



REGISTRATION AND REGULATORY AFFAIRS DIRECTORATE

SmPC Review Checklist

PRODUCT NAME:.....

SECTION	Information required (please comment below, if requirements not fully met)	YES	NO
1.	{(Invented) name strength pharmaceutical form} <i>[Dosage form description “tablets” and “capsules” in the plural]</i>		
Comment			
2.	QUALITATIVE AND QUANTITATIVE COMPOSITION <i>[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.</i> <i>For a full list of excipients, see section 6.1.</i>		
Comment			

3.	<p>PHARMACEUTICAL FORM <i>[Include a description of the visual appearance of the product pharmaceutical form as marketed, including information on pH and osmolarity as required.</i></p> <p><i>Information on appearance of reconstituted parenteral solution should appear under section 6.6.]</i> <i>Statement on score line and the appropriate instruction on scoring</i></p>		
4.	<p>CLINICAL PARTICULARS</p> <p>4.1 Therapeutic indications 4.2 Posology and method of administration: <i>It may be that device is necessary, e.g. powders for oral suspensions/solutions in multi-use containers. directions to crush, disperse, dissolve and/or disintegrate an IR (non-dispersible) tablet</i> 4.3 Contraindications 4.4 Special warnings and precautions for use 4.5 Interaction with other medicinal products and other forms of interaction 4.6 Pregnancy and Lactation 4.7 Undesirable effects 4.8 Overdose</p> <p><i>Generally, information on clinical particulars for generic product should be consistent with information approved for innovator/comparator product</i></p>		

5.	<p>PHARMACOLOGICAL PROPERTIES</p> <p>5.1 Pharmacodynamics properties</p> <p><Pharmacotherapeutic group: {group}, ATC code: {code}> <Mechanism of action> <Pharmacodynamic effects> <Clinical efficacy and safety> <Resistance> <Paediatric population></p> <p>5.2 Pharmacokinetics properties</p> <p><Absorption and Bioavailability> <Distribution> <Metabolism> <Elimination> <Special Population></p> <p>5.3 Preclinical safety data</p> <p><Mutagenicity and Carcinogenicity> <Reproductive toxicology></p>		
Comment			
6	<p>6.1 List of excipients</p> <p><i>[List all excipients except solvents removed during processing.]</i></p> <p><i>[Grades/standards should not be indicated.]</i></p> <p>6.2 Incompatibilities</p> <p><i>(E.g. this medicinal product must not be mixed with other medicinal products except those mentioned in section 6.6.)</i></p> <p><i>[This section is mostly of quality concern for parenteral products.]</i></p> <p>6.3 Shelf life</p> <p><i>[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</i></p>		

	<p>6.4 Special precautions for storage</p> <p><i>[General storage conditions of the finished product should appear here, together with a cross-reference to section 6.3 where appropriate:</i></p> <p>6.5 Nature and contents of container <and special equipment for use, administration or implantation></p> <p><i>[All pack sizes must be listed. If applicable, add:]</i> <i><Not all pack sizes may be marketed.></i></p> <p>6.6 Special precautions for disposal</p> <p><i>[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.]</i></p>		
Comment			
7.	<p><SUPPLIER></p> <p><i>[Country name in the language of the text. Telephone, fax numbers and/or e-mail addresses may be included]</i></p> <p>{Name and address} <{tel}> <{fax}> <{e-mail}></p>		

Comments on deficiencies
with reference to table above and specific sections of the SmPC

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Additional data requested
(to be communicated to the applicant)

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