

# Generic tenofovir disoproxil fumarate and emtricitabine tablets obtained from the internet – are they what they say they are?

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## Background

Pre-exposure prophylaxis (PrEP) with tenofovir disoproxil fumarate (TDF)/emtricitabine (FTC) has been shown to reduce dramatically the risk of HIV acquisition<sup>1,2</sup>. However, the National Health Service (NHS) in England has declined to commission PrEP, leading high-risk individuals to purchase generic versions on-line. Our team at Imperial College London provided therapeutic drug monitoring for tenofovir (TFV) and FTC in 2016-2017 for 293 individuals taking generic PrEP and reported that plasma concentrations were all above the target values<sup>3</sup>. More recently, concerns have arisen over the authenticity of generic PrEP purchased online. In the present study, we sampled generic PrEP from mainstream brands and suppliers and measured TDF and FTC in the purchased tablet form.

## Methods

Generic PrEP tablets in sealed bottles of different brands and from different suppliers were purchased from the internet through test purchases. Truvada for PrEP® from Gilead was purchased from Imperial College Healthcare NHS Trust. The brand and supplier of the generic PrEP samples were blinded from the researcher carrying out the analysis. The active pharmaceutical ingredient TDF and FTC was quantified using a fully validated ultra-performance liquid chromatography assay.

## Results

- A total of 14 samples were obtained for analysis, including Truvada™ from Gilead, PrEP used in the IMPACT trial<sup>4</sup> and 13 generic PrEP tablets obtained from Mylan, Cipla, Hetero Healthcare, Emcure, Adcock Ingram and GPO (Figure).
- The suppliers were All Day Chemist, Dynamix International, Green Cross Pharmacy, In House Pharmacy, Silom Pulse and United Pharmacy (in alphabetic order).
- As summarised in the table, all the PrEP tablets contained 94.3% to 104.9% of the 300 mg of TDF claimed on the label and 97.3% to 104.4% of the 200 mg FTC claimed on the label.

## Conclusions

All the PrEP tablets sampled in this study contained the stated amount of TDF and FTC. We were able to confirm the stated content of the PrEP tablets from various manufactures and suppliers. This study provides reassurance to the community purchasing generic PrEP online and is a good example of a close collaboration between academics, clinicians, HIV charities and PrEP advocates.

## References

- McCormack et al. Pre-exposure prophylaxis to prevent the acquisition of HIV-1 infection (PROUD): effectiveness results from the pilot phase of a pragmatic open-label randomised trial. *Lancet* 2016; 387: 53-60.
- Molina et al. On-demand preexposure prophylaxis in men at high risk for HIV-1 infection. *N Engl J Med* 2015; 373: 2237-2246.
- Wang et al. InterPrEP: Internet-based pre-exposure prophylaxis with generic tenofovir disoproxil fumarate/emtricitabine in London – analysis of pharmacokinetics, safety and outcomes. *HIV medicine* 2018; 19: 1-6.
- <https://www.prepimpacttrial.org.uk/>

## Table

Drug name	Manufacture	Lot No.	Expiration date	Supplier source	Tenofovir disoproxil fumarate		Emtricitabine	
					Measured amount in mg	% of label claim (300mg)	Measured amount in mg	% of label claim (200 mg)
Truvada	Gilead	5595307D	Nov-19	Imperial Healthcare NHS Trust	300.1	100.0	201.2	100.6
TENVIR-EM	Cipla	GG80516	Feb-20	All Day Chemist	300.2	100.1	205.9	103.0
RICOVIR-EM	Mylan	3067417	Apr-20	Dynamix International	307.4	102.5	201.6	100.8
TENOF-EM	Hetero Healthcare	31171625	Apr-20	Dynamix International	306.4	102.1	205.2	102.6
TENVIR-EM	Cipla	GG80516	Feb-20	Dynamix International	312.0	104.0	208.7	104.4
RICOVIR-EM	Mylan	8074289	Feb-20	Dynamix International	288.7	96.2	198.4	99.2
TENOF-EM	Hetero Healthcare	31171625	Apr-20	Green Cross Pharmacy	313.2	104.4	207.2	103.6
Adco-Emtevir	adcock ingram	W042494	Aug-19	Green Cross Pharmacy	301.6	100.5	207.0	103.5
TENVIR-EM	Cipla	GK80203	Mar-20	Green Cross Pharmacy	296.1	98.7	202.1	101.1
RICOVIR-EM	Mylan	8074289	Feb-20	Green Cross Pharmacy	286.8	95.6	197.8	98.9
Emtricitabine/Tenofovir disoproxil	Mylan	1091973	not available	IMPACT trial	299.2	99.7	198.3	99.2
TENVIR-EM	Cipla	GG80516	Feb-20	In House Pharmacy	314.8	104.9	208.4	104.2
TENO-EM	GPO	W615110	Feb-20	Silom Pulse	305.0	101.7	205.4	102.7
RICOVIR-EM	Mylan	3077012	Nov-20	Silom Pulse	296.9	99.0	200.6	100.3
TAVIN-EM	Emcure	E16HX18001	Dec-20	United Pharmacy	283.0	94.3	194.7	97.3
TENVIR-EM	Cipla	GG80114	Dec-19	United Pharmacy	307.5	102.5	203.5	101.8

