

## Liquid Chromatography

Authors:

Ross Birch

Kathryn Lawson-Wood

PerkinElmer Inc.

Seer Green, UK

## HPLC Analysis of Finasteride Using an Epic C18 Column in Accordance with the United States Pharmacopeia

Finasteride is an antiandrogenic compound or 'testosterone blocker' which is used as a treatment for an enlarged prostate and can treat male hair loss. It inhibits the production of the enzyme Type-II 5 $\alpha$ -reductase which converts testosterone into the more active metabolite 5 $\alpha$ -dihydrotestosterone (DHT).<sup>1</sup> DHT is responsible for the development and enlargement of the prostate and can contribute to hair loss by shortening hair follicles and causing them to fall out more quickly. By suppressing production of DHT, finasteride directly targets the molecule responsible for stimulation of prostatic growth. Finasteride is commonly sold under the brand name Proscar and in 2016 was the 75th most prescribed drug in the USA.<sup>2</sup>

This application brief describes the use of an Epic™ C18 column to analyze finasteride (Figure 1) in accordance with the official Finasteride Tablets USP monograph.<sup>3</sup>

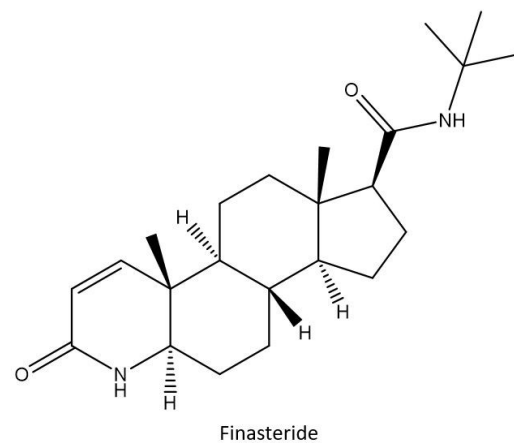


Figure 1. Structure of Finasteride.

## Experimental Conditions

### Method Parameters

All HPLC method parameters are shown in Table 1.

Table 1. HPLC method parameters.

Instrument	PerkinElmer LC 300 HPLC system with LC 300 multi-wavelength UV/Vis (MWD) Detector
Column	Epic C18 100 x 4.6 mm, 5 $\mu$ m (P/N: 125291-EC18)
Mobile Phase	<b>A:</b> 2.5 mM phosphoric acid <b>B:</b> Acetonitrile 50 % <b>A</b> 50 % <b>B</b>
Flow Rate	1.5 mL/min
Temp	45°C
Wavelength	240 nm
Injection Volume	20 $\mu$ L
Analyte	Finasteride

### Solvents and Samples

All solvents were HPLC grade and samples were filtered using a 0.45  $\mu$ m nylon filter, P/N 02542880.

A standard solution of USP finasteride (0.1 mg/mL) was prepared using a solution of acetonitrile and water (70:30) as diluent.

### Results and Discussion

The USP monograph specifies that a column with L1 packing (100 x 4.6 mm) be used. L1 packing is defined as octadecyl silane chemically bonded to porous or non-porous silica. The Epic C18 column complies with the USP monograph and is suited to the analysis of finasteride as demonstrated by the results, Table 2.

The analysis of Finasteride has been carried out using an Epic C18 (100 x 4.6 mm, 5  $\mu$ m) column (P/N:125291-EC18) in under four minutes, Figure 2. The USP monograph requires that the relative standard deviation (RSD) of five replicate injections be no more than 2.0%, the tailing factor be no more than 2.0, the capacity factor (k) be no less than 2.0 and the efficiency be no less than 1000 plates (N). The Epic C18 column met all of these requirements (Table 2) and gave an efficient and repeatable separation with an efficiency (calculated using the tangential method) of 6338 N and an RSD value of 0.14%. This is due to the superior base deactivation and high-density bonding technology of the Epic C18 phase.

The overlay of five successive replicates of finasteride, Figure 3, demonstrates the low RSD and high repeatability of the Epic C18 column with very little difference in peak shape for the five replicates.

An unretained compound (uracil) was also analyzed under the same conditions to identify the column void volume, and thus calculate the k value. The retention time of uracil was 0.6 minutes giving the finasteride peak a capacity factor of 4.2, showing good retention.

