

FDA STUDY: LIMITED DATA ON BOTANICAL KRATOM — NOT REPRESENTATIVE OF MARKET PRODUCTS

Data based on FDA pilot clinical study (2024)

A small controlled study does not reflect the products sold in gas stations and vape shops.

WHAT THE STUDY FOUND

- ❖ No serious adverse events
- ❖ Conducted in 40 healthy recreational drug users
- ❖ Used single-source botanical kratom with no 7-hydroxymitragynine (7-OH)

CRITICAL LIMITATIONS (FDA STUDY ITSELF ACKNOWLEDGES)

- ❖ Small sample size
- ❖ Controlled setting
- ❖ Did not evaluate typical retail products

THE STUDY RAISES CONCERNS

Kratom produced effects such as “high” and “feeling drunk” and showed opioid-like pharmacological activity.

Source - U.S. Food and Drug Administration Pilot Single Ascending Dose Study of Botanical Kratom (2024)



7-hydroxymitragynine (7-OH) was detectable after dosing despite not being present in the administered product.

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 www.antikratom.org