

Status: Currently Official on 14-Feb-2025
Official Date: Official as of 01-Dec-2024
Document Type: USP Monographs
DocId: GUID-B48D2F1A-EAC1-474C-9FB8-2465CAC7E621_2_en-US
DOI: https://doi.org/10.31003/USPNF_M32590_02_01
DOI Ref: g5bv4

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Factor IX Complex

(This monograph has been updated to the current USP style. No revisions or changes to tests have been made.)

DEFINITION

Factor IX Complex conforms to the regulations of the Food and Drug Administration concerning biologics (see [Biologics \(1041\)](#)). It is a sterile, freeze-dried powder consisting of partially purified Factor IX fraction, as well as concentrated Factors II, VII, and X fractions, of venous plasma obtained from healthy human donors. It contains no preservative. It meets the requirements of the test for potency in having NLT 80% and NMT 120% of the potency stated on the label in Factor IX Units by comparison with the US Factor IX Standard or with a working reference that has been calibrated with it.

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in hermetic containers in a refrigerator.
- **EXPIRATION DATE:** The expiration date is not later than 2 years from the date of manufacture.
- **LABELING:** Label it with a warning that it is to be used within 4 h after constitution, and to state that it is for intravenous administration and that a filter is to be used in the administration equipment.

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

Topic/Question	Contact	Expert Committee
FACTOR IX COMPLEX	Jennifer Tong Sun Senior Scientist II	BIO32020 Biologics Monographs 3 - Complex Biologics and Vaccines

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. Information currently unavailable

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