

PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

ANALYTICAL SPECIFICATION FOR CITRIC ACID MONOHYDRATE IP

Manufacturer Name	:		Supplier Nar	ne :
Manufacturer's Batch No	.:		Manufacture	er's Batch Size :
Manufacturing Date	:		Expiry Date	:
Quantity received	:		Sample Quai	ntity :
Document No.:		Effective Date.:		Change Control No.: N/A
Control No./A.R.No.	:		Retest Date:	

Reference: IP 96 (Page No 193)

Description: Colourless crystals or white crystalline powder; slight efflorescent in Dry air, free from foreign

particles.

Complies/ Does Not Comply

Solubility : Very Soluble in water (1 in 1); freely soluble in ethanol

(95%)(1 in 1-10); sparingly soluble in ether(1 in 30-100).

Complies/Does Not Comply

S.No.	Test	Reference	Result	Specification	Remark
1.	Identification	IP			
	(A) Citrates			(A) A white ppts soluble	
				in 6M acetic acid is	
				produced.	
	(B)				
				(B) Solution is strongly	
				acidic	
2.	Clarity and Colour	IP		Solution is clear	
	of Solution.			opalescence less than	
				OS1 and not more	
				intence coloured than	
				YS7,BYS7 or GYS7.	
3.	Arsenic	IP		Not More Than 1 ppm	
4.	Barium	IP		Shall Comply	
5.	Calcium	IP		Not More Than 200	
				ppm	
6.	Heavy Metals	IP		Not More Than 10 ppm	
7.	Iron	IP		Not More Than 50 ppm	
8.	Chloride	IP		Not More Than 50 ppm	
9.	Sulphate	IP		Not More Than 150	
				ppm	
10.	Oxalic Acid	IP		Any pink colour	



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S.No.	Test	Reference	Result	Specification	Remark
				Produced is Not More	
				Than intense than that	
				produced by using 0.2	
				mg of oxalic acid	
				dissolve in 4 ml of	
				water.	
11.	Readily	IP		Any colour produced is	
	Carbonisable			not more intense than	
	Substances			that of the mixture of	
				1.0 ml of CCS and	
				9.0ml of FCS.	
12.	Sulphated Ash	IP		Not More Than 0.1 %	
13.	Water	IP		Between 7.5 % and	
				9.0 %	
14.	Assay as C ₆ H ₈ O ₇	IP		Not Less Than 99.0 %	
	(On anhydrous			and Not More Than	
	Basis)			101.0 %	

Raw Data Reference:	
Analyst Name :	
Analyst Name :	
Analyst Name :	
Analyst Hard Book No.:	Page No.:
Analyst Hard Book No.:	Page No.:
Analyst Hard Book No.:	Page No.:
Results : Sample Conforms/Does not Cor	nform to specification
Analyzed By:	Date:
Checked By :	
Approved By:	— Date: