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| **ABRIDGED REVIEW TEMPLATE**  |

**THIS DOCUMENT SHOULD BE COMPLETED BY THE APPLICANT TO ENSURE INCLUSION OF ALL NECESSARY INFORMATION**

This abridged review template will be used for assessment in cases where the applicant’s product has been registered with a recognised regulatory authority (RRA). Please note the following:

Please ensure that the Sameness declaration (Appendix 2 of the Quality and Bioequivalence Guideline [2.02]) has been completed and attached to the eCTD / eSubmission new registration validation template (i.e. so that it forms one PDF).

If full/unredacted assessment reports cannot be obtained by the applicant from the RRA, please ensure that the Letter of access (Appendix in the General Information Guideline [2.01]) has been completed and attached to the eCTD / eSubmission new registration validation template (i.e. so that it forms one PDF).

**Please complete all sections shaded in grey.** The columns for Recognised Regulatory Authority (RRA) and SAHPRA submission must be completed with text taken directly from the relevant section in the respective reports, as well as the reference to the location in the dossier.

**References to the location in the dossier will not be accepted without the actual text accompanying them.**

Please ensure sufficient detail is included in this template to make an accurate comparison between the RRA authority and SAHPRA submission.

Do not copy and paste between the columns for RRA and SAHPRA submission. These must all be completed as per the exact information in the original documents.

1. **Product details**

|  |  |
| --- | --- |
| Applicant name |  |
| Applicant email address |  |
| Application number(s) | Master | Duplicate(s) |
|  |  |
| Product (proprietary) name | Master | Duplicate(s) |
|  |  |
| Approved name (INN or INNM) |  |
| Strength(s) |  |
| Manufacturer applied for |  |
| API manufacturer applied for |  |
| Dosage form |  |

1. **Similarity of data set: PRODUCT QUALITY**

| **Item to verify** | **RRA:** {Name of RRA} **submission** | **SAHPRA submission**  | **Evaluator comments** |
| --- | --- | --- | --- |
| Name and complete address of the applicant | {Extract from relevant report section}Location in report: | {Extract from relevant dossier section}Location in dossier: |  |
| Name(s) and complete address(es) of the manufacturer(s) of the finished pharmaceutical product(s) [FPP(s)], biological drug products(s) (DP(s)), including the final product release if different from the manufacturer. | {Extract from relevant report section}Location in report: | {Extract from relevant dossier section}Location in dossier: |  |
| **ACTIVE PHARMACEUTICAL INGREDIENT (API) (NAME, MANUFACTURER)** |
| Name of API | {Extract from relevant report section}Location in report: | {Extract from relevant dossier section}Location in dossier: |  |
| General properties that may affect the performance of the finished product (e.g. polymorphism, solubility in physiological media) | {Extract from relevant report section}Location in report: | {Extract from relevant dossier section}Location in dossier: |  |
| Name and address(es) of the manufacturer(s) of the API(s) | {Extract from relevant report section}Location in report: | {Extract from relevant dossier section}Location in dossier: |  |
| DMF/APIMF number | {Extract from relevant report section}Location in report: | {Extract from relevant dossier section}Location in dossier: |  |
| Control of the API (including, the specification reference number, version and date. The copy of the specification may be included as attachment to the report) | {Extract from relevant report section}Location in report: | {Extract from relevant dossier section}Location in dossier: |  |
| Container closure system | {Extract from relevant report section}Location in report: | {Extract from relevant dossier section}Location in dossier: |  |
| Stability summary and conclusions(including storage statement and re-test period) | {Extract from relevant report section}Location in report: | {Extract from relevant dossier section}Location in dossier: |  |
| **FINISHED PHARMACEUTICAL PRODUCT (FPP)**  |
| Description | {Extract from relevant report section}Location in report: | {Extract from relevant dossier section}Location in dossier: |  |
| Manufacturer(Name, address and responsibility) | {Extract from relevant report section}Location in report: | {Extract from relevant dossier section}Location in dossier: |  |
| Narrative description of the manufacturing process[No need to compare the whole manufacturing process, can just look at the blank master production document reference number, version and date, together with information on the site.] | {Extract from relevant report section}Location in report: | {Extract from relevant dossier section}Location in dossier: |  |
| Control of FPP/DPState the specification reference number, version and date, copy of the specification must be attached as attachment to the report. | {Extract from relevant report section}Location in report: | {Extract from relevant dossier section}Location in dossier: |   |
| Container closure system | {Extract from relevant report section}Location in report: | {Extract from relevant dossier section}Location in dossier: |  |
| Stability summary and conclusions (incl., the storage statement and shelf life) | {Extract from relevant report section}Location in report: | {Extract from relevant dossier section}Location in dossier: |  |
| Lot / batch release documents for biologicals | {Extract from relevant report section}Location in report: | {Extract from relevant dossier section}Location in dossier: |  |
| ***General comments from evaluator*** |  |
| ***Comments from peer reviewer*** |  |

