

FOR IMMEDIATE RELEASE

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U.S. Pharmacopeia (USP) Offers Support for Developers of COVID-19 Antiviral Drugs and Vaccines

Rockville, MD, March 18, 2020 – The U.S. Pharmacopeia (USP) is providing free technical assistance to developers of medical treatments such as antiviral drugs and vaccines that can support the public health response to the COVID-19 pandemic. USP is making its scientific teams available to help developers ensure the quality of their materials as they scale up manufacturing to bring products into the clinical environment as well as to design tests that ensure quality of materials. USP is extending the support to manufacturers of treatments for secondary implications of the outbreak (e.g. bacterial infections) to help facilitate a greater supply of these critical medicines.

Organizations interested in taking advantage of this resource should contact USP as soon as possible:

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We call on stakeholders to designate a point of contact from their organization with whom we can discuss how we will work as a community with the goal of creating an environment for enhanced information sharing and partnering to facilitate solutions to address the pandemic. USP will work with stakeholders developing viral testing strategies, antiviral therapies, and vaccines, as well as experts from global regulatory bodies and public health agencies (e.g., Centers for Disease Control and Prevention, U.S. Food and Drug Administration, World Health Organization).

USP scientific teams are prepared to assist with solutions in numerous areas. Examples include:

- Best practices that are broadly applicable to manufacturing and testing strategies and are aligned with global regulatory guidelines; includes test methods and procedures (e.g., sterility testing, bacterial contamination control) that can be used to manage regulatory expectations;
- Qualification of excipients and raw materials to be used in manufacturing;
- Our collection of USP Reference Standards which contain materials to demonstrate the suitability of the methods and can also be used for the development and validation of analytical methods;
- Technical assistance to those who are interested in following our processes and use our standards. We are happy to engage in further dialog with stakeholders to ensure

that their approaches to analytical methods can meet compendial and regulatory expectations.

In addition to providing technical assistance, USP is making many of its standards more widely available. [A selection of published standards \(monographs and General Chapters\) are available for free.](#) More details about these resources can be obtained from the contact above.

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About USP

U.S. Pharmacopeia (USP) is an independent, nonprofit, scientific organization that sets quality standards for medicines, dietary supplements and food ingredients worldwide. USP's quality standards are enforceable in the United States by the Food and Drug Administration and integrated into law in more than 40 countries. These standards, which are continuously developed and revised by more than 800 volunteer experts in science, industry, healthcare and academia, are also used in more than 150 countries.

Since its founding in 1820, USP has helped ensure the quality of the American drug supply. Building on its 200-year legacy, USP today works with scientists, practitioners and regulators of many nations to protect and improve global health. From the standards USP creates to the partnerships it fosters, USP continually works to build a world where everyone can trust in the quality of medicine and healthcare. USP has offices in the United States, Asia, Africa, Latin America and Europe, including five state-of-the-art laboratories, full-scale training facilities in Ghana and India, online and in-person training courses and partnerships with national quality control laboratories around the world.

The United States Pharmacopeia–National Formulary (*USP–NF*) includes more than 5,000 monographs for finished drug products (both chemical and biologic), as well as active pharmaceutical ingredients (APIs) and excipients. Specifically, the *USP–NF* includes more than 1,500 API monographs covering 50 therapeutic classes including oncology, cardiovascular, endocrine, infectious disease and mental health drugs. The first printing of the *U.S. Pharmacopeia* was in 1820. Since then, 43 editions have been published. USP published the last printed edition of the *USP–NF* in November 2019. The *USP–NF* is now available to subscribers online and via a mobile app.

For more information, visit www.usp.org