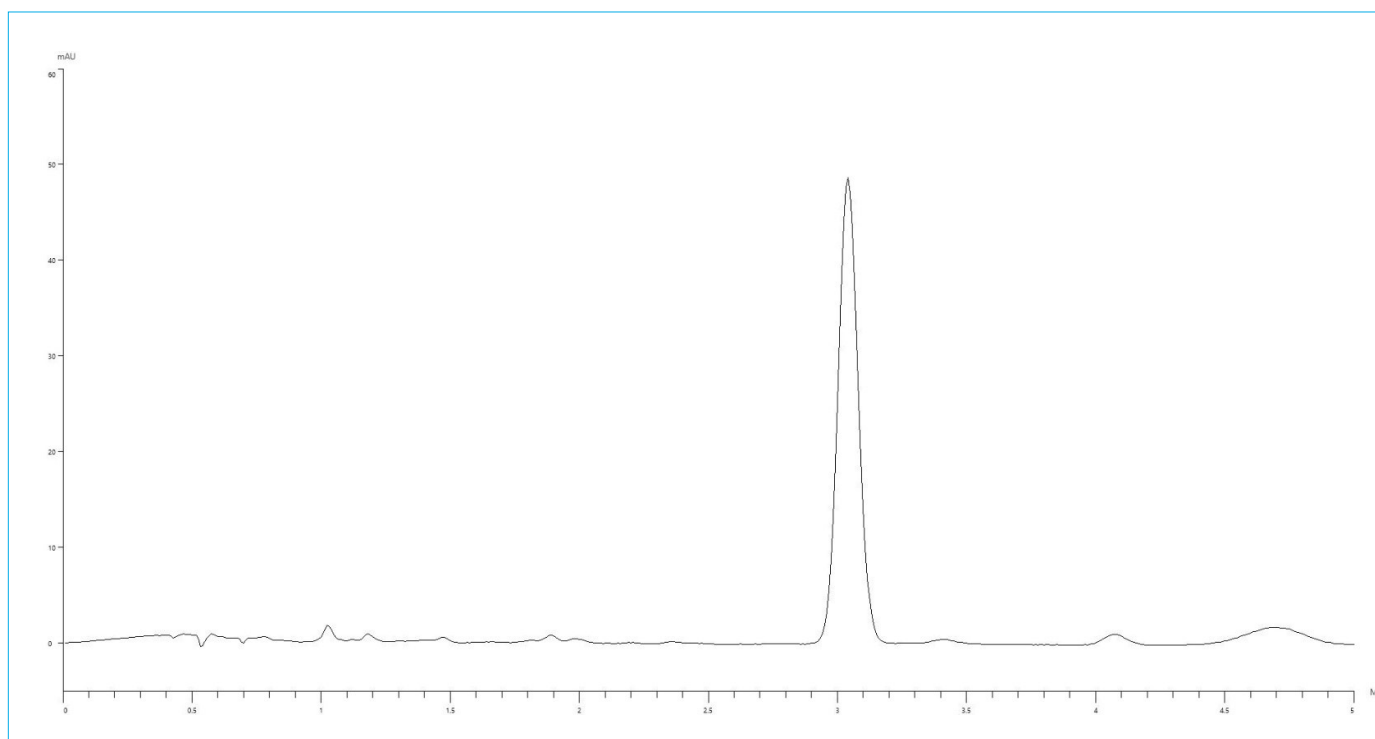


Figure 2. Analysis of finasteride using an Epic C18 column (100 x 4.6 mm, 5  $\mu$ m).

