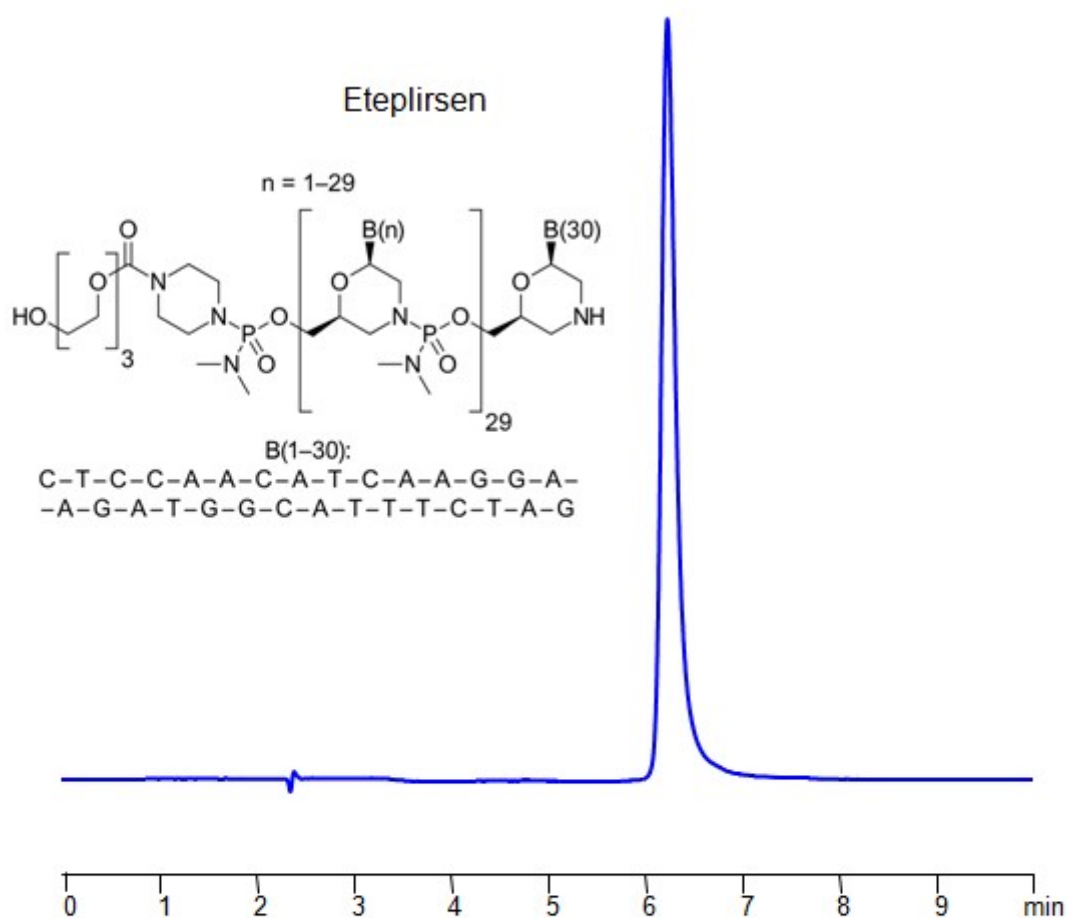


HPLC Method for Analysis of Eteplirsen on Primesep B Column

<https://sielc.com/hplc-determination-of-eteplirsen>

Chromatogram



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 ₂ SO ₄ - 0.2%
Flow rate:	1.0 mL/min
Detection:	UV 260 nm

Description

· High Performance Liquid Chromatography (HPLC) Method for Analysis of Eteplirsen .

Eteplirsen (brand name Exondys 51) is an antisense oligonucleotide with the chemical formula C 364 H 569 N 177 O 122 P 30 . It is 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. It works by binding to exon 51 of dystrophin pre-mRNA. This results in the exclusion of exon 51 during mRNA processing, producing a truncated but still functional form of dystrophin protein. 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. 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.

Method Parameters

Mobile Phase	Gradient MeCN – 10-60%, 10 min
Buffer	H2SO4 – 0.2%
Flow Rate	1.0 ml/min
Detection	UV 260 nm
Peak Retention Time	6.26 min
LOD*	94 ppb
Class of Compounds	Oligonucleotide
Analyzing Compounds	Eteplirsen

HPLC Column Used

Primesep B, 4.6 x 150 mm, 5 µm, 100 A, dual ended

[Order this column at hplc-shop.de →](https://www.hplc-shop.de)