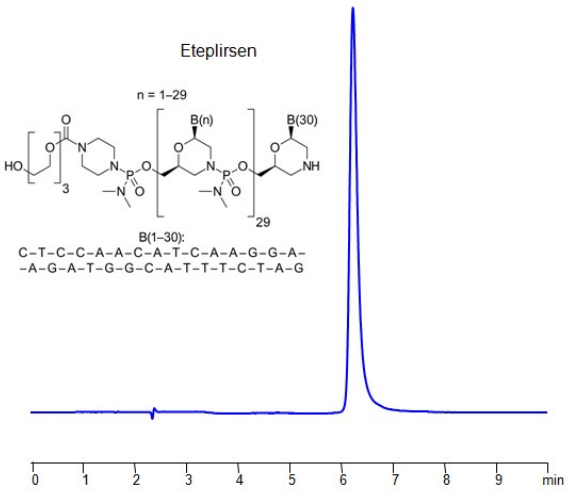
HPLC Method for Analysis of Eteplirsen on Primesep B Column



Column:	Primesep B
Column size:	4.6 × 150 mm, 5 µm
Column part number:	B-46.150.0510
Mobile phase:	Gradient MeCN – 10-60%, 10 min
Buffer:	H_2SO_4 - 0.2%
Flow rate:	1.0 mL/min
Detection:	UV 260 nm

Separation type: Liquid Chromatography Mixed-mode

Eteplirsen (brand name Exondys 51) is an antisense oligonucleotide used for the treatment of some types of Duchenne muscular dystrophy (DMD), a rare genetic disorder characterized by progressive muscle degeneration and weakness. Eteplirsen specifically targets patients who have a confirmed mutation of the DMD gene that is amenable to exon 51 skipping.

Approval: Eteplirsen was granted accelerated approval by the U.S. Food and Drug Administration (FDA) in 2016. This approval was based on an increase in dystrophin protein in skeletal muscle observed in some patients treated with Eteplirsen. The FDA has required the manufacturer to conduct a clinical trial to confirm the drug's clinical benefit.

Administration: Eteplirsen is administered as an intravenous infusion.

Chemical Structure: Eteplirsen is an oligonucleotide, a short sequence of nucleic acids. Its full chemical structure is detailed and specific, given its nature as an oligonucleotide.

Safety and Efficacy: Common side effects include balance disorder and vomiting. The clinical benefit of Eteplirsen, including improved motor function, has not been definitively established.

Eteplirsen can be retained, and analyzed on a Primesep B mixed-mode stationary phase column using an isocratic analytical method with a simple mobile phase of water, Acetonitrile (MeCN), and a sulfuric acid as a buffer. This analysis method can be detected using UV at 260 nm.

*LOD was determined for this combination of instrument, method, and analyte, and it can vary from one laboratory to another even when the same general type of analysis is being performed.

AugustaChrom - Dr. Roland Kießwetter
Tel.: +49 821 599 783 70
Fax: +49 821 599 783 71
E-Mail: info@hplc-shop.de

Method Parameters

Column	Primesep B, 4.6 x 150 mm, 5 µm, 100 Å, dual ended
Mobile Phase	Gradient MeCN – 10-60%, 10 min
Buffer	H2SO4 – 0.2%
Flow Rate	1.0 mL/min
Detection	UV 260 nm

Quelle: https://sielc.com/hplc-determination-of-eteplirsen

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E-Mail: info@hplc-shop.de