

Status: Currently Official on 15-Feb-2025
Official Date: Official Prior to 2013
Document Type: USP Monographs
DocId: GUID-195A355A-9B18-4A2A-AC2A-9B0F02C9B114_2_en-US
DOI: https://doi.org/10.31003/USPNF_M34880_02_01
DOI Ref: lok0l

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Gentamicin Sulfate Ointment

» Gentamicin Sulfate Ointment contains the equivalent of not less than 90.0 percent and not more than 135.0 percent of the labeled amount of gentamicin.

Packaging and storage—Preserve in collapsible tubes or other tight containers, and avoid exposure to excessive heat.

USP REFERENCE STANDARDS (11).—
[USP Gentamicin Sulfate RS](#)

Identification—Shake a quantity of Ointment, equivalent to about 5 mg of gentamicin, with a mixture of 200 mL of chloroform and 5 mL of water. Allow to separate, and filter the aqueous layer: the filtrate so obtained meets the requirements of the [Identification](#) test under [Gentamicin Injection](#).

MINIMUM FILL (755): meets the requirements.

WATER DETERMINATION, Method I (921): not more than 1.0%, 20 mL of a mixture of toluene and methanol (7:3) being used in place of methanol in the titration vessel.

Assay—Proceed with Ointment as directed under [Antibiotics—Microbial Assays \(81\)](#), using an accurately weighed quantity of Ointment, equivalent to about 1 mg of gentamicin, shaken with about 50 mL of ether in a separator, and extracted with four 20-mL portions of *Buffer B.3*. Combine the aqueous extracts, and dilute quantitatively and stepwise with *Buffer B.3* to obtain a *Test Dilution* having a concentration assumed to be equal to the median dose level of the Standard.

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

Topic/Question	Contact	Expert Committee
GENTAMICIN SULFATE OINTMENT	Ying Han Associate Science & Standards Liaison	BIO42020 Biologics Monographs 4 - Antibiotics

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. Information currently unavailable

Current DocID: [GUID-195A355A-9B18-4A2A-AC2A-9B0F02C9B114_2_en-US](#)
Previous DocID: [GUID-195A355A-9B18-4A2A-AC2A-9B0F02C9B114_1_en-US](#)
DOI: https://doi.org/10.31003/USPNF_M34880_02_01
DOI ref: [lok0l](#)