National Agency for Food & Drug Administration & Control (NAFDAC)

Registration & Regulatory Affairs (R & R) Directorate

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC) TEMPLATE

[Instructions in this font/colour are from the World Health Organisation Public Assessment Report WHOPAR guidelines.]

[Additional instructions and examples]
{<example text>}

1. NAME OF THE MEDICINAL PRODUCT

{(Product) name strength pharmaceutical form}[1]

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

[API and strength: e.g.:
Each film-coated tablet contains:
Lamivudine 150 mg]

Excipients with known effect:
Each tablet (unit dose) contains x mg of <excipient known to have safety concern> (add as many as present in the unit dose). Note that even if the excipient is present in the FPP below the threshold in the EC guideline, the amount of each excipient in the guideline should be specified.

Both names of the azo dyes should be given, due to different practices in different countries, e.g.: FD&C Yellow #5/Tartrazine

{For a full list of excipients, see section 6.1}

3. PHARMACEUTICAL FORM

[Include a description of the visual appearance of the product pharmaceutical form as marketed, including information on pH and osmolarity as required.

Information on appearance of reconstituted parenteral solution should appear under section 6.6.]

[e.g.: White coloured, biconvex capsule-shaped film-coated tablet having a score on one side and "XL 5" debossed on the other side.]

<The scoreline is only to facilitate breaking for ease of swallowing and not to divide into equal doses.>

<The tablet can be divided into equal halves.>

<The tablet should not be divided.>

[Product scoring may be recommended or required when a WHO Prequalified product is scored, or scoring is specified for an innovator or comparator product(s), or when division into fractional doses may be necessary according to recommended posology.

4. Clinical particulars

4.1 Therapeutic indications

< {Product name, strength, dosage form} is indicated in <adults> <neonates> <infants> <children> <adolescents> <aged {x to y}> <years> <months>>.>

4.2 Posology and method of administration

Posology

Pediatric population

<The <safety> <and> <efficacy> of {X} in children aged {x to y} <months> <years> {or any other relevant subsets e.g. weight, pubertal age, gender} <has> <have> not <yet> been established.>

<No data are available.> <Currently available data are described in Section <4.8> <5.1> <5.2> but no recommendation on a posology can be made.>

< {Product name, strength, dosage form} should not be used in children aged {x to y} <years> <months> {or any other relevant subsets e.g. weight, pubertal age, gender} because of <safety> <efficacy> concern(s).>

<There is no relevant use of {product name, strength, dosage form} <in the pediatric population> <in children aged {x to y} <years>,
<Months> {or any other relevant subsets e.g. weight, pubertal age, gender} <in the indication...>

< {Product name, strength, dosage form} is contraindicated in children aged {x to y} <years> <months> {or any other relevant subsets e.g. weight, pubertal age, gender} <in the indication...> (see Section 4.3).>

Method of administration

4.3 Contraindications

<Hypersensitivity to the active substance(s) or to any of the excipients <or {name of the residue(s)}>.>

4.4 Special warnings and precautions for use

4.5 Interaction with other medicinal products and other forms of interaction

<No interaction studies have been performed.>

<Interaction studies have only been performed in adults.>

4.6 Pregnancy and Lactation

<Pregnancy>

<Lactation>

<Fertility>

[See prequalification guidance: Section Guidance for Part 4 — Summary of Product Characteristics (SmPC) — Of a WHO Public Assessment Report (WHOPAR).*]*

<Women of childbearing potential>

<Contraception in males and females>

<Pregnancy>

<Lactation>

<Fertility>

4.7 Effects on ability to drive and use machines

< {Product name, strength, dosage form} has <no <or negligible> influence> <minor influence>, <moderate influence> <major influence> on the ability to drive and use machines.>

<No studies on the effects on the ability to drive and use machines have been performed.>

