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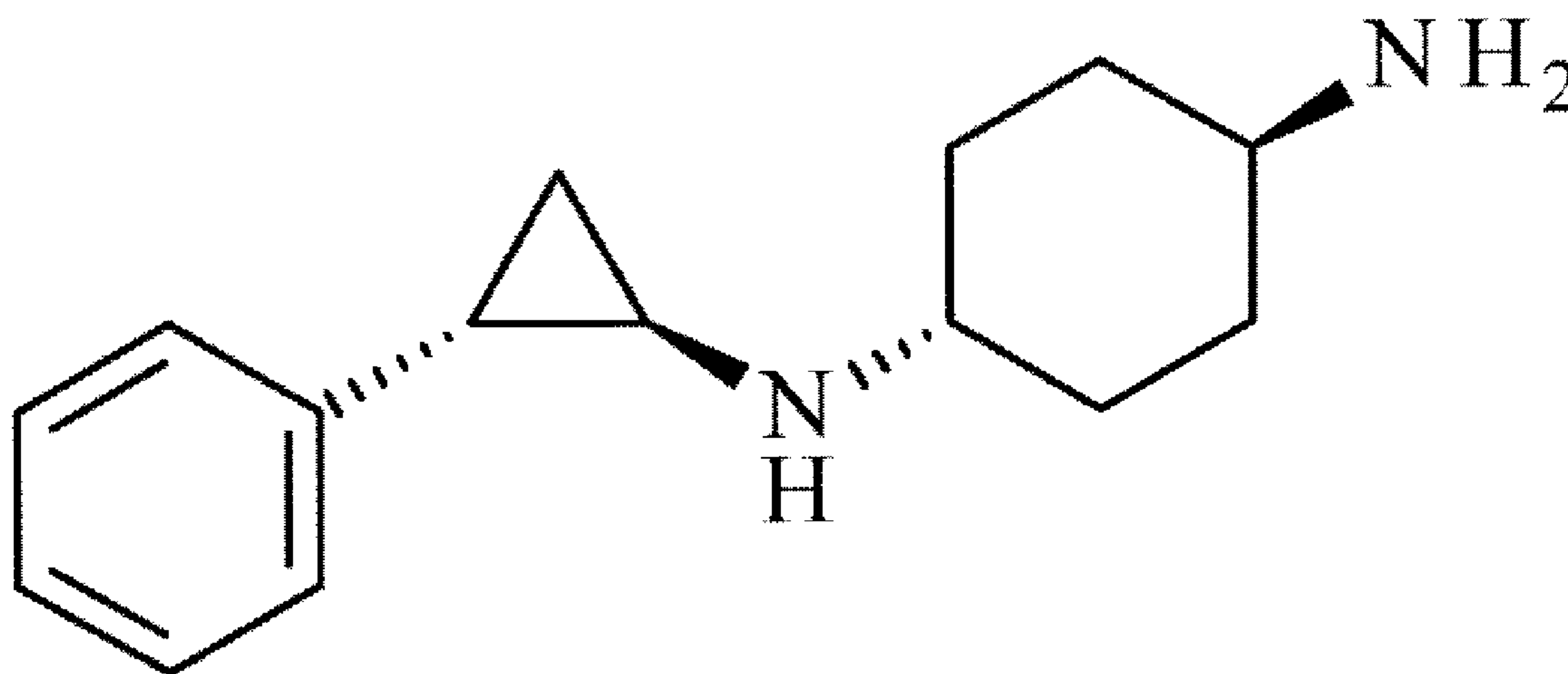
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(54) Titre : FORMES SOLIDES

(54) Title: SOLID FORMS



(I)

(57) Abrégé/Abstract:

The instant invention relates to novel solid forms of the compound of formula (I) or salts thereof (formula I) as well as processes for their manufacture, pharmaceutical compositions comprising them, and their use as medicaments.



