TITLE PAGE

NAME OF SPONSOR

Product

Name

Chemical and generic (if approved)

Trade name (if legally permissible and desired by the sponsor)

INVESTIGATOR’S BROCHURE

Edition number

Release date

Previous edition and its numbers

Dates of previous editions

TABLE OF CONTENTS OF INVESTIGATOR’S BROCHURE

Confidentiality Statement (optional)

Signature page (optional)

1. Table of contents
2. Summary
3. Introduction
4. Physical, chemical and pharmaceutical properties formulation
5. Non clinical studies
   1. Non clinical pharmacology
   2. Pharmacokinetics and product metabolism in animals
   3. Toxicology
6. Effects in humans
   1. Pharmacokinetics and product metabolism in humans
   2. Safety and efficacy
   3. Marketing experience
7. Summary of data and guidance for the investigator.
8. Reference on publications and reports (to be provided at the end of each chapter)
9. Appendices (if any)