<Not relevant.>

4.8 Undesirable effects

[See prequalification guidance: Section Guidance for Part 4 — Summary of Product Characteristics (SmPC) — Of a WHO Public Assessment Report (WHOPAR).*]*

<Pediatric population>

4.9 Overdose

<No case of overdose has been reported.>

<If overdose occurs the patient should be monitored for evidence of toxicity and standard supportive treatment applied as necessary>

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics properties

Pharmacotherapeutic group: {group}, ATC code: {code}

<Mechanism of action>

<Pharmacodynamic effects>

<Clinical efficacy and safety>

<Resistance>

<Paediatric population>

5.2 Pharmacokinetic properties

<Absorption and Bioavailability>

<Distribution>

<Metabolism>

<Elimination>

<Special Population>

5.3 Preclinical safety data

<Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, toxicity to reproduction and development.>

<Effects in non-clinical studies were observed only at exposures considered sufficiently in excess of the maximum human exposure indicating little relevance to clinical use.>

<Adverse reactions not observed in clinical studies, but seen in animals at exposure levels similar to clinical exposure levels and with possible relevance to clinical use were as follows:>

<Mutagenicity and Carcinogenicity>

<Reproductive toxicology>

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

[List all excipients **except solvents removed during processing**.]

[Grades/standards should **not** be indicated.]

[The ingredients of mixtures (colourants, inks, capsule shells) should be listed. Flavour ingredients do not need to be listed. Only the **solids** of the printing ink should be included, usually shellac and black iron oxide.]

[Check colourants to ensure they are acceptable for use (EU, Japan, US lists). If a colourant is noted that is discouraged for use, a note should be made in the assessment report.]

6.2 Incompatibilities

<Not applicable.>

<In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.>

<This medicinal product must not be mixed with other medicinal products except those mentioned in Section 6.6.>

<This section is mostly of quality concern for parenteral products.>

6.3 Shelf life

[Information on the finished product shelf life and on the in-use stability after 1st opening and/or Reconstitution/dilution should appear here. Only one overall shelf life for the finished product is to be given even if different components of the product may have a different shelf life (e.g. powder & solvent).]

If different pack types differ in shelf life, this should be clear.

<...> <6 months> <...> <1 year> <18 months> <2 years> <30 months> <3 years> <...>

Sterile products: Refer to max. In-use period of sterile after first opening and reconstitution: http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500003476.pdf

In-use period: <established period e.g. for hygroscopic product stored in bottles>

6.4 Special precautions for storage

[General storage conditions of the finished product should appear here, together with a cross-reference to section 6.3 where appropriate:

<For storage conditions of the <reconstituted> <diluted> medicinal product, see Section 6.3.>

[For blisters in cartons where the carton is necessary for light protection, the statement, "Store tablets in the blisters in the provided carton" is necessary.]

6.5 Nature and contents of container <and special equipment for use, administration or implantation>

[All pack sizes must be listed. If applicable, add:]

<Not all pack sizes may be marketed.>

[The container/closure description should include all parts of the primary packaging including desiccant, void filler or adsorbent cotton filler and dosing device(s) if relevant. Dimensions/volume/capacity may be listed. Shape and colour of the bottle and the cap type (including plastic e.g. PP), should be stated.

[E.g. sealed LDPE bag, placed inside a round white HDPE bottle with plain PP screw cap and aluminium tagger (packs of 100 Tablets & 1000 Tablets]

[For blisters in cartons where the carton is necessary for light protection, the carton is an important aspect of the package description.]

<Not all pack sizes may be marketed.>

6.6 Special precautions for disposal <and other handling>

[Include practical instructions for preparation and handling of the product including disposal of the medicinal product, and waste materials derived from the used medicinal product.]

[Information on appearance of reconstituted parenteral solution should appear here]

<No special requirements.>

<Any unused product or waste material should be disposed of in accordance with local requirements.>

7. <APPLICANT/MANUFACTURER>

{Name and address}

< {Tel}>

< {Fax}>

< {Email}>