

Second Laureate Invention & Innovation



- **Research Work Title:** Industrial Production of Anti-cancer Active Pharmaceutical Ingredients
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- **Collaborators:** Ahmad Yari, Javad Borozmand Shad & Seyed Reza Majid
- **Collaborator Organization:** Arasto Pharmaceutical Chemicals Inc.



Abstract:

Laboratory synthesis and optimization, scale-up and pilot production of the anti-cancer APIs were carried out according to regulatory guidelines set by the International Commission on Harmonization (ICH). Subsequently, three validation batches of each anti-cancer API were produced and used for short- and long-term stability studies and preparation of Drug Master Files (DMFs), which were submitted to the Division of Pharmaceutical & Narcotic Affairs (DPNA) of the Iranian Ministry of Health. Production lines were inspected and sampling were completed and Good Manufacturing Practice.

The most important achievements of this national project include:

1. Three international patent applications which divulge improved methods of production of these APIs
2. Production of high potency (hazardous) APIs on industrial scale using closed system manufacturing conditions and equipment for the first time in Iran
3. Design of closed system production equipment by the project leader and their fabrication by domestic equipment fabricators
4. Measurement of Occupational Exposure Limits (OEL) according to Internationally recognized guidelines
5. Export of anti-cancer APIs to India
6. Training of highly trained industrial chemists and chemical engineers as well as design and fabrication of closed system production equipment

