



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 60TABLETS

Generic Name : Vardenafil Hydrochloride Trihydrate Tablets 60mg

Batch No.	:	224-33	A.R. No.	:	F/12.11.2022
Batch Size	:	1,02,000 Tablets	A.R. Date	:	05.11.2022
Mfg. Date	:	November, 2022	Sampling Date	:	04.11.2022
Exp. Date	:	October, 2025	Sampled Qty.	:	100 Tablets

COMPOSITION:

Each film coated tablet contains:

Vardenafil Hydrochloride Trihydrate

Equivalent to Vardenafil 60 mg

Excipients..... q. s.

Colour: Approved colour used.

SR. NO.	TESTS	SPECIFICATIONS	OBSERVATIONS
1	Description	Light Buff Yellow coloured, circular, biconvex, film coated tablet having a break-line on one side & another side plain of each tablet.	Light Buff Yellow coloured, circular, biconvex, film coated tablet having a break-line on one side & another side plain of each tablet.
2	Identification :		
	(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	4.157g $\pm$ 3 %	4.170 g
4	Average weight	207.874 mg $\pm$ 3 %	208.5mg
5	Uniformity of weight	$\pm$ 7.5% of the Average Weight	Complies
6	Physical Parameters:		
	Thickness	3.20 mm $\pm$ 0.2 mm	3.20 mm to 3.26 mm
7	Disintegration	Not more than 30 minutes	6 mins. 31 secs. to 7mins. 28secs.
8	Assay:		
	Each film coated tablet contains: Vardenafil Hydrochloride Trihydrate Equivalent to Vardenafil 60 mg	90.0 % to 110.0 % of the Labeled Amount (54.0 mg to 66.0 mg)	97.83 % 58.70 mg

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

	ANALYSED BY	CHECKED BY	APPROVED BY
SIGNATURE			
DATE	05.11.2022	05.11.2022	05.11.2022
DESIGNATION	QC CHEMIST	Sr. QC EXECUTIVE	QC MANAGER
NAME	Mr. Himanshu Pandey	Mr. Poonam Shukla	Mr. Ashish Tiwari