



1 14 November 2013  
2 CHMP/PKWP/EMA/422605/2013  
3 Committee for Medicinal Products for Human Use (CHMP)

4 **Telithromycin Product-Specific Bioequivalence Guidance**  
5 **Draft**

<b>Draft Agreed by Pharmacokinetics Working Party</b>	<b>October 2013</b>
Adoption by CHMP for release for consultation	24 October 2013
Start of public consultation	15 November 2013
End of consultation (deadline for comments)	15 February 2014

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Comments should be provided using this [template](#). The completed comments form should be sent to [PKWPsecretariat@ema.europa.eu](mailto:PKWPsecretariat@ema.europa.eu).

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<b>Keywords</b>	<b><i>Bioequivalence, generics, telithromycin</i></b>
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11 Disclaimer:

12 *This guidance should not be understood as being legally enforceable and is without prejudice to the need to ensure that the data submitted in support of*  
13 *a marketing authorisation application complies with the appropriate scientific, regulatory and legal requirements.*

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15 **Requirements for bioequivalence demonstration (PKWP)\***

<b>BCS Classification**</b>	<b>BCS Class:</b> <input type="checkbox"/> I <input type="checkbox"/> III <input checked="" type="checkbox"/> <b>Neither of the two</b> <b>Background:</b> Telithromycin may be considered a high solubility compound.
<b>BE Study design</b>	<b>single dose</b>
	<b>cross-over</b>
	<b>healthy volunteers</b>
	<input checked="" type="checkbox"/> <b>fasting</b> <input type="checkbox"/> <b>fed</b> <input type="checkbox"/> <b>both</b> <input type="checkbox"/> <b>either fasting or fed</b>



	<p><b>Strength:</b> 400 mg, because it is the highest strength.</p> <p><b>Background:</b> Telithromycin exhibits non-linear pharmacokinetics with a more than dose-proportional increase in AUC with increasing dose within the dose-range 400-1600 mg.</p>
	<p><b>Number of studies:</b> one single dose study</p>
<b>Analyte</b>	<p><input checked="" type="checkbox"/> parent    <input type="checkbox"/> metabolite    <input type="checkbox"/> both</p>
	<p><input checked="" type="checkbox"/> plasma    <input type="checkbox"/> blood    <input type="checkbox"/> urine</p>
	<p><b>Enantioselective analytical method:</b>    <input type="checkbox"/> yes    <input checked="" type="checkbox"/> no</p>
<b>Bioequivalence assessment</b>	<p><b>Main pharmacokinetic variables:</b> AUC<sub>0-t</sub>, C<sub>max</sub></p>
	<p><b>90% confidence interval:</b> 80.00– 125.00</p>

- 16 \* As drug variability has not been reviewed, this guidance is not applicable to highly variables drugs.
- 17 \*\* The BCS classification should be confirmed by the Applicant at time of submission based on available data (solubility experiments, literature, etc.). If
- 18 a drug substance has been classified as BCS class II or IV, no further solubility investigations are needed.