Email: info@blissindasi.com

Product Name: : Caspofungin acetate for Injection 50 mg
(Lyophilized)

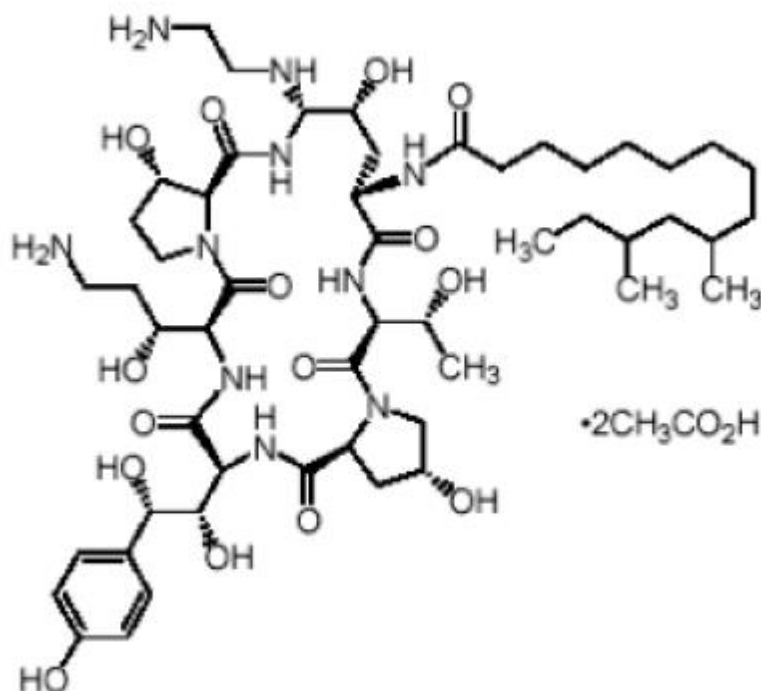


General Information

Nomenclature

- a) **Recommended International Non-proprietary Name (INN):** Caspofungin acetate
- b) **Compendial name:** Caspofungin acetate
- d) **Chemical Name:** 1-[(4*R*,5*S*)-5-[(2-aminoethyl)amino]-*N*2-(10,12-dimethyltetradecanoyl)-4-hydroxy-L -ornithyl-L-threonyl-*trans*-4-hydroxy-L-prolyl-(*S*)-4-hydroxy-(*p*-hydroxyphenyl)-L-threonylthreo-3-hydroxy-L-ornithyl-*trans*-3-hydroxy-L-proline cyclic (6@1)- peptide, diacetate salt
- e) **Company or laboratory code:** Not Applicable
- f) **Other non-proprietary name:** Not Applicable
- g) **Chemical Abstracts Service (CAS) registry number:** 179463-17-3

Structure:



Molecular Formula: C₅₂H₈₈N₁₀O₁₅ . 2 C₂H₄O₂

Molecular Weight: 1213.43 g/mol (as diacetate salt)

**Product Name: : Caspofungin acetate for Injection 50 mg
(Lyophilized)**



General Properties

Description	Caspofungin Acetate is a white to off-white powder.
Crystal Morphology	Caspofungin acetate contains irregular shaped particles.
Solubility	Caspofungin Acetate is freely soluble in water and methanol, slightly soluble in ethanol.
<i>Therapeutic Category</i>	Antifungal
Description	Caspofungin Acetate is a white to off-white powder.
Crystal Morphology	Caspofungin acetate contains irregular shaped particles.
Solubility	Caspofungin Acetate is freely soluble in water and methanol, slightly soluble in ethanol.
<i>Therapeutic Category</i>	Antifungal

**Product Name: : Caspofungin acetate for Injection 50 mg
(Lyophilized)**



Finished Product Specification:

Standard (e.g. Ph. Int., BP, USP, House)		In-House
Specification reference number and version		----
Test	Acceptance criteria (release)	Analytical procedure
Description	A white to off white powder / cake filled in 10 ml glass vial sealed with the white flip off seal, packed in a monocarton with pack insert.	In-House
Identification by HPLC	The retention time of the major peak in the chromatogram of sample preparation corresponds to that in the chromatogram obtained with standard preparation, as obtained in the assay.	In-House
Completeness and clarity of solution	(a) The solid should dissolve completely, leaving no visible residue as undissolved matter. (b) The constituted injection should not be significantly less clear than an equal volume of the diluents or water for injections contained in a similar container and examined in the same manner.	In-House
Uniformity of weight	Not more than two of the individual weight should deviate from the average weight by more than 10.0 % and none should deviate by more than 20.0 %	In-House
pH of reconstituted solution	5.3 to 7.0	In-House
Particulate matter: ≥ 10 µm ≥ 25 µm	NMT 6000/container NMT 600/container	In-House
Sterility	It should be sterility	In-House
Bacterial Endotoxins	NMT 6.0 EU/mg	In-House
Water by KF	NMT 4.00 %	In-House
Related substances	(a) Individual impurity : NMT 2.0 % (b) Total impurity : NMT 2.0 %	In-House
Assay: Each vial contains Caspofungin Acetate equivalent to Caspofungin 50 mg	NLT 90.0 and NMT 120.0 % of labelled amount.	In-House

