

Technology information form

Technology title
A platform for the expression and production of multiple recombinant proteins in the milk of transgenic non-human mammals.
One sentence description of technology
Technology regarding new methods to efficiently and cost-effectively produce recombinant proteins from the milk of genetically-modified farm animals, applying methodologies of genetic engineering and transgenesis to pharmaceutical manufacturing.
Development status
Early stage <input type="checkbox"/> Preclinical <input checked="" type="checkbox"/> Phase I <input type="checkbox"/> Phase II <input type="checkbox"/> Phase III <input type="checkbox"/> Phase IV <input type="checkbox"/> <input type="checkbox"/> Preregistration <input type="checkbox"/> Registered <input type="checkbox"/>
Full description (Less than 400 words)
<p>A platform has been developed to efficiently and cost-effectively produce recombinant proteins from the milk of genetically-modified farm animals, applying the methods of genetic engineering and transgenesis to pharmaceutical manufacturing.</p> <p>ATIT-IX, a 55 kDa protein, is expressed in the milk of transgenic sows at 250 µg/mL. After lactation, ATIT-IX is purified from sow milk to homogeneity via anion and affinity chromatographic procedures, and the physical and chemical properties of ATIT-IX have been evaluated.</p> <p>The platform uses manufacturing processes that are well-managed and carefully scrutinized in terms of quality control, quality assurance and production efficiency.</p> <p>Currently, biological activity of ATIT-IX at higher levels than other commercial products has been demonstrated.</p> <p>Bio-safety issues are always an important consideration in the production of biopharmaceutical proteins. Adventitious agents must be considered when dealing with biological products from transgenic animals. For this platform, bio-safety tests (endotoxin and virus) have been used to establish quality control for all the</p>

manufacturing processes; including those involved in milk production, milk collection, protein isolation and purification. Model viruses detection (porcine parvovirus and pseudorabies virus) and pyrogen tests were established to assess the safety of therapeutic proteins derived from swine in this platform.

Patent status and no.

US and Taiwan patents of ATIT-IX production issued.

Type of business relationship sought

Patent licensing; technology transfer; partnering

Licensing contact

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<http://www.atit.org.tw/>