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	ISSUE DATE:	MONTH 00, YYYY	
	IMPLEMENTATION DATE:	MONTH 00, YYYY	
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TITLE : PROCESS – DEVELOPING – AQUEOUS SOLUTION INJECTIONS FOR HOSPITALS – COMPOUNDING PRACTICES

DRAFTED BY:	**SIGNATORY:**			
☐ n/a	**TITLE:**		SIGNATURE	DATE
VERIFIED BY:	**SIGNATORY:**			
☐ n/a	**TITLE:**		SIGNATURE	DATE
APPROVED BY:	**SIGNATORY:**			
	TITLE:	**DESIGNATED PERSON**	SIGNATURE	DATE
APPROVED BY:	**SIGNATORY:**			
☐ n/a	**TITLE:**	**DESIGNATED PERSON**	SIGNATURE	DATE

This SOP contains procedural steps for use against SARS-CoV-2, the novel coronavirus that causes the disease COVID-19.

RELATED LOGS & FORMS

RECORD	SPECIFICATION / DESCRIPTION

RELATED STANDARD OPERATING PROCEDURES

SOP CODE	SOP TITLE

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TITLE : PROCESS – DEVELOPING – AQUEOUS SOLUTION INJECTIONS FOR HOSPITALS – COMPOUNDING PRACTICES

RESPONSIBILITIES

1. Designated Person oversees this SOP.
2. All compounding personnel must comply with this SOP.

PURPOSE

1. To provide *products that are aqueous solutions for injection* to hospitals during the COVID-19 pandemic in accordance with FDA requirements.

SCOPE

1. Applies to all compounding practices.
2. Applies to non-hazardous and hazardous sterile compounding.
3. Applies to the list if drugs used for hospitalized patients with COVID-19 maintained on the FDA's website and contains only one active ingredient.
    a. http://www.fda.gov/media/138279/download

DEFINITIONS

1. Not applicable.

FREQUENCY

1. Comply with this SOP with each Work Order Filled.
2. Recommended to check the FDA website link to the list of permitted active ingredients under the provisions of this FDA policy.

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SPECIAL CIRCUMSTANCE

1. This SOP does not address *products that are aqueous solutions for injection* not listed in on the following FDA website link:
    a. http://www.fda.gov/media/138279/download

PROCEDURE

1. Before filling the Work Order…
    1. Confirm the compounded drug product appears on the FDA website list of drugs used for hospitalized patients with COVID-19 and contains only one of the active ingredients listed.
    2. Ensure the compounded drug is provided directly to the hospital and that…
        a. The hospital is treating patients with COVID-19, and…
        b. The hospital has made reasonable attempts to obtain, and has not been able to obtain:
            i. Adequate supplies of an FDA-approved drug product containing the same active ingredient for the same route of administration, and…
            ii. Adequate supplies of a product made by an outsourcing facility containing the same active ingredient for the same route of administration.
2. Before filling the Work Order…
    1. Establish the beyond-use-date (BUD) for the prepared compounded product in accordance with the following rules and BUD table:
        a. If the literature or other scientific information, including relevant commercially available product labeling for a similar drug (e.g., components, dosage form, route of administration, primary container-closure type) indicates that the drug product is not physicochemically stable for the duration of the BUD period listed in Table 1: Beyond-Use Dating, then…
            i. The pharmacy must use a shorter BUD that is supported by the literature or other scientific information, and…
        b. If the pharmacy is unable to obtain a sufficient supply of the personal protective equipment (PPE) in compliance with the *insanitary condition provision*[1] in the FD&C Act 11 (or PPE that is equivalent or better), then…
            i. The pharmacy must apply BUDs of 24 hours for products stored at room temperature and 3 days for products stored refrigerated.

[1] https://www.fda.gov/drugs/human-drug-compounding/regulatory-policy-information

c. If the conditions of Procedural steps 2.1.a. and 2.1.b can be met, and the requirements of Table 1: Beyond-Use Dating can be met, then the beyond-use dating in Table 1: Beyond-Use Dating can be applied.

Table 1: Beyond-Use Dating

Processing Conditions	Storage Conditions	
	Controlled Room Temperature (20° to 25°C)	**Refrigerator (2° to 8°C)**
▪ Finished drug product is aseptically processed; and ▪ A sterility test has not been completed before release	4 days	6 days
▪ Finished drug product is terminally sterilized; ▪ A verified sterilization cycle that uses biological indicators is employed; and ▪ A sterility test has not been completed before release	10 days	12 days
▪ Finished drug product is aseptically processed or terminally sterilized and has a completed, passing sterility test before release[2]	20 days Suggested with 'Passed' sterility test completed.	22 days Suggested with 'Passed' sterility test completed.