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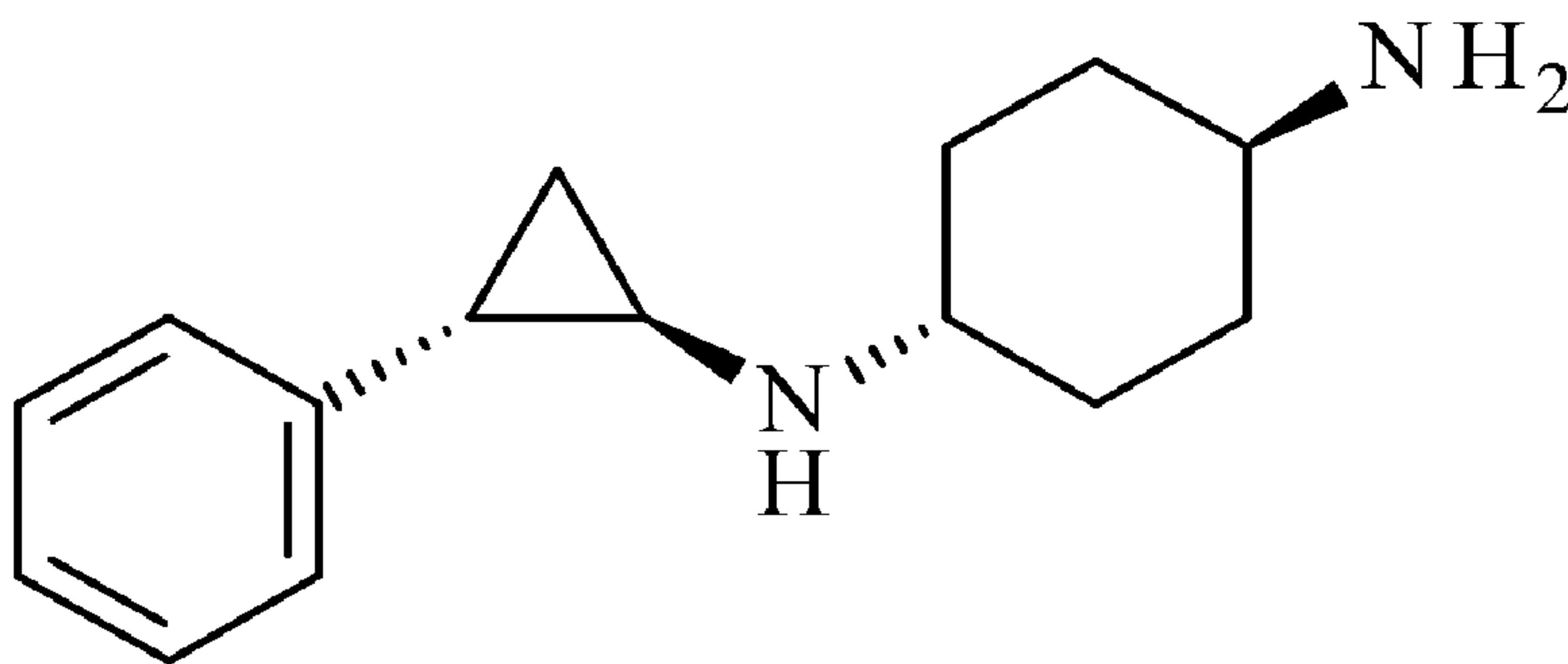
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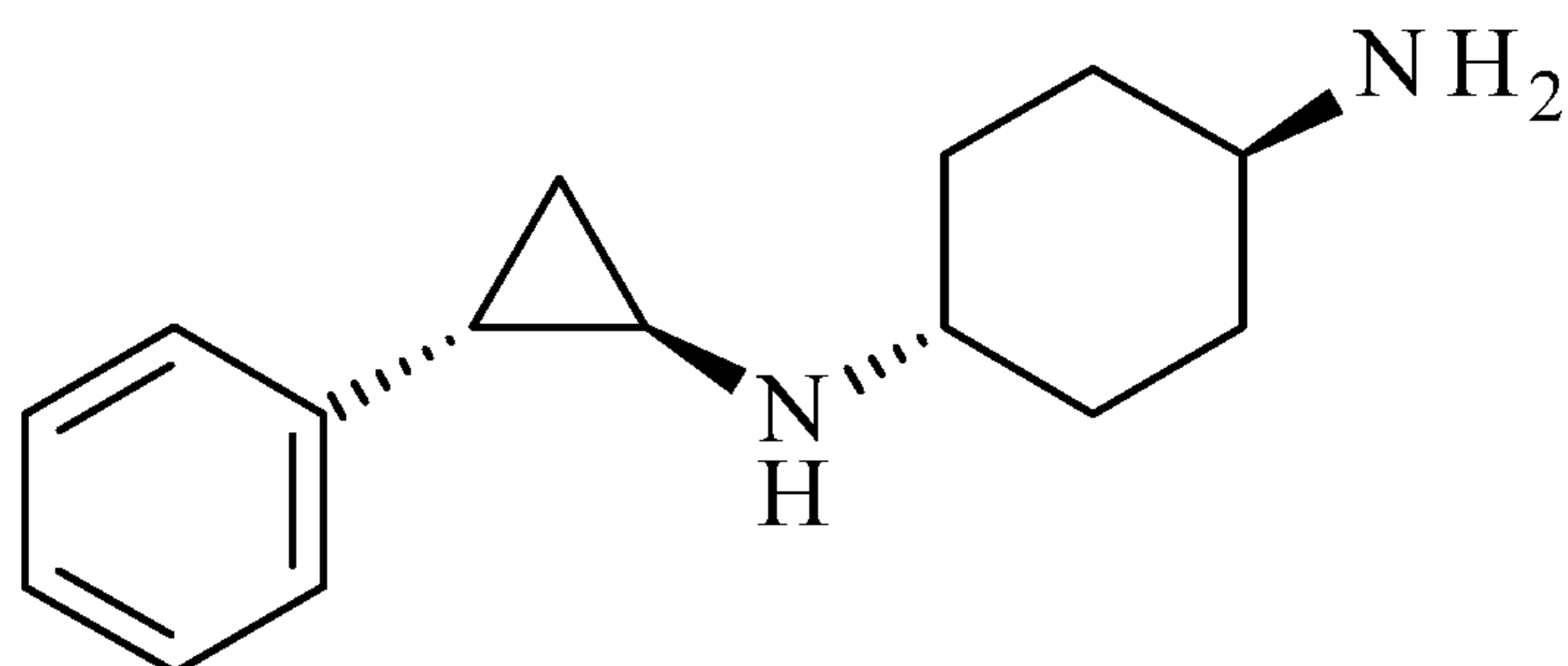
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## Claims

