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

Ta- Savli, Dist. Vadodara, Gujarat, India

Quality Control

Standard	Test	Specifica	tions

Title: Magnesium Citrate BP 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

Name : Nilesh Shah (Unit Head / Designee)

Approved By: _____ Date: 03/08/2021

Name : <u>Naresh Solanki</u>

(QA/QC In Charge / Designee)

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

Certified By (Sign/Date):



04/08/2021

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

Ta- Savli, Dist. Vadodara, Gujarat, India

Quality Control

Standard Test Specifications

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

Specification No.:Revision No.:Effective DateReview DateACPL/FP/SP/0640004/08/202103/08/2024

Change Control No. NA

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: Mg₃(C₆H₅O₇)₂

7.0 MOLECULAR WEIGHT: 451.1 gm/mol.

1.0 CATEGORY: Excipient.

2.0 STORAGE: In a non-metallic, airtight container.

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 BP Page No.: 3 of 3

 Specification No.:
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TEST PARAMETERS AND SPECIFICATIONS

REF: BP

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 %). It dissolves in dilute hydrochloric acid		
3.	Identification A	To Pass test		
	It gives the reaction of citrates.			
	Identification B	To Pass test		
	It gives the reaction of magnesium.			
	Identification C	To Pass test		
	pH (see Tests).			
	Identification D	To Pass test		
	Loss on drying (see Tests).			
4.	Appearance of solution	Solution S is not more opalescent than reference suspension III and not more intensely coloured than reference solutions Y7 or BY6.		
5.	рН	6.0 to 8.5		
6.	Oxalates	Max. 280 ppm		
7.	Sulfates	Max. 0.2 %		
8.	Calcium	Max. 0.2 %		
9.	Iron	Max. 100 ppm		
10.	Loss on drying (180 \pm 10°C for 5 h.)	Max. 3.5 %		
11.	Assay % (Dried substance)	15.0 % to 16.5 %		

REVISION HISTORY:

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

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

Certified By (Sign/Date):



04/08/2021