

Research Work Title

Synthesis of Topiramate Drug Substance



Representative: Professor Farajollah Mohanazadeh

Collaborator: Elnaz Mohammadi

Organization: Iranian Research Organization for Science and Technology,
Kavosh Farayand Chemi Co.

Abstract:

Topiramate, marketed under the brand name Topamax, is an oral medication used to treat epilepsy and prevent migraines, as well as to address alcohol dependence and essential tremors. It is a compound with the chemical formula $C_{12}H_{21}NO_8S$, existing as a crystalline powder with a melting point of 124-125 °C. This drug represents a new generation of antiepileptic medications whose usage is steadily increasing worldwide each year, gradually replacing older medications such as carbamazepine. In this project, Topiramate was synthesized and purified using diacetone fructose and sulfamide as the primary starting materials, along with eight additional chemicals. The characteristics of the active pharmaceutical ingredient produced comply with international pharmaceutical pharmacopoeias, including the United States Pharmacopeia and the British Pharmacopoeia. The pharmaceutical ingredient is produced industrially in accordance with USP 41 standards and meets the needs of the country. Kavash Faradayn Chemi Company is the sole producer of the Topiramate's active ingredient in Iran.

- › Conducting stability tests
- › Obtaining Common Technical Document (CTD) approval from the FDA
- › Obtaining approvals from the General Directorate of Laboratories of the Ministry of Health, Arya Pharmaceuticals, and Darupakhsh
- › Mass production
- › Saving 62% on foreign exchange currency

