



# HETERO LABS LIMITED (UNIT-II)

## (Formulations Division)

### CERTIFICATE OF ANALYSIS

Product Name: TAFFIC (Bictegravir 50mg, Emtricitabine 200mg and Tenofovir Alafenamide 25mg Tablets)			
Product Code	4023167	A.R. No.	H5FP23003959
Specification ID	FPS/B-3010509-1-03	Batch No.	HH2309428
Mfg. Date	09/2023	Batch Size	600000 Tablets
Exp. Date	08/2025	Date Of Release	30-10-2023

S. No.	TEST	RESULT	SPECIFICATION
1	Description	White colored, capsule shaped, film coated tablets debossed with "B44" on one side and "H" on the other side.	White to off white colored, capsule shaped, film coated tablets debossed with "B44" on one side and "H" on the other side.
2	Identification (By HPLC)	The retention time of the major peaks in the chromatogram of the sample solution corresponds to that in the chromatogram of the standard solution, as obtained in the assay.	The retention time of the major peaks in the chromatogram of the sample solution should correspond to that in the chromatogram of the standard solution, as obtained in the assay.
3	Average weight	740.99 mg	721.00mg $\pm$ 3% (699.37mg to 742.63mg)
4	Uniformity of weight	Highest : 1.73 % Lowest: -0.97 %	$\pm$ 5% of Average weight.
5	Water content (By KF)	3.63 % w/w	Not more than 6.0% w/w
6	Uniformity of Dosage units		
6.1	Bictegravir (Content uniformity, By HPLC) Acceptance value (L1)	1.6	Not more than 15.0
6.2	Tenofovir Alafenamide (Content uniformity, By HPLC) Acceptance value (L1)	2.5	Not More than 15.0
6.3	Emtricitabine (By Weight variation) Acceptance Value (L1)	2.2	Not more than 15.0
7	Dissolution (By HPLC)		
7.1	Bictegravir	Tablet -1 : 86.2 %	Not less than 70% (Q) of the labeled amount of

Remarks: APPROVED (Sample Conforms to above Specification)

Checked By	ARIMARDAN.SINGH	Approved By	Naveen Kumar.Pundir
Date	30-10-2023 17:52	Date	30-10-2023 17:54
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		Tablet -2 : 85.8 % Tablet -3 : 94.4 % Tablet -4 : 97.3 % Tablet -5 : 97.1 % Tablet -6 : 98.7 % Average::93.3 %	Bictegravir is dissolved in 45 minutes
7.2	<b>Emtricitabine</b>	Tablet -1 : 102.8 % Tablet -2 : 102.7 % Tablet -3 : 99.4 % Tablet -4 : 100.2 % Tablet -5 : 100.1 % Tablet -6 : 99.5 % Average::100.8 %	Not less than 70% (Q) of the labeled amount of Emtricitabine is dissolved in 45 minutes
7.3	<b>Tenofovir Alafenamide</b>	Tablet -1 : 103.3 % Tablet -2 : 103.3 % Tablet -3 : 96.7 % Tablet -4 : 97.2 % Tablet -5 : 97.3 % Tablet -6 : 96.2 % Average::99.0 %	Not less than 70% (Q) of the labeled amount of Tenofovir Alafenamide is dissolved in 45 minutes.
8	<b>Related Substances (By HPLC)</b>		
8.1	<b>Emtricitabine related compound-02</b>	0.18 %w/w	Not more than 1.0%w/w
8.2	<b>Emtricitabine related compound-04</b>	0.04 %w/w	Not more than 1.0%w/w
8.3	<b>Tenofovir related compound-01</b>	0.08 %w/w	Not more than 1.5%w/w
8.4	<b>Tenofovir related compound-02</b>	0.21 %w/w	Not more than 0.5%w/w
8.5	<b>Tenofovir related compound-07</b>	Not Detected	Not more than 0.5%w/w

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8.6	Phenol	0.01 %w/w	Not more than 0.5%w/w
8.7	Maximum single unknown impurity	0.15 %w/w	Not more than 0.5%w/w
8.8	Total impurities	0.80 %w/w	Not more than 5.0%w/w
9	<b>Assay (By HPLC) Each film coated tablet contains:</b>		
9.1	Bictegravir sodium eq. to Bictegravir (C <sub>21</sub> H <sub>18</sub> F <sub>3</sub> N <sub>3</sub> O <sub>5</sub> ) (%) Labeled amount	97.3 %	Not less than 95.0 and Not more than 107.5
9.2	Emtricitabine IP (C <sub>8</sub> H <sub>10</sub> FN <sub>3</sub> O <sub>3</sub> S) (%) Labeled amount	102.2 %	Not less than 95.0 and Not more than 107.5
9.3	Tenofovir Alafenamide fumarate IP eq. to Tenofovir Alafenamide (C <sub>21</sub> H <sub>29</sub> N <sub>6</sub> O <sub>5</sub> P) (%) Labeled amount	100.0 %	Not less than 95.0 and Not more than 107.5

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