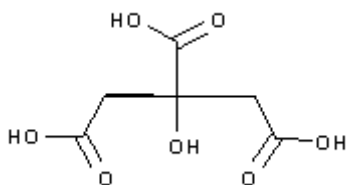
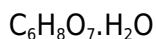


**PRODUCT CODE: 631018****Citric Acid 1-hydrate (Ph. Eur, BP, USP) GMP - IPEC grade**

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M. = 210,14

CAS [5949-29-1]

EINECS 201-069-1

TARIC 2918 14 00 00

**SYNONYMS:** 2-Hydroxy-1,2,3-Propanetricarboxylic Acid**PHYSICAL DATA:** Small crystals, in water at 20°C D 1,542 • M.P.: 135 °C • pH(50g/l)1,8 •**BIBLIOGRAPHY:** Merck Index **13**, 2.350 Safety **2**, **892 D** • Römpp **8**, **879** • Beilstein **3**, **556 IV**, **1272** • BRN 4018641 • ACS **XI** • ISO 6353/2-1983 R - 8, 10 • BP.**2018** • USP **41** • Ph. Eur. **8.0** (2014) **9.0** (2017) • F.C.C **11** • BOE **243**(8-10-2009) • Regulation (EU) n° 231/2012 •**HAZARDOUS:** RTECS: GE 7810000 • LD50 ipr rat 375 mg/kg

H: H319 •

P: P264 • P280 • P305+P351+P338 • P337+P313 •

**SPECIFICATIONS:**Assay (Acidim.) (calc. a.a.s)  
Identity :

99,5-100,5%

Identity according to Pharmacopoeias:

Identity (A Ph. Eur)

Identity (B Ph. Eur / USP)

Identity (C Ph. Eur)

Identity (D Ph. Eur)

Identity (E Ph. Eur)

passes test

IR passes test

passes test

passes test

passes test

### **Maximum limit of impurities**

Appearance of solution

Appearance Clear < formazin I

Appearance Colour

Residue on ignition (as SO<sub>4</sub>)

Sulfate (SO<sub>4</sub>)

Readily carbonisable substances

Residual solvents (Ph.Eur/USP)

Oxalic acid (C<sub>2</sub>H<sub>2</sub>O<sub>4</sub>)

Water (H<sub>2</sub>O)

Heavy metals (as Pb)

**Residual metals ICP: (according to  
EMA/CHMP/SWP/4446/2000)**

**Class 1A (Pt, Pd)**

**Class 1B (Ir, Rh, Ru, Os)**

**Class 1C (Mo, Ni, Cr, V)**

**Class 2 (Cu, Mn)**

**Class 3 (Fe, Zn)**

passes test

< Y7 : < BY7; or GY7

0,1 %

0,0150%

passes test

passes test

0,0360%

7,5-9,0 %

0,0010%

**10 ppm**

**10 ppm**

**25 ppm**

**250 ppm**

**1.300 ppm**

As

0,00015 %

Cd

0,00005 %

Hg

0,00015 %

Pb

0,00005 %