1. A solid form of a compound of formula (I) or a salt thereof



(I),

characterized by an XRPD diffraction pattern comprising XRPD peaks at an angle of diffraction 2Theta of 24.8° and 14.9° ( $\pm 0.1^\circ$ ).

2. The solid form according to claim 1, characterized by an XRPD diffraction pattern comprising a further XRPD peak at an angle of diffraction 2Theta of 16.0° ( $\pm 0.1^\circ$ ).
3. The solid form according to any of claims 1 or 2, characterized by an XRPD diffraction pattern comprising a further XRPD peak at an angle of diffraction 2Theta of 20.6° ( $\pm 0.1^\circ$ ).
4. A solid form of a compound of formula (I) or a salt thereof, characterized by an XRPD diffraction pattern comprising XRPD peaks at angles of diffraction 2Theta of 14.9°, 16.0° and 24.8° ( $\pm 0.2^\circ$ ).
5. The solid form according to claim 4, characterized by an XRPD diffraction pattern comprising XRPD peaks at angles of diffraction 2Theta of 14.9°, 16.0°, 20.6° and 24.8° ( $\pm 0.2^\circ$ ).
6. The solid form according to any of claims 4 or 5, characterized by an XRPD diffraction pattern comprising XRPD peaks at angles of diffraction 2Theta of 14.9°, 16.0°, 20.6°, 24.8°, 25.7° and 31.5° ( $\pm 0.2^\circ$ ).
7. The solid form according to any of claims 4 to 6, characterized by an XRPD diffraction pattern comprising XRPD peaks at angles of diffraction 2Theta of 14.9°, 16.0°, 20.6°, 24.8°, 25.7°, 31.5° and 35.9° ( $\pm 0.2^\circ$ ).
8. The solid form according to any of claims 4 to 7, characterized by an XRPD diffraction pattern comprising XRPD peaks at angles of diffraction 2Theta of 14.6°, 14.9°, 16.0°, 17.7°, 18.7°, 19.4°, 20.6°, 21.7°, 24.4°, 24.8°, 25.7°, 31.5°, 35.2° and 35.9° ( $\pm 0.2^\circ$ ).