**Product Name: : Caspofungin acetate for Injection 50 mg
(Lyophilized)**



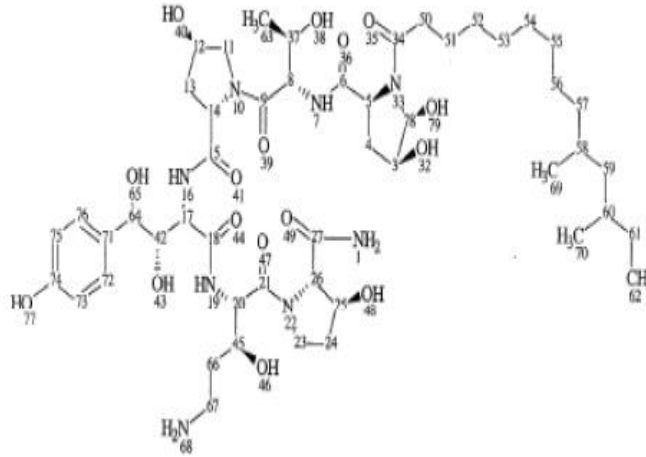
Impurities

API-related impurity (chemical name or descriptor)	Structure	Origin
Organic Impurities		
<p>Pneumocandin B₀ : NMT 0.15%</p>		<p>starting material of Caspofungin drug substance. Pneumocandin B₀ is eluted at RRT=1.82 by method ARD-52749. It is effectively purified during the synthesis and not a relevant impurity.</p>
<p>Impurity A at RRT=0.95: NMT 1.0%</p>		<p>Impurity A is eluted at RRT=0.95 by method ARD-52749. It is effectively removed by chromatographic purification of Caspofungin.</p>

**Product Name: : Caspofungin acetate for Injection 50 mg
(Lyophilized)**

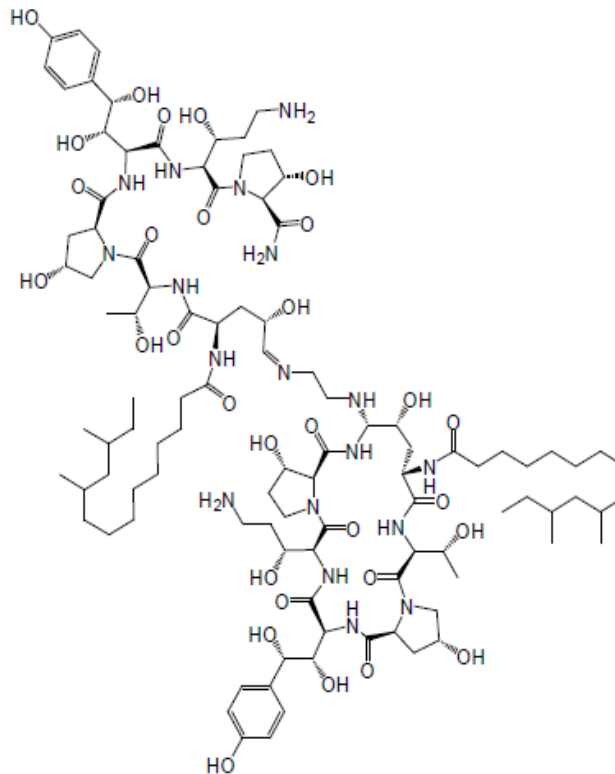


Impurity B1 +
B2 at RRT=1.86:
NMT 0.30%



Impurity B1+B2 are degradation products of Caspofungin Acetate, eluted at RRT=1.86 by method ARD-52749. They are effectively removed by chromatographic purification.

