



Republic of the Philippines
DEPARTMENT OF HEALTH
OFFICE OF THE SECRETARY

22 February 2016

JANETTE LORETO GARIN, MD, MBA-H

Secretary

Department of Health

Dear **Secretary Garin:**

After evaluating the documents submitted by the proponent pertinent to the request to reconsider the inclusion of the fixed dose combination (FDC) of tramadol hydrochloride + paracetamol 37.5mg/325mg and 18.75mg/162.50mg tablets in the Philippine National Formulary (PNF), the Formulary Executive Council (FEC) respectfully recommends its **DISAPPROVAL** because of its prohibitive cost compared to the single dose preparations:

Price offer from the proponent (based on submission):	
Tramadol 37.5 /paracetamol 325 (Dolcet)	Php 43.96/tab
Tramadol 18.75 /paracetamol 162.50 (Dolcet Mini)	Php 28.56/tab

Market prices of the other available fixed dose combination		
Paracetamol + Tramadol tab 325/37.5mg (DOLCETAL)	TGP	Php 20/tab
Paracetamol + Tramadol tab 325/37.5mg (DOLCET)	MIMS	Php 46.96/tab
Paracetamol + Tramadol tab 325/37.5mg (ALGESIA)	MIMS	Php 34.42 – Php 34.75
Paracetamol + Tramadol tab 325/37.5mg (CETADOL)	MIMS	Php 25/tab
Paracetamol + Tramadol tab 325/37.5mg (CETRA)	MIMS	Php 22.875/tab

2015 DOH-Drug Price Reference Index:	
Paracetamol 500 mg tab	Php 0.23
Tramadol 50 mg capsule	Php 2.24
Tramadol 100 mg MR tablet	Php 70.56

It was noted that the FDC has similar efficacy with the single dose preparations of tramadol and paracetamol and the only advantage is in terms of decreasing the adverse drug reactions related to high dose tramadol, e.g., dizziness and nausea.

Attached herewith is the evidence summary considered by the Council.

For your disposition, Ma'am.

Very truly yours,

For the Formulary Executive Council

Froilan A. Bagabaldo

ATTY. FROILAN BAGABALDO

Chair

Formulary Executive Council

Recommending disapproval:



KENNETH HARTIGAN-GO, MD

Undersecretary of Health

Office for Health Regulation

Official disapproval of the above medicines:

JANETTE LORETO GARIN, MD, MBA-H

Secretary of Health

