

Status: Currently Official on 16-Feb-2025
Official Date: Official as of 01-Dec-2016
Document Type: USP Monographs
DocId: GUID-C72675E5-C90B-4CEF-958A-858F3A233E9D_1_en-US
DOI: https://doi.org/10.31003/USPNF_M1397_01_01
DOI Ref: rv4ei

© 2025 USPC
Do not distribute

Metoprolol Tartrate Compounded Oral Suspension

DEFINITION
Metoprolol Tartrate Compounded Oral Suspension contains NLT 90.0% and NMT 110.0% of the labeled amount of metoprolol tartrate $[(C_{15}H_{25}NO_3)_2 \cdot C_4H_6O_6]$.
Prepare Metoprolol Tartrate Compounded Oral Suspension 10 mg/mL as follows (see [Pharmaceutical Compounding—Nonsterile Preparations \(795\)](#)).

Metoprolol Tartrate	1 g
Vehicle: a 1:1 mixture of Vehicle for Oral Solution, (regular or sugar-free), NF, and Vehicle for Oral Suspension, NF, a sufficient quantity to make	100 mL

Place the required number of tablets in a suitable mortar, and comminute to a fine powder, or use *Metoprolol Tartrate* powder. Add the *Vehicle* in small portions, and mix well. Transfer the contents of the mortar, stepwise and quantitatively, to a calibrated bottle. Add the *Vehicle* in portions to rinse the mortar. Add sufficient *Vehicle* to bring to final volume, and mix well.

ASSAY

- PROCEDURE**
Mobile phase: 961 mg of 1-pentanesulfonic acid sodium salt (monohydrate) and 82 mg of anhydrous sodium acetate in a mixture of 550 mL of methanol and 470 mL of water. Add 0.57 mL of glacial acetic acid. Filter, and degas.
Standard solution: 100 µg/mL of [USP Metoprolol Tartrate RS](#)
Sample solution: Agitate the container of Oral Suspension for 30 min on a rotating mixer, remove a 5-mL sample, and store in a clear glass vial at -70° until analyzed. At the time of analysis, remove the sample from the freezer, allow it to reach room temperature, and mix with a vortex mixer for 30 s. Pipet 1.0 mL of the sample to a 100-mL volumetric flask, and dilute with *Mobile phase* to volume.
Chromatographic system
(See [Chromatography \(621\), System Suitability](#).)
Mode: LC
Detector: UV 254 nm
Column: 4.6-mm × 25-cm; 5-µm packing L1
Flow rate: 1.0 mL/min
Injection volume: 20 µL
System suitability
Sample: *Standard solution*
[NOTE—The retention time for metoprolol tartrate is about 7.3 min.]
Suitability requirements
Relative standard deviation: NMT 1.3% for replicate injections

Analysis
Samples: *Standard solution* and *Sample solution*
Calculate the percentage of the labeled amount of metoprolol tartrate $[(C_{15}H_{25}NO_3)_2 \cdot C_4H_6O_6]$ in the portion of Oral Suspension taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_s = concentration of [USP Metoprolol Tartrate RS](#) in the *Standard solution* (µg/mL)

C_u = nominal concentration of metoprolol tartrate in the *Sample solution* (µg/mL)

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

- [pH \(791\)](#): 3.6–4.6

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Package in tight, light-resistant containers. Store at controlled room temperature, or in a refrigerator.
- **BEYOND-USE DATE:** NMT 60 days after the date on which it was compounded when stored at controlled room temperature, or in a refrigerator
- **LABELING:** Label it to state that it is to be well shaken, and to state the *Beyond-Use Date*.
- **USP REFERENCE STANDARDS (11).**
[USP Metoprolol Tartrate RS](#)

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

Topic/Question	Contact	Expert Committee
METOPROLOL TARTRATE COMPOUNDED ORAL SUSPENSION	Brian Serumaga Science Program Manager	CMP2020 Compounding 2020
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	CMP2020 Compounding 2020

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. PF 40(6)

Current DocID: GUID-C72675E5-C90B-4CEF-958A-858F3A233E9D_1_en-US

DOI: https://doi.org/10.31003/USPNF_M1397_01_01

DOI ref: [rv4ei](#)

OFFICIAL