



1 24 October 2013
2 CHMP/PKWP/EMA/422457/2013
3 Committee for Medicinal Products for Human Use (CHMP)

4 **Carglumic Acid Product-Specific Bioequivalence Guidance**
5 **Draft**

Draft Agreed by Pharmacokinetics Working Party	October 2013
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.

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Keywords	<i>Bioequivalence, generics, carglumic acid</i>
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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)***

BCS Classification**	BCS Class: <input type="checkbox"/> I <input type="checkbox"/> III <input checked="" type="checkbox"/> Neither of the two Background: Carglumic acid may be considered a low solubility compound.
BE Study design	single dose
	cross-over
	healthy volunteers



	<input checked="" type="checkbox"/> fasting <input type="checkbox"/> fed <input type="checkbox"/> both <input type="checkbox"/> either fasting or fed
	Strength: 200 mg
	Number of studies: one single dose study
Analyte	<input checked="" type="checkbox"/> parent <input type="checkbox"/> metabolite <input type="checkbox"/> both
	<input checked="" type="checkbox"/> plasma <input type="checkbox"/> blood <input type="checkbox"/> urine
	Enantioselective analytical method: <input type="checkbox"/> yes <input checked="" type="checkbox"/> no
Bioequivalence assessment	Main pharmacokinetic variables: AUC _{0-72h} , C _{max}
	90% confidence interval: 80.00– 125.00

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.