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| **SAHPRA PRE-SUBMISSION MEETING REQUEST FORM** | |
| **APPLICANT INFORMATION** | |
| Name & Address |  |
| Responsible Pharmacist/ Delegate |  |
| Position |  |
| Mailing Address |  |
| Phone |  |
| Email |  |
| **PRODUCT INFORMATION** | |
| Proposed Proprietary name |  |
| API(s) |  |
| Strength(s) |  |
| Dosage Form |  |
| Type of application (NCE/Generic/Clone/Replica) |  |
| Proposed indication |  |
| Regulatory Pathway  Full review/ Verified/Zazibona/ Abridged/ WHO-PQ etc |  |
| Preferred submission date (MM/YYYY) |  |
| **Other relevant Information** | |
| Inspectorate | Applicant/FPRR – Licensing Status with SAHPRA  Manufacturer / Packer / FPRC– if local, SAHPRA licence status and Inspectorate Resolution details OR GMP certificate/report details from a Recognised Regulatory Authority satisfying the requirements as per the SA GMP Guide |
| Clinical Evaluation Management | The therapeutic indication being applied for as well as details on the clinical data package supporting the claimed indication |
| Pharmaceutical Evaluation Management | Quality issues for non -standard manufacturing |
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| **For office use only (SAHPRA)** | |
| Proposed meeting date |  |
| Proposed meeting time |  |