NAMIBIA MEDICINES REGULATORY COUNCIL

MINISTRY OF HEALTH AND SOCIAL SERVICES

APPLICATION FOR REGISTRATION OF A MEDICINE

- **Namibia Module 1**
- **CTD-Modules 2 - 5**

NMRC Edition August 2014

Namibia Common Technical Document

Nam Module 1 – Administrative Information

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1.7.8 Registration with Registrar of Companies in Namibia (if the applicant is a company)

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1.11 Bioequivalence trial information

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1.11.5 Proof of procurement of the biostudy reference product

1.11.6 Name and address of the Research Organisation(s) / Contract Research Organisation(s) where the bioequivalence studies were conducted

1.11.7 Sponsor and responsible sponsor representative: name and address, contact details

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2.3.S.6 Container Closure System *(name, manufacturer)*

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2.6.2.4 Safety Pharmacology

2.6.2.5 Pharmacodynamic Medicine Interactions

[2] *The CTD defines these further heading levels and navigation should be provided within the document to these subheadings.*

2.6.2.6 Discussion and Conclusions

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[3] *The CTD defines these further heading levels and navigation should be provided within the document to these subheadings.*

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3.2.R.1.1.8 Confirmation that the test product was manufactured with API(s) manufactured by the same manufacturer(s) as being applied for

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