

COPY No. 2

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

**Title :** Nonoxynol-9 USP  
(Item No. 41022440)

**Spec. No :** SP-AK30-N16

**Reference(s) :** USP 35 p.4071-4073

**Rev. No :** 02

**Other Requirements :** -

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USP 35

Description

: Clear, colorless to light yellow, viscous liquid; odorless.

Solubility

: Soluble in water, in alcohol, and in corn oil.

Identification

: A. By Infrared absorption spectrophotometer

B. The retention time of the major peak in the chromatogram of the Assay preparation corresponds to that in the chromatogram of the Standard preparation as obtained in Assay.

Cloud point (1% solution)

: Between 52°C and 56°C.

Acid value

: Not more than 0.2.

Water

: Not more than 0.5%.

Polychethylene glycol

: Not more than 1.0%.

Free ethylene oxide

: Not more than 1 ppm.

Limit of dioxane

: Not more than 10 µg per g.

Assay

: It contains not less than 90% and not more than 110% of nonoxynol 9.

เอกสารไม่ควบคุม

ใช้ในการจัดซื้อ

Prepared by : จ. นอปปาเดช / 09/03/12 Head of Raw Material Standard Section 2	Reviewed by : อ. สุวณณภพ / 10/03/12 Director of Raw Material Standard Division	Approved by : น. พงษ์ชนน / 12/07/12 Director of Regulatory Compliance and Documentation Division	Eff. Date 09/08/12
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## Product Information

Approved source (s)	Refer to current version of Approved Vendor List of Nonoxynol-9 USP (Item No. 41022440).
Sampling plan	√ N + 1 plan.
Testing procedure	Tests to be performed as per current version of WI-AK30-N16.
Storage condition	Store in tight container(s) at a condition stated on the label from the manufacturer.
Retest period	2 years after first testing date.

เอกสารไม่ควบคุม

ใช้ในการจัดซื้อ

Prepared by : อ. นพ. ปอดเดช / ๐๙/๐๔/๑๒ Head of Raw Material Standard Section 2	Reviewed by : อ. นพ. นพ. ปอดเดช / ๑๐/๐๔/๑๒ Director of Raw Material Standard Division	Approved by : น. พงษ์ ๑๒/๐๔/๑๒ Director of Regulatory Compliance and Documentation Division	Eff. Date 09/08/12
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