TITLE: Template for Summary Product Characteristics (SmPC)

<text> signifies text to be selected or deleted as appropriate.

{text} refers to information to be added.

[For further guidance on how to use this template and populate the different sections, please refer to guideline on medical information for Summary product characteristics, patient information leaflet, package and labelling in Bangladesh]

1. NAME OF THE MEDICINAL PRODUCT AND STRENGTH

{(Invented) name strength pharmaceutical form}

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

<Excipient(s) with known effect>
<For the full list of excipients, see section 6.1>

3. PHARMACEUTICAL FORM

4. Clinical Particulars

4.1 Therapeutic indications

<{X} is indicated in <adults> <neonates> <infants> <children> <adolescents> <aged {x to y}> <years> <months>.>

4.2 Posology and method of administration

4.3 Contraindications

<Hypersensitivity to the active substance(s) or to any of the excipients listed in section 6.1 <or {name of the residue(s)}>.>

4.4 Special warnings and precautions for use

<Paediatric population>

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 Fertility, pregnancy and lactation

<Pregnancy>

<Breast-feeding>

<Fertility>

4.7 Effects on ability to drive and use

<{(Invented) name} 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.>
<Not relevant.>

4.8 Undesirable effects

<Paediatric population>

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the DGDA, Bangladesh reporting system mentioned in www.dgda.gov.bd/

4.9 Overdose

<Paediatric population>
<No case of overdose has been reported.>

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

<{(invented) name} is a biosimilar medicinal product.>
<Mechanism of action>
<Pharmacodynamic effects>
<Clinical efficacy and safety>
<Paediatric population>

5.2 Pharmacokinetic properties

<Absorption>
<Distribution>
<Biotransformation>
<Elimination>
<Linearity/non-linearity>
<Pharmacokinetic/pharmacodynamic relationship(s)>

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:>

<Environmental risk assessment (ERA)>

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

<None>

6.2 Incompatibilities

<Not applicable.>

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

<This medicinal product must not be mixed with other medicinal products except those mentioned in section <6.6> <and> <12>.>.

6.3 Shelf life

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

6.4 Special precautions for storage

<For storage conditions after <reconstitution> <dilution> <first opening> of the medicinal product, see section 6.3.>

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

<Not all pack sizes may be marketed>

6.6 Special precautions for disposal and other handling

<Use in the Paediatric population>

7. Marketing Authorization holder name and address

{Name and address}

<{tel}>

<{fax}>

<{e-mail}>

8. Marketing Authorization Number(s)

9. Date of first authorization/Renewal of the Authorization

<Date of first authorization: {DD month YYYY}>

<Date of latest renewal: {DD month YYYY}>

10. Date of revision of the text

<{MM/YYYY}>

<{DD/MM/YYYY}>

<DD month YYYY}>