EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human Use (CHMP)

Paclitaxel (nanoparticle albumin-bound) powder for suspension for infusion, 5mg/ml

Draft

Draft Agreed by Methodology Working Party (MWP)	21 October 2024
Adopted by CHMP for release for consultation	04 November 2024
Start of public consultation	31 January 2025
End of consultation (deadline for comments)	30 April 2025

Comments should be provided using this EUSurvey form. For any technical issues, please contact the EUSurvey Support.

Keywords	***Bioequivalence, generics, paclitaxel nanoparticle albumin-bound***

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Requirements for bioequivalence demonstration (MWP)

Bioequivalence study design**	**Single dose:** 260 mg/m^2 Q3W in patients with breast cancer **Background:** In principle, suspensions for infusion are not waived from the *in vivo* demonstration of bioequivalence. However, in this case a waiver based on in vitro similarity might be applicable if certain conditions are met, taking into account that the suspension rapidly disassembles upon infusion in blood (see below).
	cross-over
	Other critical aspects:
Analyte	☒ **parent** ☐ **metabolite** ☐ **both**
	☒ **plasma/serum** ☐ **blood** ☐ **urine**
	Enantioselective analytical method: ☐ **yes** ☒ **no**
Bioequivalence assessment	**Main pharmacokinetic variables:** C_{max} and AUC_{0-t}.
	90% confidence interval: 80.00– 125.00%
Waiver of bioequivalence study	A waiver of *in vivo* bioequivalence study may be granted, when similarity of the following physicochemical characteristics has been demonstrated: • qualitative and quantitative composition, including paclitaxel:albumin ratio • particle size distribution • crystallinity of paclitaxel (amorphous form)

	• fraction of free versus bound paclitaxel • nature of paclitaxel/HSA bond • morphology of particles • *in vitro* release kinetics upon dilution in plasma • oligomeric status of albumin in the reconstituted solution (SEC) • surface potential in plasma At least 3 batches of the test and reference product should be included in the comparability studies, where ten samples per batch are tested. The choice of statistical methods and acceptance criteria should be predefined and justified.