PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

ANALYTICAL SPECIFICATION FOR DISODIUM EDETATE IP

Manufacturer Name :		**Supplier Name :**
Manufacturer's Batch No. :		**Manufacturer's Batch Size :**
Manufacturing Date :		**Expiry Date :**
Quantity Received :		**Test Quantity :**
Document No. :	**Effective Date :**	**Change Control No. : N/A**
Control No./ A.R. No. :		**Retest Date :**

Reference : IP 96 (Page No 266)

Description : White crystalline powder; odourless; free from foreign particles
Complies/Does Not Comply.

Solubility : Soluble in water(1 in 10-30);sparingly soluble in ethanol (95%) (1 in 30-100), practically insoluble in chloroform and in ether(More than10,000)
Complies/Does Not Comply.

S.No.	Test	Reference	Result	Specification	Remark
1.	Identification (IP) (A) IR (B) Identification (IP) C) D)Reaction of sodium salts:	IP		A) IR absorption spectrum.of test concordant with reference spectrum of Disodium edetate working standard. B) No precipitate is produced. C) No precipitate is produced. D)Reaction of sodium salts Test A A dense ,white precipitate is formed. Test B A yellow,crystalline precipitate is formed.	
2.	pH – 5 % w/v Solution	IP		Between 4.0 and 5.0	
3.	Clarity and	IP		Solution is clear and	

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S.No.	Test	Reference	Result	Specification	Remark
	Colour of solution			colourless.	
4.	Heavy Metals	IP		Not More Than 20 ppm	
5.	Iron	IP		Not More Than 80 ppm	
6.	Assay as $C_{10}H_{14}N_2Na_2O_8,2H_20$	IP		Not Less Than 98.5 % and Not More Than 101.0 %	

Raw Data Reference :

Analyst Name :

Analyst Name :

Analyst Name :

Analyst Note Book No. : **Page No. :**

Analyst Note Book No. : **Page No. :**

Analyst Note Book No. : **Page No. :**

Results :

Analyzed By : _____ **Date :** _____

Checked By : _____ **Date :** _____

Approved By : _____ **Date :** _____