Caspofungin
dimer 1 at
RRT=2.08: NMT
0.25%

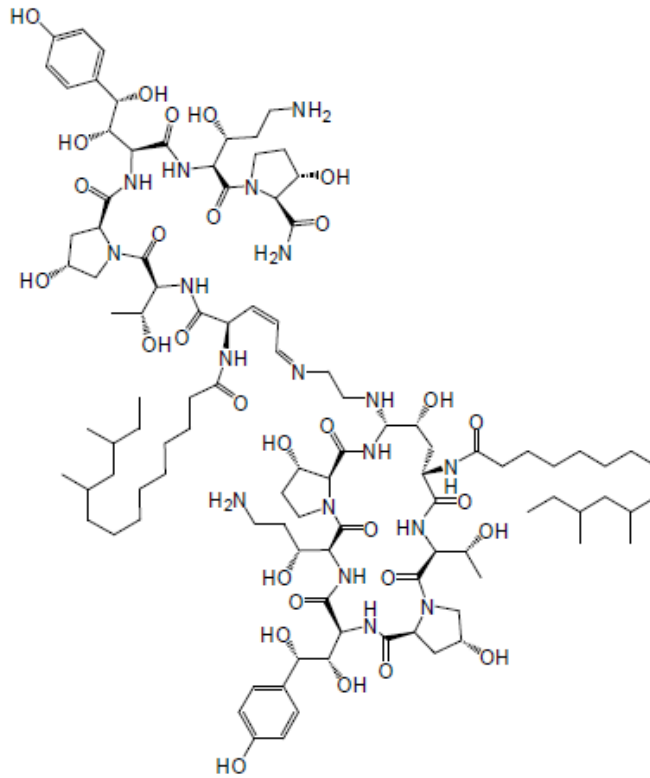


Degradation products of Caspofungin acetate drug substance.

Product Name : Caspofungin acetate for Injection 50 mg
(Lyophilized)

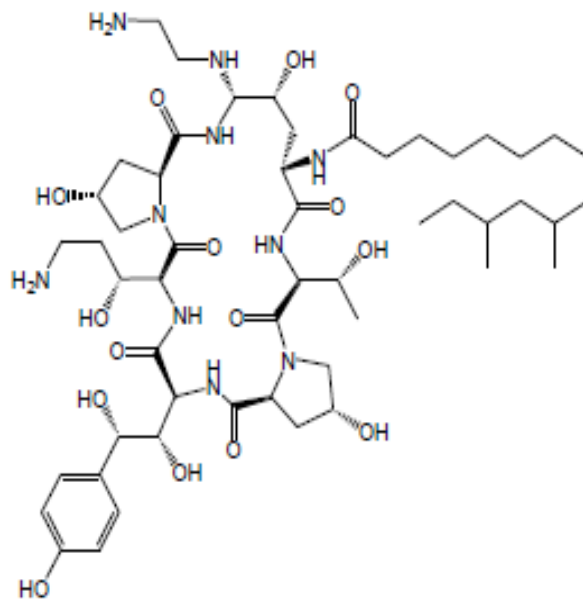


Caspofungin dimer 2 at RRT=2.26 : NMT 0.15%



Degradation products of Caspofungin acetate drug substance.

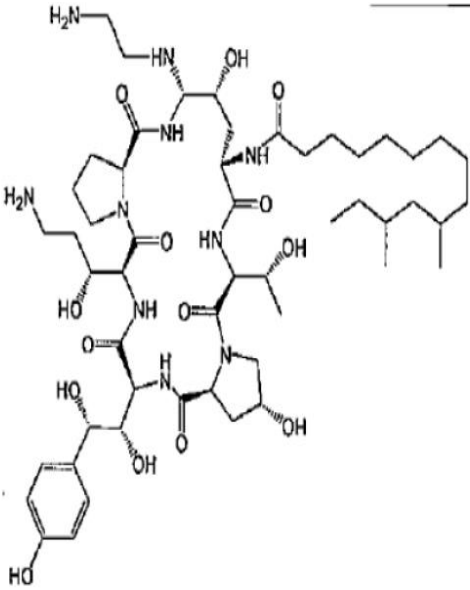
Caspofungin C₀ at RRT=1.24: NMT 0.50%



Starting material related impurity, eluted at RRT=1.19 by method ARD-52984.

**Product Name: : Caspofungin acetate for Injection 50 mg
(Lyophilized)**



<p>Impurity F at RRT=0.78: NMT 0.15%</p>	 <p>The image shows the chemical structure of Caspofungin, a cyclic lipopeptide antifungal drug. It features a complex macrocyclic core with multiple amide bonds, hydroxyl groups, and a long fatty acid side chain. A piperidine ring is attached to the core, and a 4-hydroxyphenyl group is also present.</p>	<p>Starting material related impurity of Caspofungin.</p>
<p>Any unspecified impurity: NMT 0.10%</p>	<p>---</p>	<p>---</p>
<p>Total impurities: NMT 2.50%</p>	<p>---</p>	<p>---</p>