

Clinical Pharmacology Memo	
NDA	205649 Supplement 022
Submission Date:	12/12/2023
PDUFA Date:	6/12/2024
Brand Name:	Xigduo XR
Generic Name:	dapagliflozin and metformin HCL
Sponsor:	AstraZeneca
Dosing regimen:	5 mg dapagliflozin and 2000 mg metformin HCl extended release, once daily. Do not exceed a daily dose of 10 mg dapagliflozin and 2000 mg metformin HCl extended release.
Dosage Form	Extended-release tablets
Proposed Indication:	adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
OCP Reviewer:	Dong Guo, PhD (Clinical Pharmacology and Pharmacometrics)
OCP Team Leader:	Pharmacometrics: Justin Earp, PhD, Clinical Pharmacology: Edwin Chiu Yuen Chow, PhD
OCP Division:	Division of Cardiometabolic and Endocrine Pharmacology (DCEP)
OND Division:	Division of Diabetes, Lipid Disorders, and Obesity (DDLO)

The Office of Clinical Pharmacology (OCP) review is complete and has been uploaded to DARRTS under NDA 202293/S031. Our recommendation for this application is that approvable from a Clinical Pharmacology perspective.

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/s/

DONG GUO
05/31/2024 03:21:14 PM

EDWIN C CHOW
05/31/2024 03:23:14 PM