Characteristic of PrEP samples. Supplier source of the generic PrEP samples was listed in alphabetic order.

## Figures



Bottle package of all the PrEP samples analysed in the study



Blinded PrEP samples ready for processing



Truvada by Gilead

Ricovir-EM by Mylan

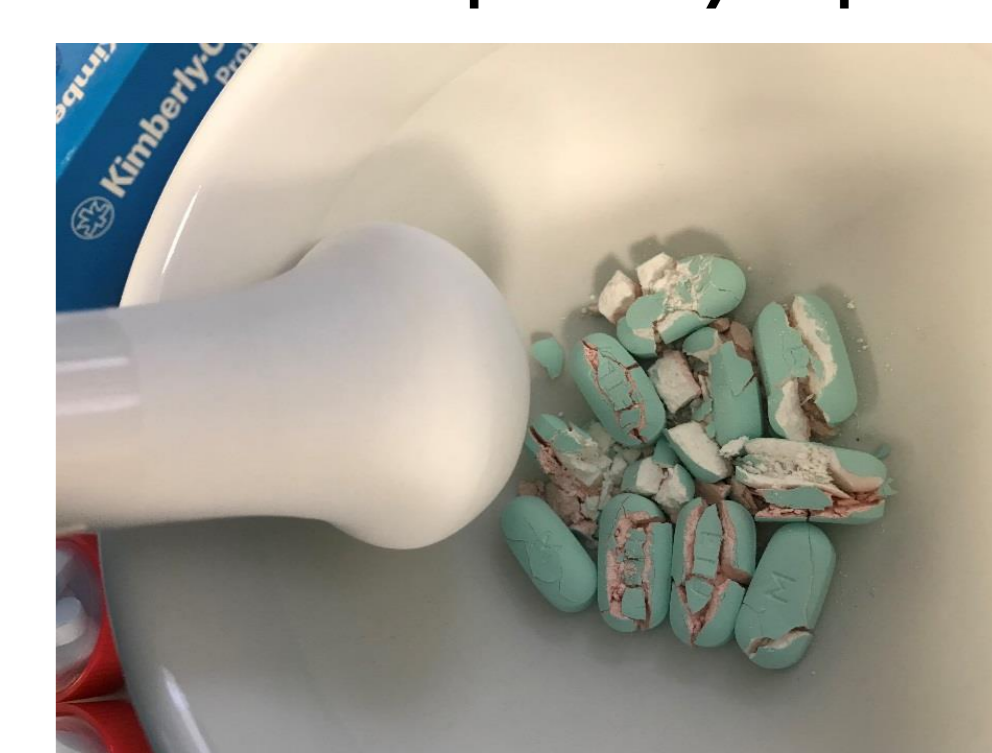
Adco-Emtevir by adcock ingram

TENO-EM by GPO

TENOF-EM by Hetero Healthcare

TAVIN-EM by Emcure

TENVIR-EM by Cipla



Grinding PrEP tablets (from IMPACT trial) using Pestle & Mortar



Fine powder ready to be dissolved in solvent