

The logo for Koura, featuring the word "Koura" in a bold, yellow, sans-serif font, set against a dark teal rectangular background.

To whom it may concern:

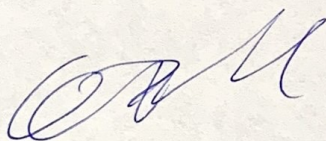
Technical Review of European Pharmacopoeia Monograph for Norflurane (HFA 134a)
- Version 10.0 Update

The European Pharmacopoeia is reviewed and updated on a regular basis. A consequence of this is that Koura must show that the methods employed in the analysis of Zephex® 134a remain in compliance with the Monograph for Norflurane.

Koura chooses to use analytical techniques that are not identical to the Monograph methods but are deemed equivalent. In order to demonstrate and confirm equivalence a project was undertaken with an independent, third-party test laboratory. This was successfully concluded and documented in report "EP/COMP/001 - Comparison of Mexichem Fluor's Analytical Methods for ZEPHEX® 134a with Norflurane Ph Eur 7.7 Monograph Methods". This is available upon request.

The Norflurane Ph Eur 7.7 Monograph was current at the time the equivalence work was undertaken. As the Pharmacopoeia is regularly updated it is necessary to ensure that the Koura methods remain equivalent.

A technical review was undertaken in January 2021. No updates to the Monograph were found. Therefore, the analytical methods employed in the release of Zephex® 134a remain equivalent to version 10.0 of the EP Monograph for Norflurane.

A handwritten signature in blue ink, appearing to read "Chris Dodd".

Chris Dodd
Koura Regulatory Affairs Manager Medical Products

Koura Global Ltd (formerly Mexichem UK Ltd)

chris.dodd@kouraglobal.com

Phone: +44 (0)1928 51 8873

www.kouraglobal.com

www.zephex.com