

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title : Carbopol 934 [Carbomer 934 USP/NF] (Item No. 41020540)	Spec. No : SP-AK30-C58
Reference(s) : USP36/NF31 p.1924-1925	Rev. No : 04
Other Requirements : GPO Specification	Page : 1/2

USP36/NF31

Description	: White, fluffy powder, having a slight, characteristic odor. Is hygroscopic.
pH	: About 3. (use 1 in 100 dispersion)
Solubility	: When neutralized with alkali hydroxides or with amines, it dissolves in water, in alcohol, and in glycerin.
Identification	: A. To one portion of the Sample dispersion add thymol blue TS, an orange color is produced. To another portion of the Sample dispersion add cresol red TS, a yellow color is produced. [Sample dispersion: 10 mg/mL] B. Adjust the Sample dispersion with 1 N sodium hydroxide to a pH of 7.5, a very viscous gel is produced. [Sample dispersion: 10 mg/mL]
Heavy metals	: Not more than 0.002%.
Limit of benzene	: Not more than 0.5%.
Loss on drying	: Not more than 2.0%, Dry a sample under vacuum at 80°C for 1 hour.
Assay	: It contains not less than 56.0% and not more than 68.0% of carboxylic acid (-COOH) groups, calculated on the dried basis.

GPO Specification

Viscosity	: At 25°C; between 2,050 and 5,450 cps. (Use 0.2% neutralized solution, determined by means of Brookfield Viscometer RVF or RVL series, spindle no.6, for 1 minute, 20 rpm.)
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Prepared by :	Reviewed by :	Approved by :	Eff. Date
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Product Information

Approved source (s)	Refer to current version of Approved Vendor List of Carbopol 934 [Carbomer 934 USP/NF] (Item No. 41020540).
Sampling plan	1 + \sqrt{N} plan.
Testing procedure	Tests to be performed as per current version of WI-AK30-C58.
Storage condition	Preserve in well-closed containers.
Retest period	1 year after first testing date.

Prepared by : J. Rappadey 19/05/14 Head of Raw Material Standard Section 2	Reviewed by : C. Sumanth 20/05/14 Director of Raw Material Standard Division	Approved by : Prapadey 19/06/14 Director of Regulatory Compliance and Documentation Division	Eff. Date 19/06/14
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