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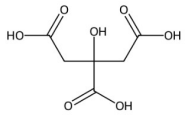
CIN U46909GJ2025PTC164345

CERTIFICATE OF ANALYSIS Standard product specification

Citric Acid Anhydrous Pharma Grade

CAS 77-92-9 · C6H8O7 · IP/BP/USP/EP



STRUCTURAL FORMULA

1. PRODUCT IDENTITY

Product name	Citric Acid Anhydrous Pharma Grade
C.A.S. number	77-92-9
Molecular formula	C6H8O7
Molecular weight	192.12 g/mol
Grade / standard	IP/BP/USP/EP
Description	White crystalline powder
Product group	Buffering Agents
Category	Pharmaceutical Excipients
Country of origin	India
Packing	Bags, drums, carboys, IBC or ISO tank as applicable — customer-specified packing available
Storage	Cool, dry, well-ventilated place in tightly closed original packing

2. ANALYTICAL SPECIFICATION

S. NO.	TEST PARAMETER	SPECIFICATION	TYPICAL RESULT	METHOD
1	Description	White crystalline powder	Complies	Visual
2	Identification (A) — Infrared absorption	Concordant with reference spectrum	Complies	IR Spectrophotometry
3	Identification (B) — Chemical / chromatographic	Positive for the substance	Complies	As per monograph
4	Solubility	As per specification	Complies	Visual / Monograph

5	Assay (on dried basis)	98.0 – 102.0 % w/w	99.70	HPLC / Titrimetry (Monograph)
6	pH (aqueous dispersion)	As per monograph	5.8	Potentiometry
7	Bulk Density	As per specification	0.33 g/mL	USP <616>
8	Tapped Density	As per specification	0.61 g/mL	USP <616>
9	Particle Size (d50)	As per specification	114 µm	Laser diffraction
10	Loss on Drying	Not more than 1.0 % w/w	0.16	Gravimetry (Monograph)
11	Sulphated Ash / Residue on Ignition	Not more than 0.1 % w/w	0.055	Gravimetry (Monograph)
12	Heavy Metals	Not more than 20 ppm	Less than 10 ppm	ICP-OES / Limit test
13	Related Substances — any individual impurity	Not more than 0.10 %	0.025	HPLC
14	Related Substances — total impurities	Not more than 0.50 %	0.122	HPLC
15	Residual Solvents	Complies with ICH Q3C limits	Complies	Headspace GC
16	Total Aerobic Microbial Count	Not more than 1000 cfu/g	97 cfu/g	IP / USP <61>
17	Total Yeast & Mould Count	Not more than 100 cfu/g	6 cfu/g	IP / USP <61>
18	Escherichia coli	Absent in 1 g	Absent	IP / USP <62>
19	Salmonella species	Absent in 10 g	Absent	IP / USP <62>

3. DECLARATION

This document sets out the standard specification for Citric Acid Anhydrous Pharma Grade and applies to all consignments of this product and grade supplied by Scapex Exports Pvt. Ltd. It is not a lot-specific release document; a lot-specific certificate carrying the analysis of the material actually shipped is issued with, and travels with, each consignment. Scapex Exports supplies against customer-specified assay limits and pharmacopoeial standards — send your specification sheet and we confirm compliance in writing before the order is accepted.

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