

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%.
Polychylene 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.

Prepared by : J. Meppadech / 09/07/12 Head of Raw Material Standard Section 2	Reviewed by : C. Suwamornpim / 10/07/12 Director of Raw Material Standard Division	Approved by : G. R. / 10/07/12 Director of Regulatory Compliance and Documentation Division	Eff. Date R. Tanyavansuk 12/07/2012 Director of Quality Assurance Department 09/08/12
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THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

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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	$\sqrt{N} + 1$ 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.

Prepared by : S. Noppadech / 09/07/12 Head of Raw Material Standard Section 2	Reviewed by : C. Suwananond / 10/07/12 Director of Raw Material Standard Division	Approved by : G. R. / 12/07/12 Director of Regulatory Compliance and Documentation Division	Eff. Date N. Tanchaisri / 12/07/12 Director of Quality Assurance Department 09/08/12
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