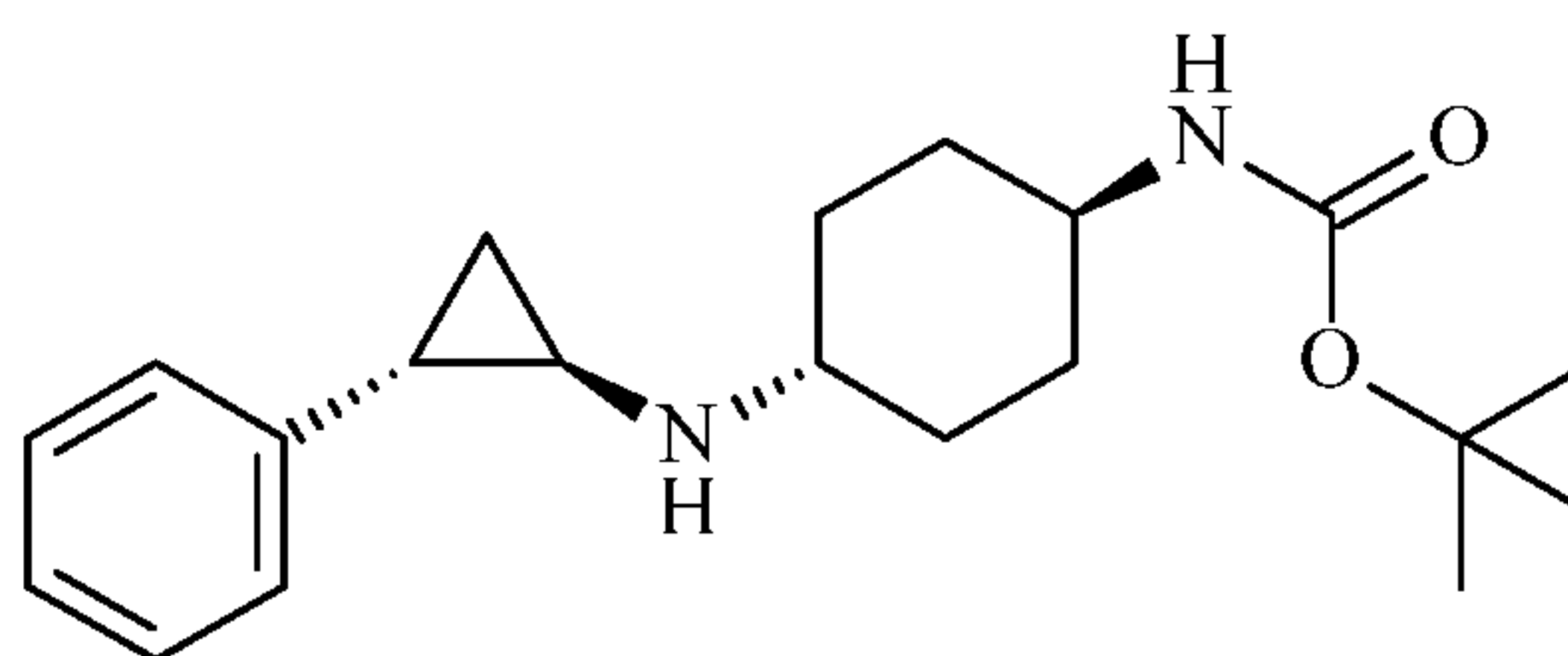
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9. The solid form according to any of claims 1 to 8, characterized by the XRPD diffraction pattern comprising XRPD peaks at angles of diffraction 2Theta as listed in Table 4 Table 5, Table 10 and/or Table 11 ( $\pm 0.2^\circ$ ).
10. The solid form according to any of claims 1 to 9, characterized by the XRPD diffraction  
5 pattern of Figure 2, Figure 3, Figure 15 and/or Figure 16.
11. The solid form according to any of claims 1 to 10, characterized by characteristic bands ( $\text{cm}^{-1}$ ) in the IR spectrum as denoted in Table 7.
12. A solid form of a compound of formula (I) or a salt thereof, characterized by a band in the Raman spectrum at  $1225 \text{ cm}^{-1}$  ( $\pm 1 \text{ cm}^{-1}$ ).
- 10 13. The solid form according to any of claims 1 to 11, characterized by a band in the Raman spectrum at  $1225 \text{ cm}^{-1}$  ( $\pm 1 \text{ cm}^{-1}$ ).
14. The solid form according to claims 12 or 13, characterized by characteristic bands in the Raman spectrum at  $1225 \text{ cm}^{-1}$  and  $745 \text{ cm}^{-1}$  ( $\pm 1 \text{ cm}^{-1}$ ).
15. The solid form according to any of claims 12 to 14, characterized by characteristic bands in  
15 the Raman spectrum at  $1225 \text{ cm}^{-1}$ ,  $745 \text{ cm}^{-1}$ ,  $207 \text{ cm}^{-1}$ , and  $106 \text{ cm}^{-1}$  ( $\pm 1 \text{ cm}^{-1}$ ).
16. The solid form according to any of claims 12 to 15, characterized by a Raman spectrum comprising characteristic bands in the Raman spectrum as listed in Table 9.
17. The solid form according to any of claims 1 to 16, wherein the solid form is present in the specified solid form in a purity of at least 90% (w/w).
- 20 18. The solid form according to any of claims 1 to 17, wherein the solid form is a di-hydrochloride salt.

