

MASTER COPY



Plot no. 1116/P, Lamadapura Road,
Manjusar – 391 775,
Ta- Savli, Dist. Vadodara, Gujarat, India

Quality Control

Standard Test Specifications

Title: EDTA Di Sodium Salt LR

Page No.: 1 of 3

Specification No.:
ACPL/FP/SP/054


Revision No.:
00

Effective Date
29/07/2021

Review Date
28/07/2024


Change Control No.

NA

Prepared By: 

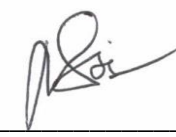
Date: 26/07/2021

Name : Pankaj Patel
(QC Officer / Designee)

Reviewed By: 

Date: 27/07/2021

Name : Nilesh Shah
(Unit Head / Designee)

Approved By: 

Date: 28/07/2021

Name : Naresh Solanki
(QA/QC In Charge / Designee)

UNCONTROLLED COPY

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

Certified By (Sign/Date) :  29/07/2021

MASTER COPY

Plot no. 1116/P, Lamadapura Road,
Manjusar – 391 775,
Ta- Savli, Dist. Vadodara, Gujarat, India

Quality Control**Standard Test Specifications****Title: EDTA Di Sodium Salt LR****Page No.: 2 of 3****Specification No.:**
ACPL/FP/SP/054**Revision No.:**
00**Effective Date**
29/07/2021**Review Date**
28/07/2024**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 RETEST DATE: Two year**5.0 CAS No:** 6381-92-6**6.0 MOLECULAR FORMULA:** $C_{10}H_{14}N_2Na_2O_8 \cdot 2H_2O$.**7.0 MOLECULAR WEIGHT:** 372.2 gm/mol.**8.0 CATEGORY:** Pharmaceutical aid; chelating agent in metal poisoning.**9.0 STORAGE:** Protected from light.**10.0 SAFETY PRECAUTIONS TO BE TAKEN WHILE SAMPLING AND HANDLING :**

Use hand gloves, goggles and apron during Handling.

11.0 CONTROL SAMPLE: 3 X 100 gm.**UNCONTROLLED COPY****Format No.** QC/017/F/01-00**Certified By (Sign/Date) :**

29/07/2021

MASTER COPY

Plot no. 1116/P, Lamadapura Road,
Manjusar – 391 775,
Ta- Savli, Dist. Vadodara, Gujarat, India

Quality Control**Standard Test Specifications****Title: EDTA Di Sodium Salt LR****Page No.:** 3 of 3**Specification No.:**
ACPL/FP/SP/054**Revision No.:**
00**Effective Date**
29/07/2021**Review Date**
28/07/2024**Change Control No.**

NA

TEST PARAMETERS AND SPECIFICATIONS**REF: LR**

Sr. No.	TEST PARAMETER	SPECIFICATION
1.	Description	White or almost white, crystalline powder.
2.	Solubility	Soluble in water, practically insoluble in ethanol (96 %)
3.	pH (5% aqueous solution)	4.3 – 5.0
4.	Chloride (Cl)	Max. 300 ppm
5.	Sulphate (SO ₄)	Max. 100 ppm
6.	Copper (Cu)	Max. 2.5 ppm
7.	Iron (Fe)	Max. 5 ppm
8.	Heavy Metals (as Pb)	Max. 10 ppm
9.	Assay %	Min. 99.0%

REVISION HISTORY:

Revision No.	Effective Date	Revision Description	Change Control No.
00	29/07/2021	First Issuance	NA

UNCONTROLLED COPY**Format No.** QC/017/F/01-00**Certified By (Sign/Date) :**  29/07/2021