

Application of Leaps Pro Bio Bioinert Liquid Chromatography System in Oligonucleotide Drug Analysis

Small interfering RNA (siRNA) drugs, as one of the most promising therapeutic agents at present, are characterized by high specificity, a wide range of targets, and long-acting effects. siRNA generally refers to double-stranded RNA with a nucleotide sequence length of 19–23. Chemical synthesis is the most direct and reliable method to obtain siRNA. Liquid chromatography methods commonly used for purity and impurity analysis include reversed-phase ion-pair chromatography and ion-exchange chromatography.

In this paper, the Chromai Leaps Bio bioinert system was employed to rapidly separate the sense and antisense strands and their impurities in siRNA drugs using anion-exchange chromatography. The experimental results are reliable and consistent with those obtained from a foreign brand bioinert instrument in terms of peak shape and performance. The Leaps Bio bioinert system meets the requirements of oligonucleotide drugs for bioinert high-performance liquid chromatography systems and can be applied to purity analysis, impurity analysis, and other tests of oligonucleotide drugs.

1 Chromatographic Conditions

- Instrument: Chromai Leaps Bio Bioinert System
- Column: LotusBio SAX (4.6×250 mm, 5 μm)
- Flow rate: 0.5 mL/min
- Mobile phase: A: 20 mM buffer salt; B: A + 1.5 M NaCl
- Column temperature: 30 °C
- Injection volume: 5 μL (sample concentration ~2 mg/mL)
- UV detection wavelength: 260 nm

Figure 1 Chromatogram of a mixed sample containing sense and antisense strands of siRNA and impurities — Leaps Bio

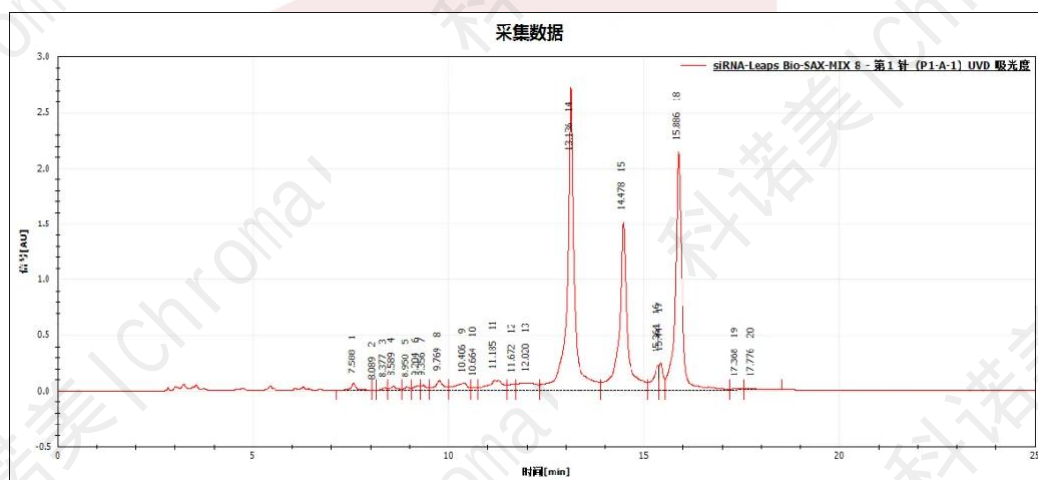


Table 1 Results of siRNA sense and antisense strands and impurity sample

序号	保留时间[min]	峰面积[mAU.s]	峰面积[%]	峰高[mAU]
1	7.588	590.525	0.626	61.011
2	8.089	6.392	0.007	1.185
3	8.377	158.661	0.168	20.453
4	8.589	348.685	0.369	35.987
5	8.950	254.129	0.269	26.789
6	9.204	404.642	0.429	38.434
7	9.356	413.057	0.438	41.379
8	9.769	1176.583	1.246	81.781
9	10.406	1333.033	1.412	59.919
10	10.664	237.106	0.251	23.075
11	11.185	2276.111	2.411	81.724
12	11.672	644.747	0.683	54.136
13	12.020	2001.797	2.120	61.050
14	13.136	33247.311	35.219	2722.720
15	14.478	21133.489	22.386	1505.522
16	15.364	2258.933	2.393	222.591
17	15.444	1709.195	1.811	238.872
18	15.886	25732.940	27.259	2135.799
19	17.368	187.280	0.198	9.680
20	17.776	288.280	0.305	8.373
总计		94402.894	100.000	7430.482



