

Status: Currently Official on 16-Feb-2025  
 Official Date: Official as of 01-Aug-2023  
 Document Type: USP Monographs  
 DocId: GUID-F1D32F9F-2CAA-4072-87DB-351A5EDE24C4\_2\_en-US  
 DOI: [https://doi.org/10.31003/USPNF\\_M16595\\_02\\_01](https://doi.org/10.31003/USPNF_M16595_02_01)  
 DOI Ref: dw82c

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**Add the following:**

## ^Morphine Sulfate Compounded Oral Solution

### DEFINITION

Morphine Sulfate Compounded Oral Solution contains NLT 90.0% and NMT 110.0% of the labeled amount of morphine sulfate pentahydrate ( $C_{17}H_{19}NO_3)_2 \cdot H_2SO_4 \cdot 5H_2O$ .

Prepare Morphine Sulfate Compounded Oral Solution, 0.4 mg/mL, as follows<sup>1</sup> (see *Pharmaceutical Compounding—Nonsterile Preparations (795)*).

Morphine Sulfate Oral Solution <sup>a,b</sup>	20 mL
Purified Water, a sufficient quantity to make	100 mL

<sup>a</sup> Morphine Sulfate Oral Solution 2 mg/mL, Roxane Laboratories, Columbus, OH.

<sup>b</sup> Morphine Sulfate, *USP*, is morphine sulfate pentahydrate; therefore no additional calculation is needed to account for the waters of hydration.

Measure *Morphine Sulfate Oral Solution* into a calibrated container. Add a sufficient amount of *Purified Water* to final volume. Shake to mix well.

### ASSAY

- **PROCEDURE**

**Solution A:** A solution of 5.44 g/L of potassium phosphate dibasic in water, adjusted with phosphoric acid to a pH of 5.8. Pass through a polyvinyl difluoride filter of 0.22-μm pore size.

**Mobile phase:** See [Table 1](#).

**Table 1**

Time (min)	Solution A (%)	Acetonitrile (%)
0	100	0
3	100	0
10	95	5
15	78	22
18	40	60
20	100	0
25	100	0

**Standard solution:** 0.1 mg/mL of [USP Morphine Sulfate RS](#) in water. Sonicate for 1 min and shake for 2 min.

**Sample solution:** Vortex the bottle for 1 min, then allow 1 min for bubbles to dissipate. Transfer about 8 mL of solution into a plastic cup.

Transfer 5.0 mL with a class A glass pipette into a 20-mL volumetric flask. Rinse the pipette 2 times using water and transfer the contents into the volumetric flask. Bring to volume with water. Vortex at least for 2 min.

### Chromatographic system

(See [Chromatography \(621\), System Suitability](#).)

**Mode:** LC

**Detector:** UV 284 nm

**Column:** 4.6-mm × 15-cm; 3-μm packing L1

**Temperatures**

**Autosampler:** 10°

**Column:** 35°

**Flow rate:** 1 mL/min

**Injection volume:** 40 μL

#### System suitability

**Sample:** Standard solution

[NOTE—The retention time for morphine sulfate is about 13.5 min.]

#### Suitability requirements

**Tailing factor:** NMT 2.0

**Relative standard deviation:** NMT 2.0% for replicate injections

#### Analysis

**Samples:** Standard solution and Sample solution

Calculate the percentage of the labeled amount of morphine sulfate pentahydrate ( $C_{17}H_{19}NO_3)_2 \cdot H_2SO_4 \cdot 5H_2O$  in the portion of Oral

Solution taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

$r_U$  = peak response of morphine sulfate from the Sample solution

$r_S$  = peak response of morphine sulfate from the Standard solution

$C_S$  = concentration of [USP Morphine Sulfate RS](#) in the Standard solution (mg/mL)

$C_U$  = nominal concentration of morphine sulfate in the Sample solution (mg/mL)

**Acceptance criteria:** 90.0%–110%

#### SPECIFIC TESTS

• [pH \(791\)](#): 2.9–3.9

**Appearance:** Clear, blue solution with no particulates

#### ADDITIONAL REQUIREMENTS

• **PACKAGING AND STORAGE:** Package in tight, light-resistant, plastic containers. Store in a refrigerator or at controlled room temperature.

• **Beyond-Use Date:** NMT 90 days after the date on which it was compounded when stored at controlled room temperature or in a refrigerator.

• **LABELING:** Label to indicate the Beyond-Use Date.

• [USP Reference Standards \(11\)](#).

[USP Morphine Sulfate RS](#)▲ (USP 1-Aug-2023)

<sup>1</sup> This formulation meets the requirements in [Antimicrobial Effectiveness Testing \(51\)](#).

**Auxiliary Information** - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
MORPHINE SULFATE COMPOUNDED ORAL SOLUTION	<a href="#">Selma Mitiche</a> Associate Scientific Liaison	CMP2020 Compounding 2020
REFERENCE STANDARD SUPPORT	RS Technical Services <a href="mailto:RSTECH@usp.org">RSTECH@usp.org</a>	CMP2020 Compounding 2020

**Most Recently Appeared In:**

Pharmacopeial Forum: Volume No. 47(6)

**Current DocID: GUID-F1D32F9F-2CAA-4072-87DB-351A5EDE24C4\_2\_en-US**

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