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Committee for Medicinal Products for Human Use (CHMP)

Overview of comments on Sitagliptin film-coated tablets 25, 50 and 100 mg product-specific bioequivalence guidance (EMA/CHMP/PKWP/36869/2015)

Interested parties (organisations or individuals) that commented on the draft document as released for consultation.

Stakeholder no.	Name of organisation or individual
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1. General comments

Stakeholder number	General comment (if any)	Outcome (if applicable)
	1. If we are developing the product using an alternative salt strategy, can we apply the BCS Biowaiver? Or is there any requirement to submit the Permeability references for such alternative salt strategy? 2. If Qualitative & Quantitative composition of test and reference product is different and excipient used in test product is not affecting the Bioavailability in vivo based on the references. Can we apply the BCS biowaiver based on EMEA guidance for Sitagliptin product?	1. The tentative BCS classification of sitagliptin is BCS 1 and should be confirmed by the Applicant at time of application. Please, refer to the **GUIDELINE ON THE INVESTIGATION OF BIOEQUIVALENCE (CPMP/EWP/QWP/1401/98 Rev. 1/ Corr) – appendix 3:** Biowaiver may also be applicable if test and reference contain different salts provided that both belong to BCS-class I (high solubility and complete absorption). No modification of the product specific guideline is required. 2. Please, refer to the **GUIDELINE ON THE INVESTIGATION OF BIOEQUIVALENCE (CPMP/EWP/QWP/1401/98 Rev. 1/ Corr) – appendix 3:** excipients that might affect bioavailability are qualitatively and quantitatively the same. In general, the use of the same excipients in similar amounts is preferred. No modification of the product specific guideline is required.

2. Specific comments on text

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes	Outcome