



**EMIL  
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AN ISO 9001:2008 Certified Company

## PACK PRODUCT ANALYTICAL REPORT

Product Name : ENHORA 50

Batch No : EJ8B001 B

Generic Name : Sildenafil Tablet 50 mg

Code No: MH/DRUGS/ KD-669-A

Buyer Order No. & Date : 5349 DTD 22-02-2018

Batch Size: 1,50,000 Tablets	Pack Size: 2 x 5's	Q.C. Report No.: M/18-T418-002
Sample Size: 20 x 5's	Mfg Date: 02/18	Exp. Date: 01/21
Shelf Life: 36 Months	Date of Sampling: 05/03/2018	Sampled by: Ms. Supriya
Analysis Date: 05/03/2018	Analyst: Mr. Prashil	Report Date: 14/03/2018

### Test

### Specification

### Result

Release Specification :				
Description	Light blue coloured diamond shaped film coated tablets.		Light blue coloured diamond shaped film coated tablets.	
Identification	The retention time of the principal peak for sample solution as obtained in the "Assay" test by liquid chromatography corresponds to the principal peak for Sildenafil citrate working standard.		The retention time of the principal peak for sample solution as obtained in the "Assay" test by liquid chromatography corresponds to the principal peak for Sildenafil citrate working standard.	
Average Weight	293.55 mg to 324.45 mg		307.0 mg	
Uniformity of weight	± 5% of Average Weight		Complies	
Disintegration Time	N.M.T 30.0 mins		4 Mins	
Dissolution	N.L.T. 70.0%		1] 98%    2] 96%    3] 96% 4] 95%    5] 95%    6] 93%	
Related Substances by HPLC				
3. Single Impurity	N.M.T. 1.0%		0.16%	
4. Total Impurity	N.M.T. 2.0%		0.16%	
Uniformity Content	Acceptance value : NMT 15.0 when determined on 10 individual units		2.9	
Assay	Label Claim	Limits (%)	Results (mg/Tab.)	% of Label Claim
Sildenafil Citrate equivalent to Sildenafil	50 mg	90.00% to 110.00%	50.37 mg	100.7%

### Quality Specification :

Weight of 20 Tablets	5.871 gm to 6.489 gm	6.148 gm
Thickness	4.50 mm to 4.90 mm	4.79 mm

### MICROBIAL LIMIT TEST :

#### Total aerobic microbial count :

Bacterial Count	N.M.T. 1000 cfu/gm	35 cfu/gm
Fungi	N.M.T. 100 cfu/gm	None detected

#### Test for specified microorganisms

Escherichia coli	Absent in 1 gm	Absent in 1 gm
Salmonella	Absent in 10 gm	Absent in 10 gm
Pseudomonas	Absent in 1 gm	Absent in 1 gm
Staphylococcus Aureus	Absent in 1 gm	Absent in 1 gm

**OPINION:** The sample **Complies** as per Standard specification.

The above batch is released for distribution.

*Prashil*

Analysed by :

Mr. Prashil

QC Officer

Date : 14/03/2018

*Anil*

Checked by :

Mr. Anil Deshmukh

QC Manager

Date : 14/03/2018



*S.M. Daptardar*

Approved by :

Mr. S.M. Daptardar

QA Manager

Date : 14/03/2018