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19. A process for the preparation of a solid form according to any of claims 1 to 18 comprising the reaction steps of:

a) Dissolution of a compound of formula BOC-(I) in a solvent;



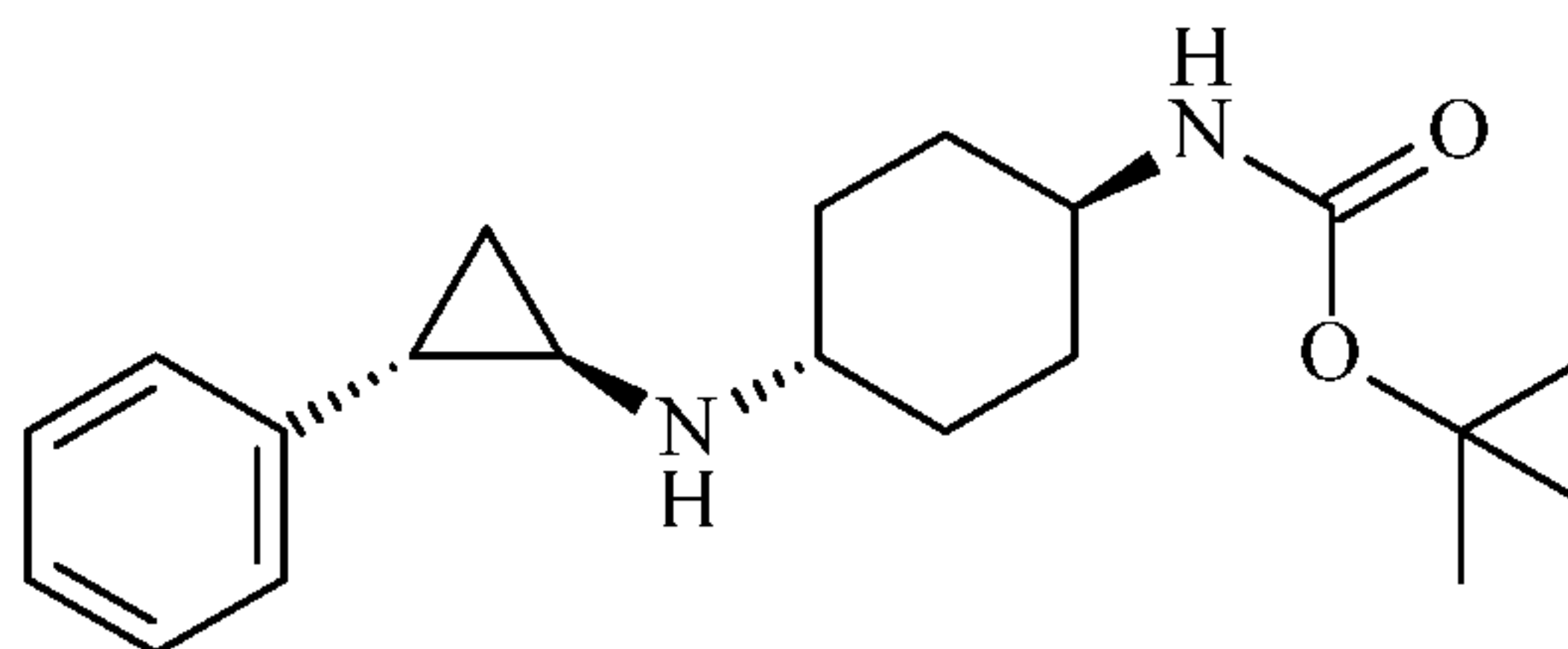
BOC-(I)

