

G. AMPHRAY LABORATORIES

E-mail : info@amphray.com

Sambava Chambers, 4th Floor, Sir P. M. Road, Mumbai – 400 001, INDIA.

Web : www.amphray.com

CERTIFICATE OF ANALYSIS

Product	:	POTASSIUM CITRATE BP	Date of Receipt	:	03.03.2008
Batch No.	:	POC – 265/08	Date of Analysis	:	03.03.2008
Date of Manufacture	:	February, 2008.	Sample Size	:	100 Grams
Date of Expiry	:	January, 2013.	Q.C. NO.	:	G-07/1817
Batch Size	:	500 Kgs.			

RESULT OF ANALYSIS

TESTS	RESULTS	LIMITS
Description	A white crystalline powder, hygroscopic.	A white crystalline powder, hygroscopic.
Solubility	Complies.	Very soluble in water, practically insoluble in alcohol.
Identification Test A : Test B :	Complies. Complies.	Gives reactions of Citrate. Gives reaction of Potassium.
Appearance of Solution	Complies.	A 10 % solution in water is clear and colourless.
Acidity & Alkalinity	0.07 ml of 0.1 M HCL	Not more than 0.2 ml of 0.1 M HCL / 0.1 M NaOH
Readily Carbonisable Substances	Complies.	Not more than intensely coloured than reference solution Y2 or GY2.
Chloride	< 50 ppm	Not more than 50 ppm
Oxalate	< 300 ppm	Not more than 300 ppm.
Sulphate	< 150 ppm	Not more than 150 ppm.
Heavy Metals	< 10 ppm	Not more than 10 ppm.
Sodium	< 0.3 %	Not more than 0.3 %
Water	5.48 %	Between 4.0 % to 7.0 %
Assay (On Anhydrous Basis)	99.64 %	Between 99.0 % to 101 % of C ₆ H ₅ K ₃ O ₇ .

ADDITIONAL TESTS :

1) Particle Size on Tyler Machine :-

MESH	% PASSING THROUGH
12	100.00 %
16	96.81 %

2) Bulk Density after 50 Tapped = 1.06 g / ml.

REPORT : THE ABOVE BATCH COMPLIES WITH THE PRESCRIBED STANDARDS OF QUALITY AS PER BP 2008.

Certified True Copy
For G. AMPHRAY LABORATORIES

AUTHORISED SIGNATORY

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Date of Manufacture	:	February, 2008.	Sample Size	:	100 Grams
Date of Expiry	:	January, 2013.	Q.C. NO.	:	G-07/1817
Batch Size	:	500 Kgs.			

RESULT OF ANALYSIS

TESTS	RESULTS	LIMITS
Description	A white crystalline powder, hygroscopic.	A white crystalline powder, hygroscopic.
Solubility	Complies.	Freely soluble in water, almost insoluble in alcohol.
Identification	Complies.	A solution (1 in 10) responds to the tests for potassium and for citrate.
Alkalinity	Complies.	To a solution of 1 gm in 20 ml of 0.1 N H ₂ SO ₄ , no pink colour is produced by the addition of 1 drop of Phenolphthalein TS.
Loss On Drying	5.60 %	Between 3.0 % to 6.0 %.
Tartrate	Complies.	No crystalline precipitate is formed.
Heavy Metals	< 0.001 %	Not more than 0.001 %
Organic Volatile Impurities	In our process we do not use any organic solvent so there is no possibility of any organic volatile impurities being present in the product.	Chloroform : NMT 60 µg / g 1,4 Dioxane : NMT 380 µg / g Methylene Chloride : NMT 600 µg / g Trichloroethylene : NMT 80 µg / g
Assay (On Dried Basis)	99.73 % C ₆ H ₅ K ₃ O ₇	Between 99 % to 100.5 %

ADDITIONAL TESTS :

1) Particle Size on Tyler Machine :-

MESH	% PASSING THROUGH
12	100.00 %
16	98.40 %

2) Bulk Density after 50 Tapped = 1.06 g / ml.

REPORT: THE ABOVE BATCH COMPLIES WITH THE PRESCRIBED STANDARDS OF QUALITY AS PER USP 31.

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AUTHORISED SIGNATORY

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Date of Expiry	:	January, 2013.	Q.C. NO.	:	G-07/1817
Batch Size	:	500 Kgs.			

RESULT OF ANALYSIS

TESTS	RESULTS	LIMITS
Description	A white, granular powder or transparent crystals, hygroscopic.	A white, granular powder or transparent crystals, hygroscopic.
Solubility	Complies.	Very soluble in water.
Identification		
Test A :	Complies.	Gives reactions of Citrate.
Test B :	Complies.	Gives reaction of Potassium.
Appearance of Solution	Complies.	A 10 % solution in water is clear and colourless.
Acidity & Alkalinity	0.07 ml of 0.1 M HCL	Not more than 0.2 ml of 0.1 M HCL / 0.1 M NaOH
Readily Carbonisable Substances	Complies.	Not more than intensely coloured than reference solution Y2 or GY2.
Chloride	< 50 ppm	Not more than 50 ppm
Oxalate	< 300 ppm	Not more than 300 ppm.
Sulphates	< 150 ppm	Not more than 150 ppm.
Heavy Metals	< 10 ppm	Not more than 10 ppm.
Sodium	< 0.3 %	Not more than 0.3 %
Water	5.48 %	Between 4.0 % to 7.0 %
Assay (On Anhydrous Basis)	99.67 %	Between 99.0 % to 101 % of C ₆ H ₅ K ₃ O ₇ .

ADDITIONAL TESTS :

1) Particle Size on Tyler Machine :-

MESH	% PASSING THROUGH
12	100.00 %
16	98.10 %

2) Bulk Density after 50 Tapped = 1.06 g / ml.

REPORT: THE ABOVE BATCH COMPLIES WITH THE PRESCRIBED STANDARDS OF QUALITY AS PER EP-5.

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AUTHORISED SIGNATORY