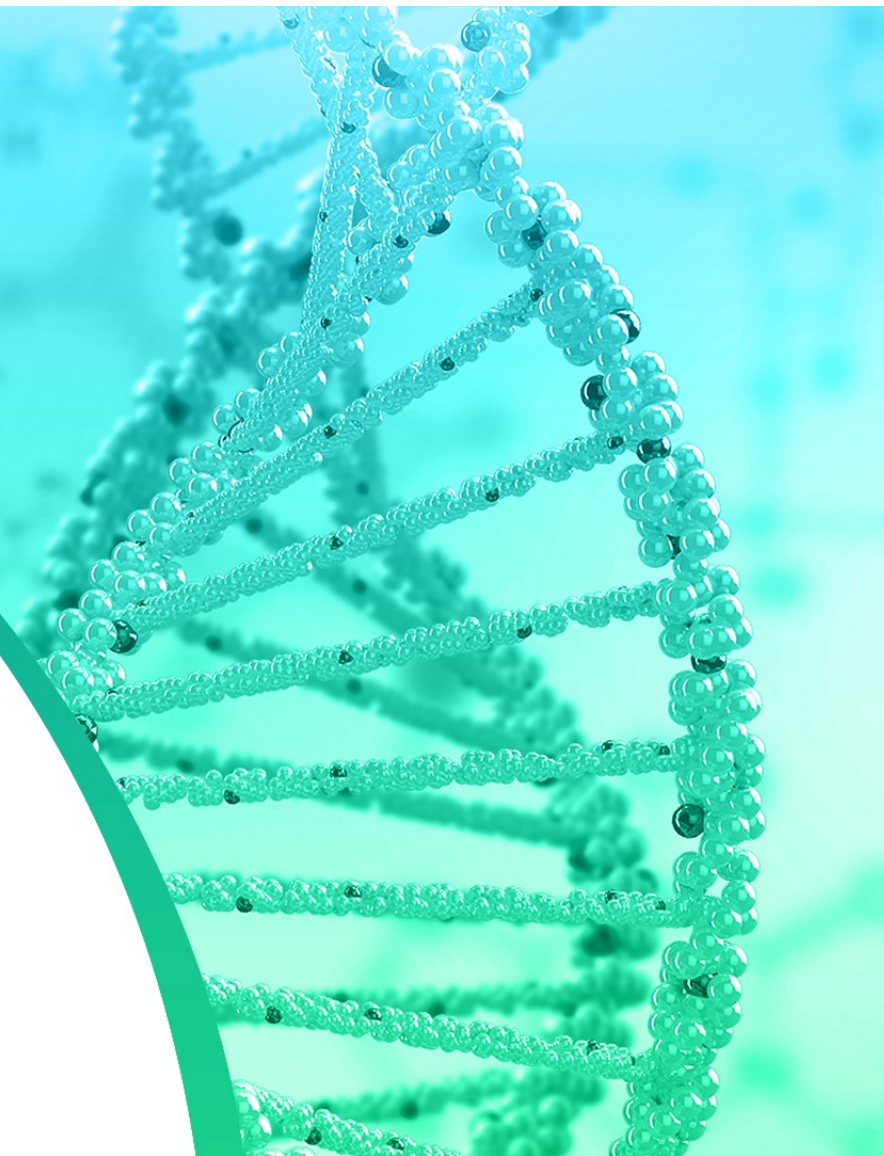




Glycogene Incorporated

**Your Trusted Partner for Nucleic Acid and
Carbohydrate Raw Materials and Product
Development**



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About us



 Glycogene was established in Wuhan, founded by a team of renowned experts in the field of nucleic acid, glycoscience and enzyme evolution. Founders and Senior Management are all US trained scientists having 10-20+ years of research, biotech and commercial experiences.

With the **chemo-enzymatic synthetic** platform, we are committed to provide global customers with high quality products and services for **nucleic acids, glycan-related** product development.

Multiple products filed FDA **with DMF (RNA related products).**

Four locations – Glycoscience related, Wuhan, China

RNA related, Qingdao, Shandong province, China

Commercial manufacture site, Panjin, Liaoning Province, China

Warehouse and Distribution, Atlanta, GA, USA 

R&D and Manufacture Centers



**Headquarter
R&D center for Glycoscience product
Wuhan, China**



**R&D center for RNA product
Qingdao, China**



**Commercial Manufacture for RNA product
Panjin, China**



R&D and Manufacture Centers





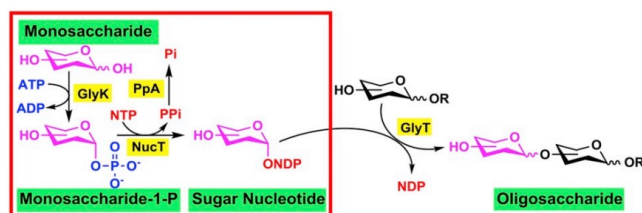
Technologies

Chemo-enzymatic synthesis platform

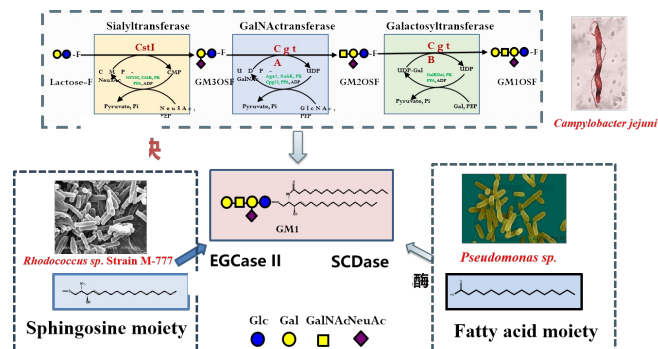


Biosynthesis in vivo & in vitro

Tool library: hundreds of characteristic enzymes; all kinds of frequently-used sugar nucleotides; complete RBS/promoter library and gene editing system