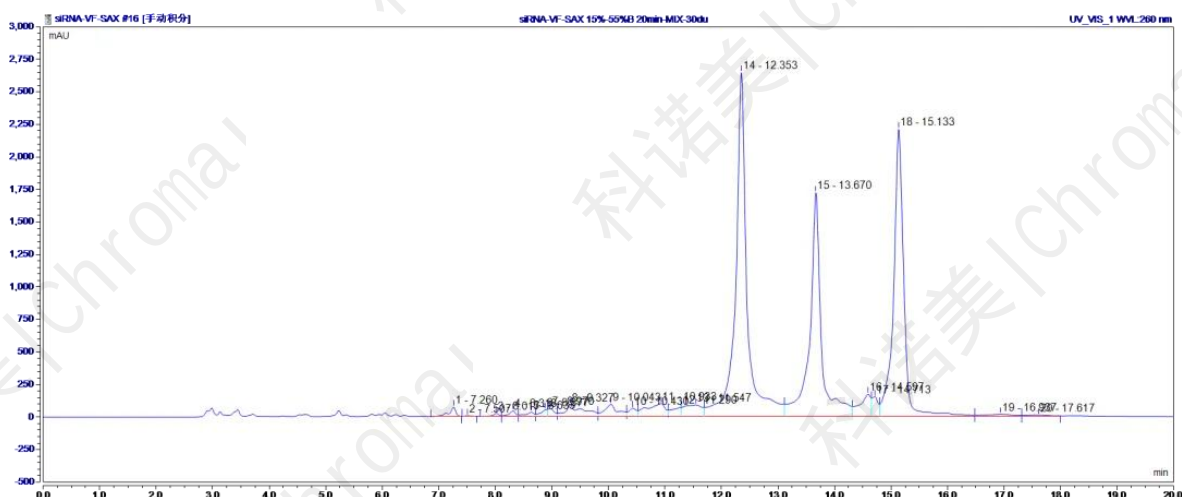


Figure 2 Chromatogram of a mixed sample containing sense and antisense strands of siRNA and impurities – A certain bioinert instrument

Leaps Bio Bioinert Liquid Chromatography System



PEEK&Ti

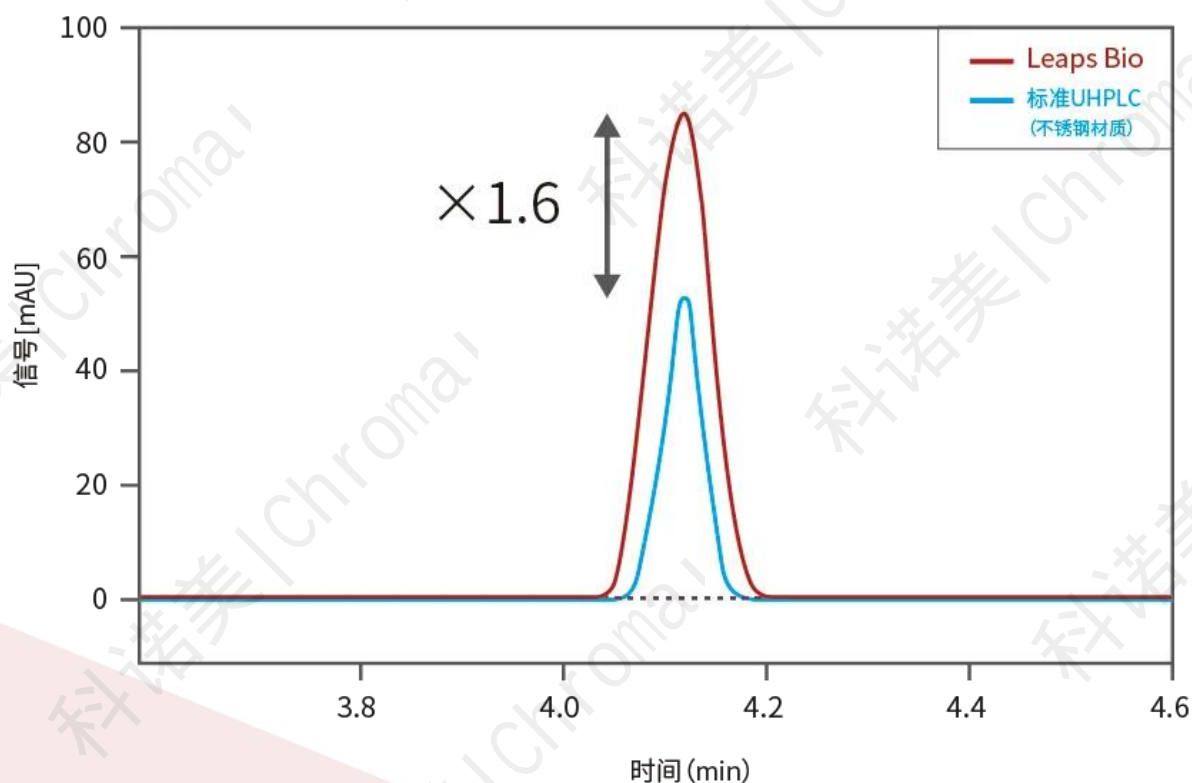
Enabling Efficient Bioanalytical Testing

