

# Certificate

## CYCLOSPORINE RESOLUTION MIXTURE

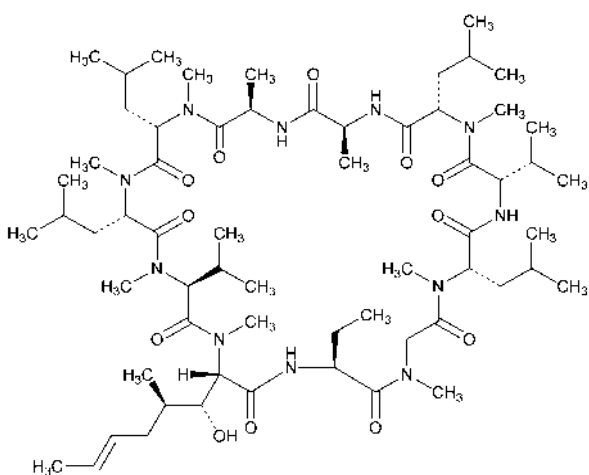
(This material is an approximate 100:1 (w/w) mixture of cyclosporine and cyclosporine U)

USP Catalog No.: 1158650

USP Lot No.: R063L0

### Cyclosporine

[[R-[R\*,R\*-(E)]]-Cyclic(L-alanyl-D-alanyl-N-methyl-L-leucyl-N-methyl-L-leucyl-N-methyl-L-valyl-3-hydroxy-N,4-dimethyl-L-2-amino-6-octenoyl-L-α-aminobutyryl-N-methylglycyl-N-methyl-L-leucyl-L-valyl-N-methyl-L-leucyl)]



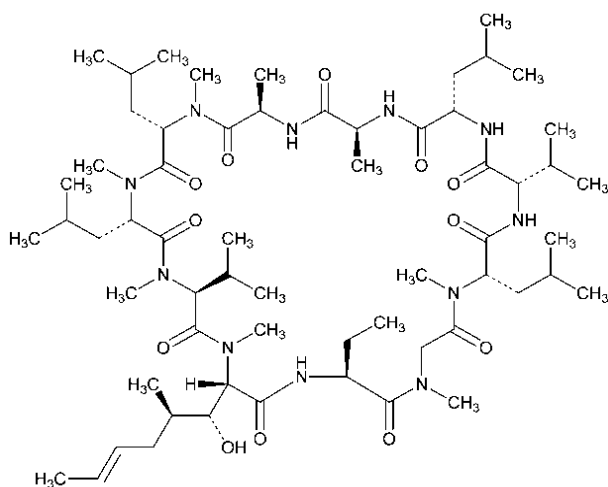
CAS No.: 59865-13-3

Molecular Formula: C<sub>62</sub>H<sub>111</sub>N<sub>11</sub>O<sub>12</sub>

Molecular Weight: 1202.61

### Cyclosporine U

(Cyclo[[[E)-(2S,3R,4R)-3-hydroxy-4-methyl-2-(methylamino)-6-octenoyl]-L-2-aminobutyryl-N-methylglycyl-N-methyl-L-leucyl-L-valyl-L-leucyl-L-alanyl-D-alanyl-N-methyl-L-leucyl-N-methyl-L-leucyl-N-methyl-L-valyl])



CAS No.: 108027-45-8

Molecular Formula: C<sub>61</sub>H<sub>109</sub>N<sub>11</sub>O<sub>12</sub>

Molecular Weight: 1188.58

**LABEL TEXT**

For use with specified USP compendial tests. Not for use as a drug. See SDS prior to use at [www.usp.org/sds](http://www.usp.org/sds).



Lot: R063L0

**USP REFERENCE STANDARD**

**CYCLOSPORINE RESOLUTION MIXTURE 25 mg**

(This material is an approximate 100:1 (w/w) mixture of cyclosporine and cyclosporine U)

**Danger!**

Harmful if swallowed. May cause cancer. Causes damage to organs (immune system, kidney) through prolonged or repeated exposure.

