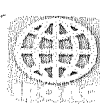




**EMIL  
PHARMACEUTICAL  
INDUSTRIES PVT. LTD.**

Reg office: 101  
Mangalam, Kurlupwadi,  
Borivali East, Mumbai  
400066, INDIA.  
Tel: +91-22-42090200  
Email: info@emilpharma.in



An ISO 9001:2008 Certified Company

## PACK PRODUCT ANALYTICAL REPORT

Product Name : ENHORA 50

Generic Name : Sildenafil Tablet 50 mg

Buyer Order No. & Date : 4901 DTD 20-03-2017

Batch No : EJ7E002

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

Batch Size: 3,00,000 Tablets	Pack Size: 2 x 5's	Q.C. Report No.: M/17-T418-002
Sample Size: 20 x 5's	Mfg Date: May-2017	Exp. Date: Apr-2020
Shelf Life: 36 Months	Date of Sampling: 14/06/2017	Sampled by: Ms. Preeti
Analysis Date: 15/06/2017	Analyst: Mr. Prashil	Report Date: 21/06/2017

Report Date: 21/06/2017

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	314.0 mg		
Uniformity of weight	± 5% of Average Weight	Complies		
Disintegration Time	N.M.T 30.0 mins	6 Mins		
Dissolution	N.L.T. 70.0%	1) 98.85% 2) 99.39% 3) 97.63% 4) 97.90% 5) 97.76% 6) 98.55%		
Related Substances by HPLC 3. Single Impurity 4. Total Impurity	N.M.T. 1.0% N.M.T. 2.0%	0.20% 0.22%		
Uniformity Content	Acceptance value : NMT 15.0 when determined on 10 individual units	1.1		
Assay	Label Claim	Limits (%)	Results (mg/Tab.)	% of Label Claim
Sildenafil Citrate equivalent to Sildenafil	50 mg	90.00% to 110.00%	49.19 mg	98.39%
Quality Specification :				
Weight of 20 Tablets	5.871 gm to 6.489 gm	6.275 gm		
Thickness	4.50 mm to 4.90 mm	4.62 mm		

### MICROBIAL LIMIT TEST :

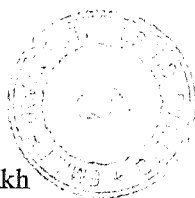
<b>Total aerobic microbial count :</b>		
Bacterial Count	N.M.T. 1000 cfu/gm	60 cfu/gm
Fungi	N.M.T. 100 cfu/gm	None detected
<b>Test for specified microorganisms</b>		
Escherichia coli	Absent in 1 gm	Absent in 1 gm
Salmonella	Absent in 10 gm	Absent in 10 gm
Pseudomonas	Absent in 1 gm	Absent in 1 gm
Staphylococcus Aureus	Absent in 1 gm	Absent in 1 gm

**OPINION:** The sample **Complies** as per Standard specification No.STP-FP-T142-S02.

The above batch is released for distribution.

Prashil  
Analysed by :  
Mr.Prashil  
QC Executive  
Date : 21/6/2017

Anil  
Checked By :  
Mr. Anil Deshmukh  
QC Manager  
Date : 21-6-17



S.M.Daptardar  
Approved by :  
Mr. S.M.Daptardar  
QA Manager  
Date : 21/6/2017