

Appendix B Medicinal Products
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B.1 will the medicinal product be:

- **Unlicensed?** Yes No

 - **A licensed product to be used outside the Terms of its product license?** Yes No
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B.2 Details of medicinal product

Please submit the data sheet for licensed products.

Approved name

Strength

Dosage, form and frequency

Route of administration

B.3 Safety, stability and data relevant to the protocol usage.

Please provide information on the following, including references where appropriate.

a) Toxicity

b) Purity

c) Stability

B.4 who will administer the product?**B.5 manufacturing information.**

a) Who is the supplier?

b) What manufacturing license(s) do they hold?

B.6 Have arrangements for dispensing been made with the pharmacy?

Yes If yes, state who your advisor was.

No If No, explain why not.