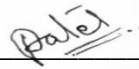

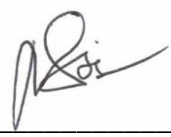


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Manjusar – 391 775,
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Quality Control**Standard Test Specifications****Title: Magnesium Citrate EP****Page No.: 1 of 3****Specification No.:**
ACPL/FP/SP/064**Revision No.:**
00**Effective Date**
04/08/2021**Review Date**
03/08/2024**Change Control No.**

NA

Prepared By: Date: 31/07/2021Name : Pankaj Patel
(QC Officer / Designee)Reviewed By: Date: 02/08/2021Name : Nilesh Shah
(Unit Head / Designee)Approved By: Date: 03/08/2021Name : Naresh Solanki
(QA/QC In Charge / Designee)**UNCONTROLLED COPY****Format No. QC/017/F/01-00****Certified By (Sign/Date) :**  04/08/2021

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Quality Control**Standard Test Specifications****Title: Magnesium Citrate EP****Page No.: 2 of 3****Specification No.:**
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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:** $Mg_3(C_6H_5O_7)_2$ **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.**UNCONTROLLED COPY****Format No.** QC/017/F/01-00**Certified By (Sign/Date) :**

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Quality Control**Standard Test Specifications****Title: Magnesium Citrate EP****Page No.: 3 of 3****Specification No.:**
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TEST PARAMETERS AND SPECIFICATIONS**REF: EP**

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 It gives the reaction of citrates. Identification B It gives the reaction of magnesium. Identification C pH (see Tests). Identification D Loss on drying (see Tests).	To Pass test To Pass test To Pass test To Pass test
4.	Appearance of solution	Solution S is not more opalescent than reference suspension III and not more intensely colored than reference solutions Y7 or BY6.
5.	pH	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 ± 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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