

CERTIFICATE OF ANALYSIS

Product : **Trisodium Citrate Dihydrate Granular**

E 331

Lot number : **UJ551** Manufacturing date : 12/2015

Date issued : 21/12/2015 Best use before : 12/2018

Date printed : 19/02/2016

CBT Delivery Number : 3722158336 **75220132**
16947525
nI02050025

The Quality Assurance Department certifies that this lot is conform our specifications.

The product meets all requirements of the following compendia, when tested accordingly : USP, FCC, EP and Commission Regulation (EC) N° 231/2012.

Test	Method	Results	Units	CB specifications
<u>Tested methods</u>				
Appearance	visual test	meets specification		colourless crystals or white, granular to fine powder
Odour	odour test *	meets specification		odourless
Water	Karl-Fisher titration	12.29 / 12.49	% H ₂ O	12.15 - 12.50
Identification	EP *	meets specification		meets requirements
Sieving on (50 g, 5 minutes)	sieve test 1190	0.2	%	max 5.0
Sieving through	sieve test 420	1.0	%	max 10.0
Colour	UV/VIS (25% w/v; 366 nm 1cm cell)	97.53	% T	> 92.00
Clarity of solution	Colour *	meets specification		meets requirements
Colour of solution	Colour *	meets specification		meets requirements
Heavy metals (sum: Cd, Cr, Cu, Pb, Hg, Zn, Ni)	ICP *	< 1	ppm	< 1
Arsenic	ICP *	< 1	ppm	< 1
Barium	ICP *	< 5	ppm	< 5
Calcium	ICP *	< 20	ppm	< 20
Chlorides	nephelometry *	< 5	ppm	< 5
Copper	ICP *	< 1	ppm	< 1
Iron	ICP *	< 5	ppm	< 5
Lead	ICP *	< 1	ppm	< 1
Magnesium	ICP *	< 2	ppm	< 2
Mercury	ICP *	< 1	ppm	< 1
Oxalates / oxalic acid	HPLC *	< 10	ppm	< 10
Sulphates	ICP *	< 30	ppm	< 30
Tartrates	HPLC *	< 5	ppm	< 5
Zinc	ICP *	< 1	ppm	< 1
Readily carbonizable substances	EP	meets specification		meets requirements
pH (aqueous solution 5%)	pH potentiometrical analyse	8.22 / 8.45		8.00 - 8.70
Acidity or alkalinity	EP *	meets specification		meets requirements
Extraneous matter	CB test	meets specification		passes CB test
Assay	calculated by water content	99.76 / 99.96	%	99.70 - 100.30

* Results are confirmed by representative testing on finished products.

This lot was analysed and released by our authorized Quality Assurance Department and was found to meet the specifications as given above. This electronically issued and approved certificate is valid without signature.

This report has been generated by C. Vanrijkel