



### CERTIFICATE OF ANALYSIS

Product Name : **HEPCITAJ - V TABLETS** Mfg. Licence No. : G/25A/4669-A  
 Generic Name : Sofosbuvir 400 mg and Velpatasvir 100 mg TABLETS Date of Receipt : 27/11/2018  
 Batch Number : 181112 Sample Quantity : 1 X 28 Tab Jar  
 Mfg. Date : 11/2018 Exp.Date : 10/2020  
 Manufactured at : 257, G.I.D.C. Phase-1, Modhera Road, Mehsana, Gujarat, India

Sr. No.	TEST	SPECIFICATION	RESULT
1.	Description	Pink coloured, DS shaped, with breakline on one side and another side plain film coated tablet .	Pink coloured, DS shaped, with breakline on one side and another side plain film coated tablet .
2.	Identification	The retention time of the major peak of the sample solution should correspond to that of the standard solution, as obtained in the assay.	The retention time of the major peak of the sample solution correspond to that of the standard solution, as obtained in the assay.
3.	Avg. Wt. of Tablets	1020 mg $\pm$ 5 %	1019.93 mg
4.	Uniformity of weight	$\pm$ 5%of average weight	1. 1019.6 mg 2. 1015.7 mg 3. 1024.9 mg 4. 1053.8 mg 5. 1019.2 mg 6. 1000.0 mg 7. 998.5 mg 8. 1015.5 mg 9. 1032.4 mg 10. 1020.0 mg 11.1012.7 mg 12. 1018.2 mg 13. 1045.1 mg 14.1006.8 mg 15. 1021.3 mg 16. 1019.5 mg 17.1032.7 mg 18. 999.4 mg 19. 1001.9 mg 20.1041.4 mg
5.	Disintegration time	NMT 30 Minutes	40 second
6.	Assay by HPLC Each film coated tablet contains: Sofosbuvir 400 mg Velpatasvir 100 mg	NLT 90.0 % and NMT 110.0 %	Sofosbuvir 98.66 % Velpatasvir 99.84 %
7.	Additional tests		
	Length	20.00mm $\pm$ 0.2 mm	20.17 mm
	Thickness	6.50mm $\pm$ 0.3 mm	6.52 mm
	width	9.00mm $\pm$ 0.2 mm	9.18 mm
8.	Microbiological Tests Total Aerobic Microbial Count Total Yeast & Mold Count <i>E.coli</i> <i>Salmonella</i> spp.	NMT 1000 cfu/gm NMT 100 cfu/gm Should be absent Should be absent	20 cfu/gm <10 cfu/gm Absent Absent

The sample is approved/~~not approved~~ as per Specification. CS No. CAS/FP/11301

Control No. CFP/0057

Date: 05<sup>th</sup> December 2018

**For, Taj Pharmaceuticals Limited**

Ankita

Prepared by

LS

Checked by

SP

Approved by