

AJINOMOTO DO BRASIL IND. E COM. DE ALIMENTOS L TDA .

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QUALITY ASSURANCE SPECIFICATIONS

Product Name: AJIDEW® A-100

PCPC INCI Name: PCA

Chemical Name: DL-Pyrrolidonecarboxylic Acid

Formula: C₅H₇N₁O₃ **P. Mol.**: 129.1

Validity: 3 years after manufacturing date

Specification

ITEM	LIMIT	TEST
(1) Description	White to colorless crystalline powder, odorless	JSQI [General Notices 27]
(2) Identification		
Infrared Spectrophotometry	Passed test	JSQI *1
Ninhydrin Test	Passed test	JSQI *2
Rotation	Passed test	JSQI *3
(3) Transmittance	NLT 95.0%	1.0g→10mL, 1mol/L NaOH, 430nm
(4) Melting Point	179 ~ 187°C	JSQI [Method-1]
(5) Chloride (Cl)	NMT 0.07%	JSQI [1.0g, Ref.: 0.01mol/L HCl 2.0mL]
(6) Sulfate (SO ₄)	NMT 0.03%	JSQI [1.0g, Ref.: 0.005mol/L H ₂ SO ₄ 0.6mL]
(7) Ammonium (NH ₄)	NMT 0.02%	15g, Atmospheric Distillation Method *4
(8) Heavy Metals (Pb)	NMT 20ppm	JSQI [1.0g, Method-1]
(9) Iron (Fe)	NMT 0.003%	1.0g, o-Phenanthrolin Test *5
(10) Arsenic (As ₂ O ₃)	NMT 2ppm	JSQI [1.0g, Method-1]
(11) Loss on Drying	NMT 0.5%	JSQI [1.0g, 105°C, 3hrs.]
(12) Residue on Ignition	NMT 0.3%	JSQI [2g, Method-1]
(13) Nitrogen Content	10.6 ~ 11.1%	JSQI [0.2g, Method-2]
(14) Content	97.0 ~ 103.0%	*6
(15) Total Viable Counts	NMT 500cfu/g	10g, MF-Method

JSQI: The Japanese Standards of Quasi-Drug Ingredients

Test Method

*1: Infrared Spectrophotometry

Determine the infrared absorption spectrum of 'AJIDEW® A-100', as directed in the potassium bromide disk method under Infrared Spectrophotometry: it exhibits the same maxima at the wave numbers as that of the standard of 'PCA'.

*2: Ninhydrin Test

Transfer about 0.5g of 'AJIDEW® A-100' and 5mL of a solution of sodium hydroxide ($9\rightarrow100$) into a sealed tube, and heat at 180°C for 30minutes. Cool, take out the contents, neutralize with diluted hydrochloric acid ($1\rightarrow5$), add 1mL of ninhydrin TS, and heat for 3minutes: a red-purple color develops.

*3: Rotation

Determine the angle of rotation of a solution of 'AJIDEW® A-100' ($1\rightarrow10$) in a 200mm cell: no optical rotation is observed.

*4: Ammonium (NH₄)

To a flask of a distillation apparatus take accurately 15g of 'AJIDEW® A-100'. Add 4.65g of sodium hydroxide TS and 100mL of water, dissolve them, and then add 3g of magnesium oxide. To the receiver take accurately 20mL of 0.05mol/L sulfuric acid. Immerse the end of the tube connected to the distillation apparatus in the solution. Until 180mL of the distillate is obtained, distill it. Add 3drops of methyl red TS. Titrate with 0.1mol/L sodium hydroxide until the color of the solution changes to yellow.

0.1mol/L sodium hydroxide 1mL=1.804mg NH₄⁺

*5: Iron (Fe)

Dissolve 'AJIDEW® A-100' (1.0 +/- 0.1g) in 10mL of diluted hydrochloric acid in boiling water, add 3mL of hydroxylamine hydrochloride TS and boil for 10minutes. After cooling to room temperature, add 5mL of ophenanthrolin TS and purified water to make 70mL. Add 20mL of sodium acetate TS and purified water to make 100mL. Test solution has no more color than 3ml of iron Standard solution in JSQI

*6: Content

Calculated as follows; Content (%)=9.215 x [Nitrogen Content (%)] (Average MW of AJIDEW® A-100 =129.1)

Please contact AJINOMOTO group, when you have questions about the trademark registration.