



# HAB PHARMACEUTICALS & RESEARCH LIMITED

Unit No. 16 to 19, Dewan & Shah Ind. Complex No.1B, Waliv Phata,  
Sativali Road, Vasai (E), 401208, Thane, Maharashtra

## QUALITY CONTROL DEPARTMENT

### CERTIFICATE OF ANALYSIS

**Product : VITARA-V 40 TABLETS**

**Generic Name : Vardenafil Hydrochloride Trihydrate Tablets**

<b>Batch No.</b>	: 224-32	<b>A.R. No.</b>	: F/58.07.2022
<b>Batch Size</b>	: 2,02,000 Tablets	<b>A.R. Date</b>	: 27.07.2022
<b>Mfg. Date</b>	: July, 2022	<b>Sampling Date</b>	: 27.07.2022
<b>Exp. Date</b>	: June, 2025	<b>Sampled Qty.</b>	: 100 Tablets

#### COMPOSITION:

Each film coated tablet contains:

Vardenafil Hydrochloride Trihydrate

Equivalent to Vardenafil 40 mg

Excipients..... q. s.

Colour: Approved colour used.

SR. NO.	TESTS	SPECIFICATIONS	OBSERVATIONS
1	<b>Description</b>	Light buff yellow coloured, circular, biconvex, filmcoated tablets a having break- line on one side & another side plain of each tablet.	Light buff yellow coloured, circular, biconvex, filmcoated tablets a having break- line on one side & another side plain of each tablet.
2	<b>Identification :</b> (By UV) Vardenafil	The sample solution complies with the absorbance obtained from Vardenafil working standard solution at the time of assay.	Complies
3	Weight of 20 tablets	4.164 gm $\pm$ 5%	4.156 gm
4	Average weight	208.2 mg $\pm$ 5%	207.8 mg
5	<b>Uniformity of weight</b>	$\pm$ 7.5% of the Average Weight	Complies
6	<b>Physical Parameters:</b>		
	Thickness	3.20 mm $\pm$ 0.2 mm	3.19 mm to 3.29 mm
7	<b>Disintegration</b>	Not more than 30 minutes	3 mins. 23 secs. to 4 mins. 29 secs.
8	<b>Assay:</b>		
	Each film coated tablet contains: Vardenafil Hydrochloride Trihydrate Equivalent to Vardenafil 40 mg	90.0 % to 110.0 % of the Labeled Amount (36.0 mg to 44.0 mg)	99.52 % 39.81 mg

**REMARKS:** The sample referred above Complies/~~Does not Comply~~ as per **IH** Specifications and of standards quality.

	ANALYSED BY	CHECKED BY	APPROVED BY
<b>SIGNATURE</b>			
<b>DATE</b>	27.07.22	27.07.2022	27.07.2022
<b>DESIGNATION</b>	QC CHEMIST	Sr. QC EXECUTIVE	QC MANAGER
<b>NAME</b>	Mrs. Nandini Sheth	Mrs. Poonam Shukla	Mr. Ashish Tiwari