3. Before filling the Work Order…

   a. If the pharmacy and the hospital are not owned and controlled by the same entity, the pharmacy must…

      i. Mark the order with a notation indicating that the drug is provided to the hospital to treat patients during the COVID-19 public health emergency, and…

      ii. Provide the hospital with a tracking document whereby the hospital can identify the patients to whom the drugs were administered.

      iii. Request that the hospital provide, to the extent allowed by applicable laws, the records that identify the patients to whom the drugs were administered, and…

         a. Document such request within one month of sending the compounded drug to the hospital.

[2] The default beyond use dates in this row include the time necessary to complete a sterility test, which may include rapid sterility test methods as well as sterility testing described under US Pharmacopeia (USP) General Chapter <71>.

4. Before filling the Work Order…
    a. The State-licensed pharmacy must notify the following State authorities, and the State authorities must inform the pharmacy that they do not object to the pharmacy providing the drug product to the hospital without first obtaining a patient-specific prescription.
        i. The State authorities include:
            a. The State authority that regulates pharmacy compounding in the State where the pharmacy is located, and…
            b. If different, the State authority that regulates pharmacy compounding in the State where the hospital is located.
    b. The pharmacy acquires State required local requirements.
    c. Products allowed to be compounded, and that are prepared, as aqueous solutions for injection must be identified at…
        i. http://www.fda.gov/media/138279/download
    d. Consider maintaining a record of when the FDA approved the use of a given active ingredient, and then when it was no longer approved under this provision.
        i. Suggested maintaining a record using the table below.
        ii. Maintain these records fully documented for your permanent record.

Table 2: List of Drugs Used for Hospitalized Patients with COVID-19

Products that are aqueous solutions for injection:	Date FDA approved…	Date no longer FDA approved…

    e. Consider storage and approved labelling requirements as per USP standards for comparable FDA-approved products.
        i. Note: Certain syringes and rubber stoppers have been associated with loss of potency in certain products.[3]

[3] https://www.fda.gov/drugs/drug-safety-and-availability/fda-notifies-health-care-professionals-becton-dickinson-replaced-problematic-rubber-stoppers-its.

5. Ensure Adverse Event reporting associated with products prepared under this provision are reported as soon as possible, and no later than 15 days after the receipt of such information.
    a. The FDA MedWatch Reporting Program applies.

https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program

https://www.accessdata.fda.gov/scripts/medwatch/index.cfm

    b. The pharmacy should complete and submit…
        i. Form FDA 3500 for Healthcare Professionals

https://www.fda.gov/media/76299/download

    c. Submit the Form FDA 3500, via fax, to 1-800-FDA-0178.
    d. At a minimum, the following information must be submitted:
        i. Compounder name and contact information
        ii. Patient information (if available).
        iii. Product information (i.e., ingredients, strength, dosage form, lot number, and beyond-use date).
        iv. Description of the Adverse Event.

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VERIFICATION

1. Confirm updated versions to this FDA GFI document on a regular basis and record the date the Work Order is filled.
2. Confirm modifications to the list of drugs used for hospitalized patients with COVID-19 maintained on the FDA's website and contains only one active ingredient.
    b. http://www.fda.gov/media/138279/download

CORRECTIVE ACTIONS

1. Modify the 'Products that are aqueous solutions for injection' list in the SOP with each Work Order filled.

PREVENTIVE ACTIONS

1. Not applicable.

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TECHNOLOGICAL RESOURCES

EQUIPMENT	MANUFACTURER	MAKE	MODEL	SERIAL NUMBER	ID CODE
Medisca Equipment & Devices					

EDUCATIONAL AND SERVICE RESOURCES

AVAILABLE OFFERINGS	
LP3 Network	Medisca Compounding Services
Sterile Training - Home Studies	Medisca Formulation Support
Sterile Training - Live Event	Medisca Specialized Consultations
Self-Directed Learning Modules	Medisca Sterile Designated Person Appraisal
eLearning	

SPECIFICATION DOCUMENTS

DOCUMENT NUMBER	DOCUMENT NAME	SOURCE	DESCRIPTION

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REVISION HISTORY

REVISION NUMBER	IMPLEMENTATION DATE	TERMINATION DATE	SUMMARY OF CHANGE TO CURRENT VERSION

REGULATORY COMPLIANCE GUIDELINES AND STANDARDS OF PRACTICE

REFERENCE SOURCE	REFERENCE CODE	REFERENCE DATE	SECTION CODE	SECTION DESCRIPTION
FDA Guidance for Industry Document		April 2020 Updated May 21, 2020		Temporary Policy for Compounding of Certain Drugs for Hospitalized Patients by Pharmacy Compounders not Registered as Outsourcing Facilities During the COVID-19 Public Health Emergency[4] (Revised)

[4] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/temporary-policy-compounding-certain-drugs-hospitalized-patients-pharmacy-compounders-not-registered