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### Plot no. 1116/P, Lamadapura Road, Manjusar – 391 775,

Ta- Savli, Dist. Vadodara, Gujarat, India

Quality Control						
<b>Standard Test Spe</b>	ecifications					

Title: Magnesium Citrate USP Page No.: 1 of 3

 Specification No.:
 Revision No.:
 Effective Date
 Review Date

 ACPL/FP/SP/064
 00
 04/08/2021
 03/08/2024

**Change Control No.** NA

Prepared By: \_\_\_\_\_ Date: 31/07/2021

Name : <u>Pankaj Patel</u>

(QC Officer / Designee)

Reviewed By: \_\_\_\_\_ Date: 02/08/2021

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(Unit Head / Designee)

Approved By: \_\_\_\_\_ Date: 03/08/2021

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(QA/QC In Charge / Designee)

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**Format No.** QC/017/F/01-00

Certified By (Sign/Date):



04/082021

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Ta- Savli, Dist. Vadodara, Gujarat, India

**Quality Control** 

**Standard Test Specifications** 

Title: Magnesium Citrate USP Page No.: 2 of 3

 Specification No.:
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 04/08/2021
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#### 1.0 SAMPLING LEVEL:

As mentioned in the "Sampling procedure" SOP.

#### 2.0 SAMPLING METHOD TO BE FOLLOWED:

100% sampling to be done from each container.

#### 3.0 TOTAL COMPOSITE SAMPLE TO BE COLLECTED:

100 gm

#### **4.0 EXPIRY:**

Five years from the Date of Manufacturing.

**5.0 CAS No:** 3344-18-1

**6.0 MOLECULAR FORMULA:** Mg<sub>3</sub>(C<sub>6</sub>H<sub>5</sub>O<sub>7</sub>)<sub>2</sub>

**7.0 MOLECULAR WEIGHT:** 451.1 gm/mol.

**1.0 CATEGORY:** Excipient.

**2.0 STORAGE:** Preserve in tight containers.

#### 3.0 SAFETY PRECAUTIONS TO BE TAKEN WHILE SAMPLING AND HANDLING:

Use hand gloves, goggles and apron during Handling.

**4.0 CONTROL SAMPLE:** 3 X 100gm.

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**Quality Control** 

**Standard Test Specifications** 

**Title: Magnesium Citrate USP Page No.:** 3 of 3

**Specification No.: Revision No.: Effective Date Review Date** ACPL/FP/SP/064 04/08/2021 03/08/2024 00

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### TEST PARAMETERS AND SPECIFICATIONS

**REF: USP** 

Sr. No.	TEST PARAMETER	SPECIFICATION	
1.	Appearance	White or almost white, fine, slightly hygroscopic powder.	
2.	Solubility	Soluble in water practically insoluble in ethanol (96 %).	
3.	Identification A Test for magnesium. Identification B Test for citrates.	To Pass test  To Pass test	
4.	Assay % (Dried substance)	14.5 % – 16.4 %	
5.	Chloride	Max. 500 ppm	
6.	Sulfate	Max. 280 ppm	
7.	Arsenic	Max. 3 ppm	
8.	Iron	Max. 200 ppm	
9.	Calcium	Max. 1.0 % on the dried basis	
10.	рН	5.0–9.0, in a suspension	
11.	Loss on drying	Max. 2.0 %	

#### **REVISION HISTORY:**

Revision No.	Effective Date	Revision Description	Change Control No.
00	04/08/2021	First Issuance	N A

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