



THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title: Carbopol 934 [Carbomer 934 USP/NF]

Spec. No

: SP-AK30-C58

(Item No. 41020540)

Reference(s): USP36/NF31 p.1924-1925

Rev. No

: 04

Other Requirements: GPO Specification

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USP36/NF31

Description

: White, fluffy powder, having a slight, characteristic odor. Is hygroscopic.

pН

: 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.)

Prepared by:	Reviewed by:		Approved by :	Eff. Date
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Head of Raw Material	Director of Raw Material	Director of Regulatory Compliance and	Director of Quality Assurance	
Standard Section 2	Standard Division	Documentation Division	Department	

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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 :	Reviewed by :		Approved by :	Eff. Date
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Standard Section 2	Standard Division	Documentation Division	Department	