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Committee for Medicinal Products for Human Use (CHMP)

Tafamidis soft gelatin capsules 20 mg and 61 mg product-specific bioequivalence guidance

Draft Agreed by Methodology Working Party (MWP)	April 2026
Adopted by CHMP for release for consultation	13 April 2026
Start of public consultation	30 April 2026
End of consultation (deadline for comments)	31 July 2026

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

Keywords	***Bioequivalence, generics, tafamidis***

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

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Disclaimer:

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 a marketing authorisation application complies with the appropriate scientific, regulatory and legal requirements.

B. Requirements for bioequivalence demonstration (MWP)

BCS Classification	**BCS Class:** ☐ **I** ☐ **III** ☒ **Neither of the two** **Background:** Tafamidis meglumine (20 mg) and tafamidis free acid (61 mg) are considered low solubility compounds.
Bioequivalence study design *in case a BCS biowaiver is not feasible or applied*	**single dose** **cross-over**
	healthy volunteers
	☒ **fasting** ☐ **fed** ☐ **both** ☐ **either fasting or fed**
	Strength: 20 mg and 61 mg.
	Number of studies: Two single dose studies (one for each strength). **Background:** 20 mg and 61 mg capsules are not bioequivalent.

Analyte	☒ **parent** ☐ **metabolite** ☐ **both**
	☒ **plasma/serum** ☐ **blood** ☐ **urine**
	Enantioselective analytical method: ☐ **yes** ☒ **no**
Bioequivalence assessment	**Main pharmacokinetic variables:** AUC_{0-72h}, C_{max}
	90% confidence interval: 80.00– 125.00%

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