Physicochemical and biological analyses demonstrated that the infliximab biosimilar PF-SZ-IFX was not affected by extended storage of the diluted preparations used for intravenous infusion” Vimpolsek et al (2019).

Abstract:

OBJECTIVE: PF-06438179/GP1111 (PF-SZ-IFX) is an infliximab biosimilar. We evaluated the extended in-use physicochemical and biological stability of PF-SZ-IFX upon preparation for intravenous infusion.

METHODS: Two batches of PF-SZ-IFX were reconstituted to a concentration of 10 mg/mL and subsequently diluted to 0.4 and 4.0 mg/mL, representing the clinically relevant range for intravenous infusion. Dilution was performed in polyethylene saline infusion bags, which are commonly used in clinical practice. To simulate product handling under worst-case conditions, reconstituted solutions were stored for up to 30 days at 5 ± 3 °C and up to 14 days at 25 ± 2 °C (60 ± 5% relative humidity); diluted solutions were stored for up to 30 days under the same sets of conditions. Physicochemical and biological stability were evaluated according to pH, osmolality, appearance, particulate content, protein concentration, proportions of molecular weight variants and charge variants and potency. Standard and state-of-the-art analytical techniques were employed, including imaged isoelectric focusing, size exclusion chromatography, reducing sodium dodecyl sulphate capillary electrophoresis and functional cell-based bioassay.
RESULTS: Across batches and concentrations of PF-SZ-IFX, all parameters resided within the predefined acceptance criteria, including pH, osmolality, particulate content, clarity, protein concentration, molecular weight variants, charge variants and potency, for up to 30 days under both storage conditions tested (up to 14 days for reconstituted samples stored at 25 ± 2 °C).

CONCLUSIONS: Physicochemical and biological analyses demonstrated that the infliximab biosimilar PF-SZ-IFX was not affected by extended storage of the diluted preparations used for intravenous infusion.

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