- 5        b) Addition of a solution of HCl;
- c) Addition of water at an elevated temperature;
- d) Crystallization of the product through gradual decrease of the temperature.
20. The process of claim 19, wherein the solvent in step a) is a C<sub>1-7</sub> alcohol.
21. The process according to any of claims 19 or 20, wherein the solvent in step a) is a 1-  
10        propanol.
22. The process according to any of claims 19 to 21, wherein the solution of step b) is an aqueous solution.
23. The process according to any of claims 19 to 22, wherein 2 to 20 equivalents of HCl are added in step b).
- 15    24. The process according to any of claims 19 to 23, wherein at least 5 equivalents of water are added in step c).
25. The process according to any of claims 19 to 24, wherein step c) is performed at a temperature above 50 °C.
26. The process according to any of claims 19 to 25, wherein the temperature in step d) is  
20        decreased to a final temperature between -20 °C and ambient temperature.
27. The process according to any of claims 19 to 26, wherein the temperature in step d) is decreased at a rate of 1 to 100 °C/h.

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28. A process for the preparation of a solid form of a compound of formula (I) comprising the reaction steps of:

e) Dissolution of a compound of formula BOC-(I) in 1-propanol;



**BOC-(I)**

- 5 f) Addition of a solution of HCl in 1-propanol;
- g) Physical separation of the precipitate.
29. The process of claim 28, wherein step e) is performed at ambient temperature.
30. The process according to claims 28 or 29, wherein the solution of step f) comprises HCl at a concentration of 5 % m/m to 40% m/m.
- 10 31. The process according to any of claims 28 to 30, wherein 2 to 20 equivalents of HCl are added in step f).
32. The process according to any of claims 28 to 31, wherein step g) is followed by rinsing with 1-propanol at a temperature below 0 °C.
- 15 33. A solid form according to any of claims 1 to 18, obtainable by the process of any of claims 19 to 27.
34. A pharmaceutical composition comprising a solid form according to any of claims 1 to 18 and 33 and a pharmaceutically acceptable excipient.
35. A solid form according to any of claims 1 to 18 and 33 for use as therapeutically active substance.
- 20 36. A solid form according to any of claims 1 to 18 and 33 for use in the treatment or prevention of diseases which are related to LSD1 or which are modulated by LSD1 inhibitors.

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37. A method for the treatment or prevention of diseases which are related to LSD1 or which are modulated by LSD1 inhibitors, which method comprises administering a solid form according to any of claims 1 to 18 and 33 to a human being or animal.
- 5 38. The use of a solid form according to any of claims 1 to 18 and 33 for the treatment or prevention of diseases which are related to LSD1 or which are modulated by LSD1 inhibitors.
39. The use of a solid form according to any of claims 1 to 18 and 33 for the preparation of medicaments useful for the treatment or prevention of diseases which are related to LSD1 or which are modulated by LSD1 inhibitors.
- 10 40. The invention as hereinbefore described.

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