

# Sepax HPLC Columns Referenced in New USP mRNA Vaccine Quality Guidelines



Photo Credit: USP

The success of the fast, flexible, and effective vaccine development to combat COVID-19 has demonstrated the potential of mRNA technology, and has paved its way as a new therapeutic agent with broad potential for other novel vaccines and therapeutic areas. To address the growing need, USP is developing a set of regulatory guidelines and industry standards of analytical methods to ensure the high quality, safety, and effectiveness of the final product.

**In its newly released *Analytical Procedures for mRNA Vaccine Quality (Draft Guidelines)*, three Sepax HPLC columns were utilized during the study for the characterization and release testing of Product related impurities.**

<p><b>mRNA Drug Substance-</b> Page 29</p> <ul style="list-style-type: none"> <li>● Aggregate quantitation in mRNA</li> <li>● Percentage of mRNA fragment</li> </ul>	<p><i>SRT SEC-1000, 5 <math>\mu</math>m, 1000 <math>\text{Å}</math>, 7.8 <math>\times</math> 300 mm Part Number: 215950-7830</i></p> <p><i>Proteomix RP-1000, 5 <math>\mu</math>m, 1000 <math>\text{Å}</math>, 2.1 <math>\times</math> 100 mm Part Number: 465950-2110</i></p>
<p><b>mRNA Drug Product-</b> Page 39</p> <ul style="list-style-type: none"> <li>● Aggregate quantitation in mRNA extracted from the mRNA-LNP</li> <li>● Percentage of mRNA fragment formed through mRNA:Lipid reactions</li> </ul>	<p><i>Zenix SEC-300, 3 <math>\mu</math>m, 300 <math>\text{Å}</math>, 4.6 <math>\times</math> 150 mm Part Number: 213300-4615</i></p>

Read the Guidelines here

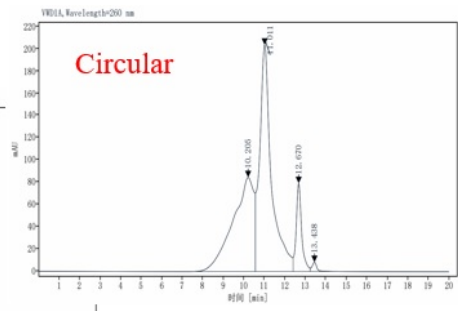
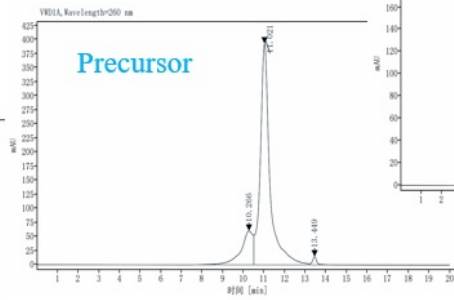
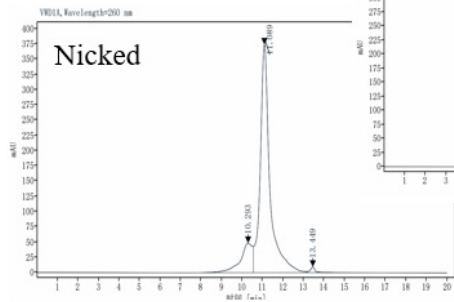
Find the mRNA Application Data PD1007 [here](#).

## ***New Sepax Application Note***

### **Circular RNA Separation by SEC and RP HPLC Methods**

At the same time, due to its fundamental limitations relating to stability and its relatively short half-life, another new promising alternative modality Circular RNA has been emerging to overcome the shortcomings of linear mRNA. Sepax also has developed the SEC and RP analytical HPLC methods to analyze the aggregation and conformations of circRNA.

*SRT SEC-2000, 5  $\mu$ m, 2000  $\text{Å}$ , 7.8  $\times$  300 mm | Part Number: 215980-7830*  
*Bio-C18, 5  $\mu$ m, 300  $\text{Å}$ , 4.6  $\times$  250 mm | Part Number: 106185-4625*



Download the full application note which includes 6 more *Literature Reviews*.

## Application Note SR1002

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