

CERTIFICATE OF ANALYSIS

Product:

NU-PVA LY-05P

Chemical Name:

POLYVINYL ALCOHOL, PARTIALLY HYDROLYZED

LOT #:

202507040

Manufacturing Date:

03-Jul-2025

Retest Date:

02-Jul-2030

	SPECIFICATION REV. PVA 5 USIC-4/24	RESULTS
TESTS	Yellowish-white powder or translucent.	Conforms
Appearance (EP)	White to cream-colored granular powder.	Conforms
Appearance (IP)	White to cream-colored granules, or white to cream-colored	Conforms
Appearance (USP)	powder It is adorless	Comornio
Solubility (EP)	Soluble in water, slightly soluble in ethanol, practically insoluble in	Conforms
Solubility (USP)	Freely soluble in water at room temperature. Solution may be effected more rapidly at somewhat higher temperatures.	Conforms
Appearance of Solution	Solution S is clear and not more intensely colored than reference solution Y7.	Conforms
Identification A – Infrared Absorption (EP/IP/USP)	Examine by infrared absorption spectrophotometry comparing the spectrum obtained for sample with the PVA standard spectrum.	Conforms
Identification B (EP/USP)	Meets the requirements in the Viscosity test.	Conforms
Identification C (IP/USP)	A white, turbid, or flocculent precipitate is formed.	Conforms
Water-Insoluble Substances (%) (USP)	NMT 0.1	0.01
Methanol (Methyl Alcohol) (%) (USP)	NMT 1.0	0.16
	NMT 1.0	0.56
Methyl Acetate (%) (USP) Apparent Viscosity (at 20°C) (mPa.s./cps)	43-58	5.0
(EP/IP/USP)		3.13
Loss on Drying (%) (EP/IP/USP)	NMT 5.0	0.12
Sulphated Ash (%w/w) (IP/EP)	NMT 1.0	0.12
Residue on Ignition (%w/w) (USP)	NMT 1.0	<10
Heavy Metals (ppm) (IP)	NMT 10	148
Ester Value (mg KOH/g) (EP/IP)	* 126 – 154 (90 percent to 110 percent of the label value*)	0.9
Acid Value (%) (EP/IP/USP)	NMT 3.0	5.1
pH (solution S) (EP)	4.5 – 6.5	5.1
pH (in a solution 1:25) (IP/USP)	5.0 - 8.0	87.8
Degree of Hydrolysis (%) (USP)	85 - 89	Conforms
Particle Size (%)	Pass through 80 mesh (180 μm) NLT 100	Conforms
	Pass through 100 mesh (150 µm) NLT 99.7	Conforms
	Pass through 120 mesh (125 μm) NLT 97.6	Comornia

^{*}Product label value 140 determined by the Chinese food additive standard.

This product has been manufactured in full compliance with cGMP for excipients and meets all requirements of current USP, EP & IP.

Mirna Grego

VP Quality & Regulatory Issuing Date: 27-Jul-2025

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