- Truly bioinert sample flow path
- Corrosion-resistant and anti-adsorption chromatography system
- Suitable for biological and extreme pH applications
- Ensures stable and reliable bioanalytical testing



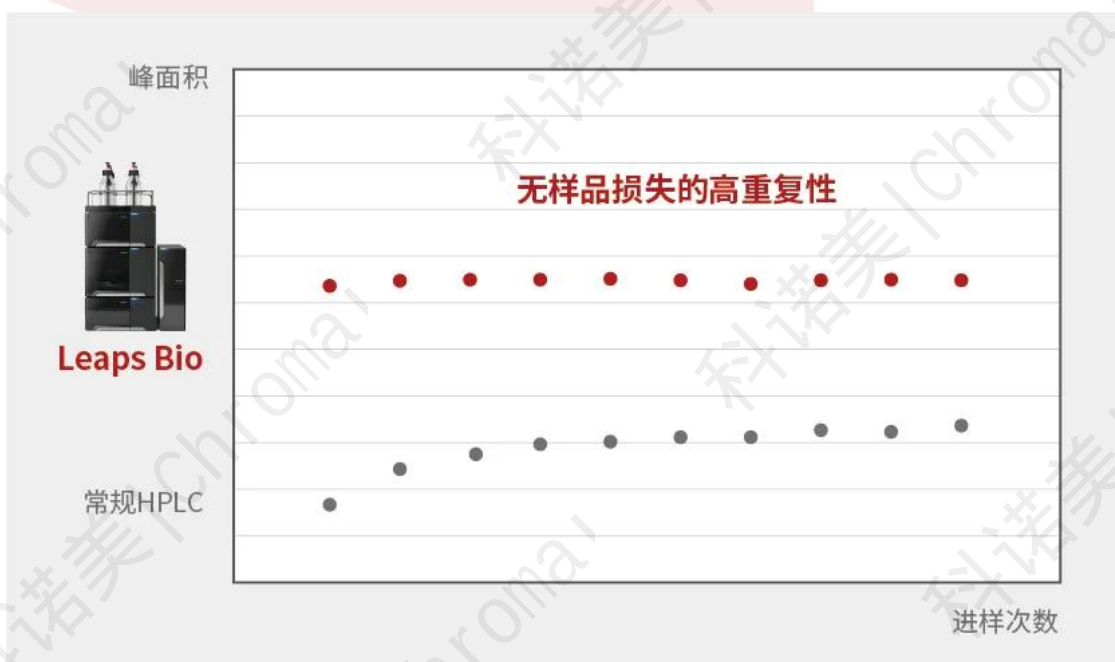
电话: 010-80429960

网址: www.chromai.com



Excellent Bioinert System

- Biocompatible materials such as PEEK and titanium
- Readily applicable to biological and extreme pH conditions
- Minimizes loss caused by metal adsorption



Superior Sample Delivery Experience

- Contact-type high-efficiency integrated cooling system, quickly reaching the set temperature range of 4 °C to room temperature
- Expandable to 4 sample trays, accommodating 216 positions (54×4) or 384 positions (96×4) for higher throughput
- High repeatability with no sample loss

