Annexure-1						
	FORM Title: Summary Product Characteristics (SmPC)					
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1. NAME OF THE MEDICINAL PRODUCT AND STRENGTH

1.1 {(Invented) name strength pharmaceutical form}

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

2.1 Excipient(s)

2.2 A full list of excipients

3. PHARMACEUTICAL FORM

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

3.2 The tablet can be divided into equal halves.

3.3 The tablet should not be divided.

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

4.2.1 Posology

4.2.2 Pediatric population

4.2.2.1 <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.>

4.2.2.2 <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.>

4.2.2.3 <{X} 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).>

4.2.2.4 <There is no relevant use of {X} <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...>

4.2.2.5 <{X} 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).

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4.2.3 Method of administration

4.3 Contraindications

4.3.1 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

4.5.1 No interaction studies have been performed.

4.5.2 Interaction studies have only been performed in adults.

4.6 Pregnancy and lactation

4.6.1 Women of childbearing potential

4.6.2 Contraception in males and females

4.6.3 Pregnancy

4.6.4 Breastfeeding

4.6.5 Fertility

4.7 Effects on ability to drive and use machines

4.7.1 {Invented name} has <no <or negligible> influence> <minor influence>, <moderate influence> <major influence> on the ability to drive and use machines.

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

4.7.3 Not relevant.

4.8 Undesirable effects

4.9 Overdose

4.9.1 No case of overdose has been reported.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

5.1.1 Pharmacotherapeutic group

5.1.2 Mechanism of action

5.1.3 Pharmacodynamic effects

5.1.4 Clinical efficacy and safety

5.1.5 Pediatric population

5.2 Pharmacokinetic properties

5.3 Preclinical safety data

5.3.1 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.

5.3.2 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.

5.3.3 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:

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

6.2 Incompatibilities

6.2.1 Not applicable.

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

6.2.3 This medicinal product must not be mixed with other medicinal products.

6.3 Shelf life

6.4 Special precautions for storage

6.5 Nature and contents of container

6.6 Special precautions for disposal and other handling

7. Marketing Authorization holder name and address

8. Drug Authorization number

9. Date of first authorization

10. Date of revision of the text