**Composition**

RRA: {Name of RRA}

|  |  |  |  |
| --- | --- | --- | --- |
| **Component and quality standard** | **Function** | **Quant. per unit (mg)** | **%** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
| Total |  |  |  |
| ***General comments from evaluator*** |  |
| ***Comments from peer reviewer*** |  |

SAHPRA submission

|  |  |  |  |
| --- | --- | --- | --- |
| **Component and quality standard** | **Function** | **Quant. per unit (mg)** | **%** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
| Total |  |  |  |
| ***General comments from evaluator*** |  |
| ***Comments from peer reviewer*** |  |

**Commercial batch size and batch formula**

RRA: {Name of RRA}

|  |  |
| --- | --- |
| **Proposed commercial batch size(s) (e.g. number of dosage units)**  |  |
| **Component and quality standard (and grade, if applicable)**  | **Quantity per batch (kg/batch)**  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
| Total  |  |
| ***General comments from evaluator*** |  |
| ***Comments from peer reviewer*** |  |

SAHPRA Submission:

|  |  |
| --- | --- |
| **Proposed commercial batch size(s) (e.g. number of dosage units)**  |  |
| **Component and quality standard (and grade, if applicable)**  | **Quantity per batch (kg/batch)**  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
| Total  |  |
| ***General comments from evaluator*** |  |
| ***Comments from peer reviewer*** |  |

1. **Similarity of data set – CLINICAL (SAFETY AND EFFICACY)**

|  |
| --- |
| **Pharmacokinetic / safety / efficacy related information used for WHO Prequalification or RRA approval. Indicate:** |
| Type of study | “X” in appropriate box | Comparator product, where applicable |
| Bioequivalence / Comparative pharmacokinetics,  |  |  |
| Biowaiver based on Biopharmaceutics Classification System (BCS) biowaiver |  |  |
| Additional strength biowaiver |  |  |
| Clinical data |  |  |
| Comparative pharmacodynamic and potential immunogenicity |  |  |
| Other (please specify) |  |  |
| ***General comments from evaluator*** |  |
| ***Comments from peer reviewer*** |  |

| **BIOEQUIVALENCE / BIOWAIVERS** |
| --- |
| **Item to verify** | **RRA:** {Name of RRA} **submission** | **SAHPRA submission** | **Evaluator comments** |
| Study number | {Extract from relevant report section}Location in report: | {Extract from relevant dossier section}Location in dossier: |  |
| Study title | {Extract from relevant report section}Location in report: | {Extract from relevant dossier section}Location in dossier: |  |
| Clinical facility or the Contract Research Organisation (CRO) | {Extract from relevant report section}Location in report: | {Extract from relevant dossier section}Location in dossier: |  |
| Bioanalytical laboratories | {Extract from relevant report section}Location in report: | {Extract from relevant dossier section}Location in dossier: |  |
| Company performing pharmacokinetic / statistical analysis | {Extract from relevant report section}Location in report: | {Extract from relevant dossier section}Location in dossier: |  |
| Overall trial design and plan: Description, study dates, sample size | {Extract from relevant report section}Location in report: | {Extract from relevant dossier section}Location in dossier: |  |
| Test Product: Name, manufacturer, batch number, batch size, location of multi-point dissolution data in physiological media and release media, if different | {Extract from relevant report section}Location in report: | {Extract from relevant dossier section}Location in dossier: |  |
| Reference product: Name, manufacturer, source, batch number, expiry date | {Extract from relevant report section}Location in report: | {Extract from relevant dossier section}Location in dossier: |  |
| Results: Conclusion and review of summary of results (table) | {Extract from relevant report section}Location in report: | {Extract from relevant dossier section}Location in dossier: |  |
| ***General comments from evaluator*** |  |
| ***Comments from peer reviewer*** |  |