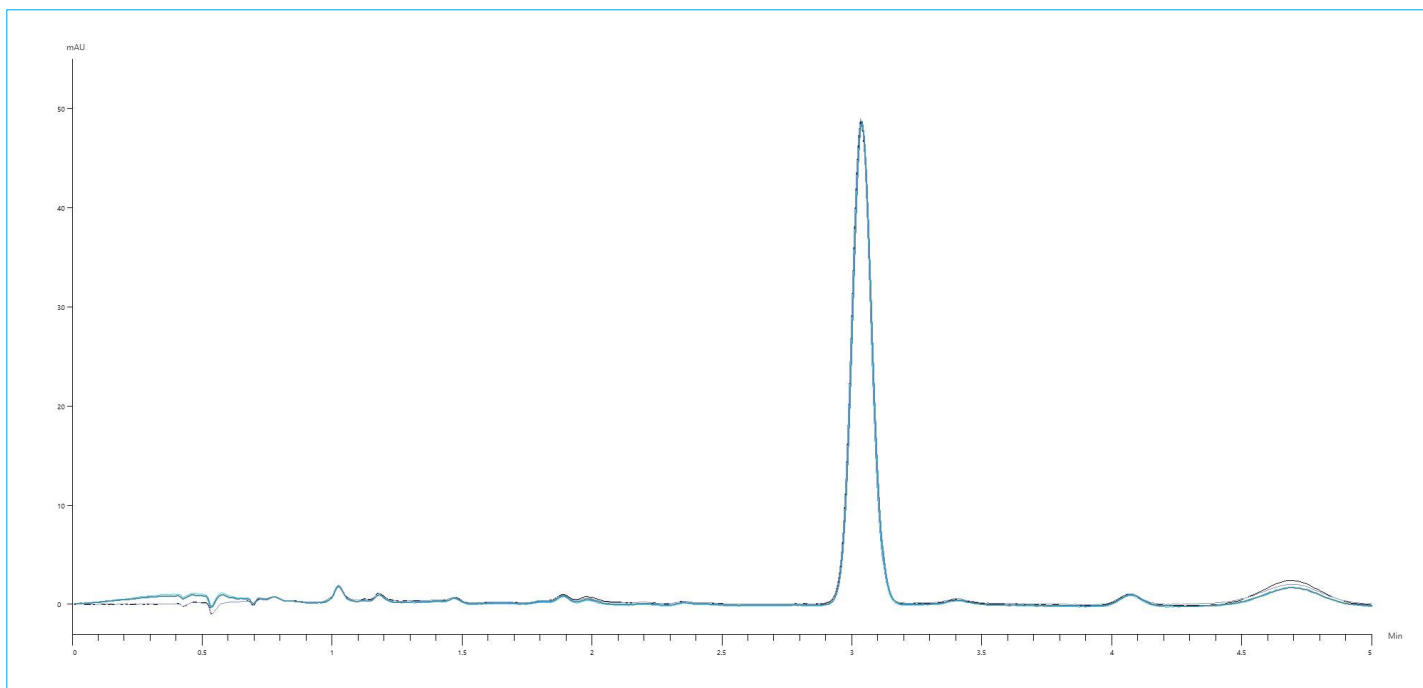


Figure 3. Overlay of five successive reps of finasteride.

## Conclusion

- Rapid analysis of finasteride (< 4 mins) was carried out on an Epic C18 column (100 x 4.6 mm, 5  $\mu$ m), allowing high sample throughput and reduced solvent costs.
- The Epic C18 column provides efficient and repeatable separations for finasteride, meeting all suitability requirements in the USP monograph.
- The superior base deactivation and high-density bonding technology of Epic generates excellent peak shape with minimal peak tailing.

## References

1. DrugBank Database, <https://www.drugbank.ca/drugs/DB01216>, (accessed 30/04/2021)
2. ClinCalc website, <https://clincalc.com/DrugStats/Drugs/Finasteride>, (accessed 30/04/2021)
3. USP monograph finasteride tablets, [https://online.uspnf.com/uspnf/document/1\\_GUID-A028892B-70C8-4CE7-B3F5-DAF21D15D8D7\\_1\\_en-US?source=Search%20Results&highlight=finasteride](https://online.uspnf.com/uspnf/document/1_GUID-A028892B-70C8-4CE7-B3F5-DAF21D15D8D7_1_en-US?source=Search%20Results&highlight=finasteride), accessed (30/04/2021)

Table 2. Results summary. RSD calculated from five successive injections.

Suitability Parameter	Epic C18 Column	USP Requirement
Peak Area RSD (%)	0.14	$\leq 2.0$
Column Efficiency (N)	6338	$\geq 1000$
Tailing Factor	1.04	$\leq 2.0$
k	4.2	$\geq 2.0$

## Consumables

Component	Description	Part Number
Column	Epic C18 (100 x 4.6 mm, 5 $\mu$ m)	125291-EC18
HPLC Vials	2 mL Amber 9 mm Screw Top Vial with Write-on Patch and Fill Lines (100/pack)	N9307802
HPLC Vial Caps	9 mm Screw Top Blue (polypropylene) Cap with PTFE/Silicone pre-slit Septa (100/pack)	N9306203
Syringes	Syringe 1 mL BD Luer-Lok Disposable (100/pack)	02542890
Syringe Filters	0.45 $\mu$ m Nylon Filter	02542880
PEEK Fittings	Finger-tight for 1/16" OD PEEK Tubing	09920513
Stainless Steel Fittings	OptiTech Reusable Nut/Ferrule for UHPLC	N9306301