Do not dry. Keep container tightly closed. Protect from light.  
Store in a freezer. Material is hygroscopic, handle in a dry place.

USP, 12601 Twinbrook Pkwy, Rockville, MD, +1-301-881-0666  
Cat. No. 1158650 Material mfd. in Ireland

Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wash thoroughly after handling. Wear protective gloves/protective clothing/eye protection/face protection. Rinse mouth. If swallowed: Call a poison center/doctor/medical professional if you feel unwell. If exposed or concerned: Get medical advice/attention. Store locked up. Dispose of contents/container in accordance with local/regional/national/international regulations.

*Jeri L. Joth*

*Quality Assurance*

**Calculation Value**

If a value is not provided on the label or accompanying documentation and the Reference Standard has a quantitative USP compendial application, a value of 100.0% is used. The purity value is not applicable for qualitative uses. Please refer to the specific Reference Standard label for further information.

**Expiration**

Current lots are identified in the current USP Catalog. In some cases, the previous lot may still be considered valid for use. If so, it is identified in the column marked "Previous Lot/Valid Use Date."

It is the responsibility of each user to determine that this lot is current or valid when used. For the most up-to-date information, please refer to the USP Store at [www.usp.org](http://www.usp.org).

**Instructions for Use**

Follow the instructions on the label of the USP Reference Standard and in the appropriate USP documentary standard(s).

**Non-Monograph Use**

The suitability of this Reference Standard for use in non-compendial applications is solely the responsibility of the user.

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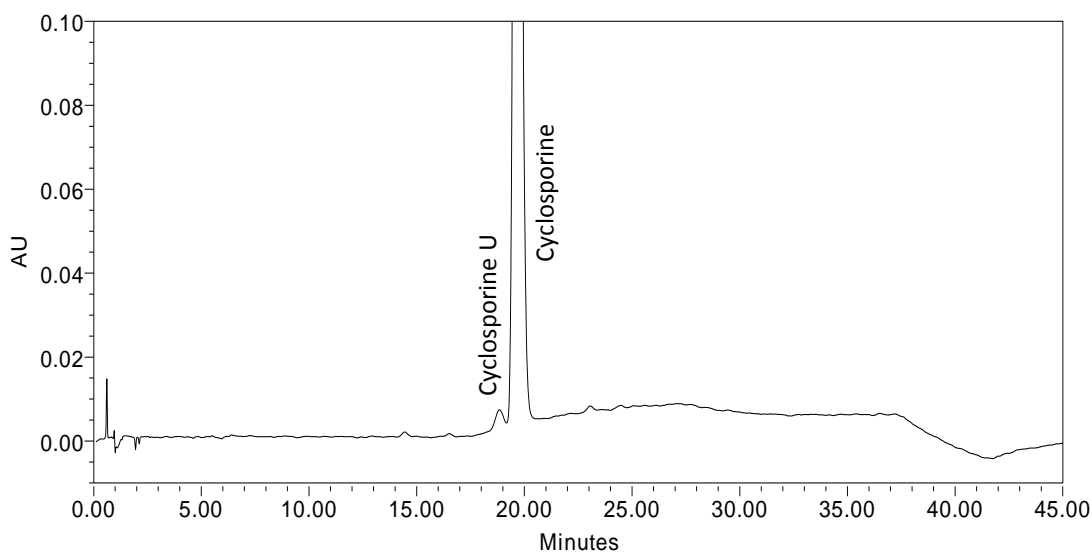
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# Typical Chromatogram

## USP Cyclosporine Resolution Mixture RS

<b>Catalog Number:</b> 1158650
<b>Lot:</b> R063L0
<b>Monograph:</b> Cyclosporine
<b>Publication:</b> PF 43(1)
<b>Test:</b> Organic Impurities
<b>Sample:</b> 1.0 mg/mL, undried samples, in <i>Diluent</i>



This chromatogram is supplied for information only, unless otherwise specified in an applicable monograph or general chapter.