1. **Labelling**

The following minimum information appears on the label:

|  |  |  |
| --- | --- | --- |
| **Particulars to appear on <the outer packaging> <and> <the immediate packaging>** | **Yes / No** | ***Evaluator comments*** |
| 1. Name of the product: {(invented) name strength pharmaceutical form} {active substance(s)}
 |  |  |
| 1. Statement of active substance(s)
 |  |  |
| 1. List of excipients {only critical/special excipients are listed here)
 |  |  |
| 1. Pharmaceutical form and contents
 |  |  |
| 1. Method and route(s) of administration /if no specific information: “read the package leaflet before use.”}
 |  |  |
| 1. Special warning that the medicinal product must be stored out of the sight and reach of children {normally: “keep out of the sight and reach of children.”}
 |  |  |
| 1. Other special warning(s), if necessary
 |  |  |
| 1. Expiry date
 |  |  |
| 1. Special storage conditions
 |  |  |
| 1. Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if appropriate
 |  |  |
| 1. Name and address of the supplier / applicant
 |  |  |
| 1. National marketing authorization number}
 |  |  |
| 1. Batch number
 |  |  |
| 1. General classification for supply in accordance with national legal requirements:
 |  |  |
| 1. Instructions on use
 |  |  |
| 1. Information in braille [Justification for not including braille accepted.]
 |  |  |
| ***Comments from peer reviewer*** |  |

Additional information as per national requirements

|  |  |  |
| --- | --- | --- |
| **Minimum particulars to appear on blisters or strips** | **Yes / No** | ***Evaluator comments*** |
| 1. **Name of the product:** {(Invented) name strength pharmaceutical form} {Active substance(s)}
 |  |  |
| 1. **Name of the supplier / applicant**
 |  |  |
| 1. **Expiry date**
 |  |  |
| 1. **Batch number**
 |  |  |
| 1. **Others**
 |  |  |
| ***Comments from peer reviewer*** |  |

Additional information as per national requirements

|  |  |  |
| --- | --- | --- |
| **Minimum particulars to appear on small immediate packaging units** | **Yes / No** | ***Evaluator comments*** |
| 1. **Name of the product:** {(Invented) name strength pharmaceutical form} {Active substance(s); Route of administration}
 |  |  |
| 1. **Method of administration**
 |  |  |
| 1. **Expiry date**
 |  |  |
| 1. **Batch number**
 |  |  |
| 1. **Contents by weight, by volume or by unit**
 |  |  |
| 1. **Others**
 |  |  |
| ***Comments from peer reviewer*** |  |

1. **APPLICANT COMMITMENTS TO RRA**

Applicant to state any commitments to RRA that may require follow up.

Please do not just state a reference to a section of a report. Please insert a summary of text as per the example below:

* [The Applicant undertook to continue long-term testing of <INN of API> for a period of time sufficient to cover the whole provisional re-test period (period ending month/year)
* The Applicant undertook to continue long-term testing of < FPP reference number, trade name (INN of API), strength, pharmaceutical form> for a period of time sufficient to cover the whole provisional shelf-life (period ending month/year)
* The Applicant committed that three consecutive production batches would be prospectively validated and a validation report —in accordance with the details of the validation protocol provided in the dossier— would be made available as soon as possible for evaluation by assessors or for verification by the inspection team.]
1. **SOUTH AFRICA SPECIFIC REQUIREMENTS (MODULE 1 AND MODULE 3.2.R)**

[For Module 3.2.R, please include summaries (if applicable) of:

1. Comparative dissolution
2. Comparison of APIs
3. Reference to batch numbers for executed BMRs and/ sizes for the blank batch manufacturing records (BMRs) provided Any other relevant information]

*P*

*\*

*D)any other relevant considerations.*

[Do we need to make this section more granular?]

**6. SAHPRA COMMENTS** – *For SAHPRA use only*