

## Elastomer Stoppers with FluroTec® Film: The Right Choice for SARS-CoV-2 Vaccines

03 September 2020 | Features

**Lack of certainty regarding whether a package system is available, and can accommodate the format needed, creates a risk**



Development and distribution of a vaccine for SARS-CoV-2 presents challenges that are, without hint of exaggeration, unprecedented. One of these challenges concerns storage, namely selection of vial/stopper primary package systems that guarantee quality and safety of the vaccine from manufacture through delivery. This selection is complicated greatly by the accelerated timelines for vaccine approval.

### **Two aspects comprise the challenge in package system selection:**

1. The first concerns the vaccine platform. Six platforms are now considered; they are listed with their proposed vehicles in Table 1. (1) Noteworthy is that two of them (RNA, DNA) are new. Ordinarily, there would be no difficulty in selecting a package system for any of the platforms, since ample time would be available for evaluation of compatibility with both the vaccine and the vehicle. But, for a SARS- CoV-2 vaccine, this is not the case, since approval timelines are accelerated. So, whether the vaccine platform is extant or new, selection of the package system must be made quickly. This creates a risk.
2. The second concerns stability during storage and distribution. A vaccine platform and package system may be identified, but other factors must be considered, such as:
  - ? Form: serum or lyophilized
  - ? Delivery: multi- or single-dose
  - ? Temperature: room (25oC), refrigerated (2-8oC), or low (-80oC)
  - ? Availability of package system components

Lack of certainty regarding whether a package system is available, and can accommodate the format needed, creates a risk.

**Table 1. Potential Vaccines for SARS-CoV-2 (1)**

<b>Vaccine Platform</b>	<b>Chemical Composition</b>	<b>Vehicle</b>	<b>Existing, Licensed Human Vaccine</b>
RNA	nucleotides (ribose groups, amino/amide groups, charged phosphate groups)	encapsulated in lipid in non-polar liquid	No
DNA	nucleotides (ribose groups, amino/amide groups, charged phosphate groups)	aqueous (saline) solution, encapsulated in lipid in non-polar liquid	No
Recombinant Protein	polypeptides (amino acid groups)	aqueous	Yes (baculovirus and yeast expression)
Viral Vector Based	virus shell comprises proteins (i.e., polypeptide: amino acid groups)	aqueous	Yes (vesicular stomatitis virus)
Live Attenuated	virus shell comprises proteins (i.e., polypeptide: amino acid groups)	aqueous	Yes
Inactivated	virus shell comprises proteins (i.e., polypeptide: amino acid groups)	aqueous	Yes

This is discussed in a new report by West scientists: Elastomer Stoppers with FluroTec Film: The Right Choice for SARS-CoV-2 Vaccines. To download the report or learn more about the FluroTec Film, please contact [Shraddha.Sharma@Westpharma.com](mailto:Shraddha.Sharma@Westpharma.com)

1. Amanat, F. and Krammer, F. SARS-CoV-2 Vaccines: Status Report. Immunity, 52, 583-589 (April 14, 2020)

(This article is abstracted from Ranjana Singh, Ph.D., William Garzon-Rodriguez, Ph.D., Peggy Frandolig, Cathy Zhao, Ph.D. and T. Page McAndrew, Ph.D. Elastomer Stoppers with FluroTec Film: The Right Choice for SARS-CoV-2 Vaccines)