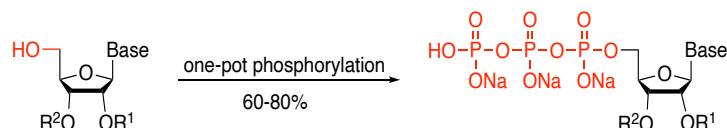
Pathway design: one-pot multienzymes synthesis, enzyme immobilization, enzymatic cycling, metabolic network model design and optimization



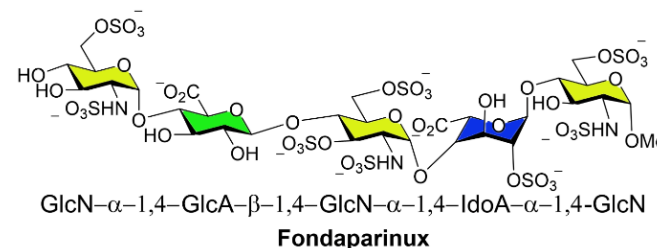
Chemical/enzymatic synthesis platform

Phosphorylation:

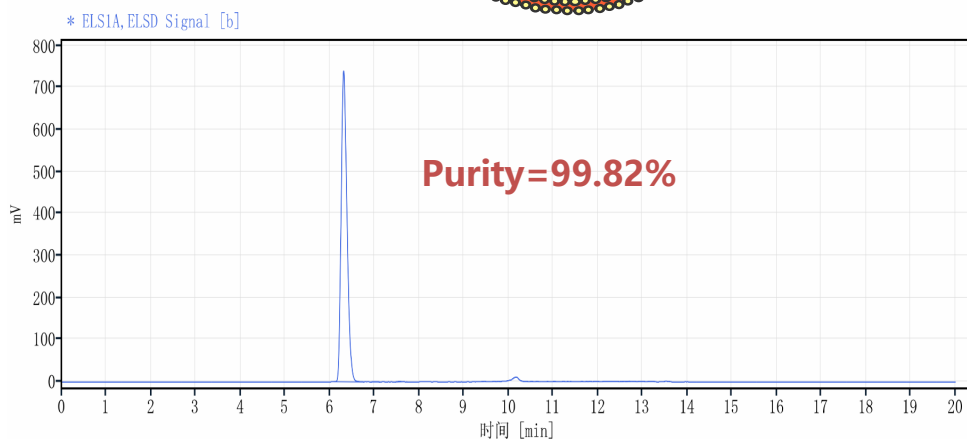
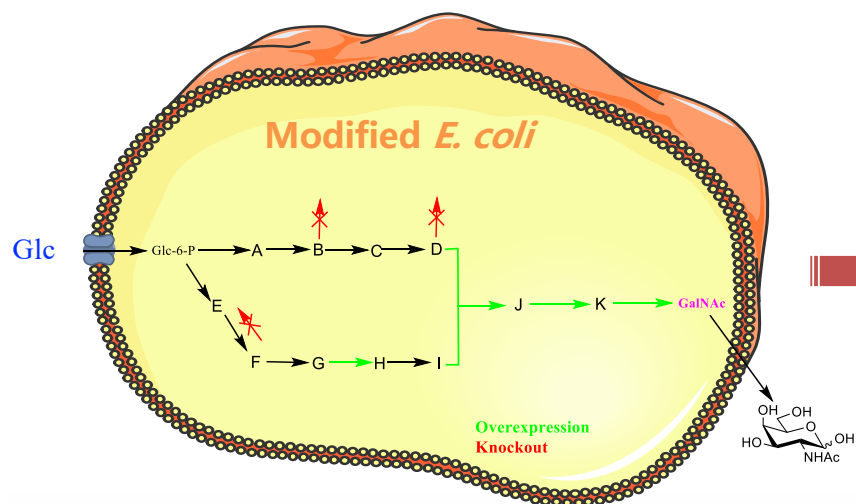
- **One-pot Phosphorylation** technology, suitable to different kinds of nucleosides with moderate to excellent yield;
- **Enzymatic** phosphorylation technology, especially suitable for natural nucleotides



Glycosylation: synthesis of complex carbohydrate, especially at the design of donors and acceptors, e.g. drug Fondaparinux, glycolipid MPLA for vaccine adjuvant



Fermentation pathway of GalNAc



- Fermentation, non-animal origin
- Purity>99% (HPLC-ELSD), Endotoxin<50 EU/g
- Capacity: multiple Metric ton, GMP grade available



Product Pipeline

Product pipeline: GMP-like production of glycoscience and RNA material



RNA related raw materlas

Nucleosides/tides
Cap analogs
Phosphoramidites
GalNAc series(non-animal origin)
Custom synthesis

siRNA&ASO: Amidites, GalNAc series

- Quality: Quality specification follows ICHQ7 & Q11:Critical impurities<0.1% and non-critical impurities<0.2%;
- Capacity: annual 2-5 tons for amidites; 100s kg for GalNAc delivery molecules;
- Technology: GalNAc(non-animal origin) and modified nucleosides prepared in house

mRNA: NTP, Cap analogs

- Quality: GMP or GMP-like grade with high purity;
- Capacity: annual 4000-5000L for NTPs and 1000L for cap analogs
- Technology: Pseudouridine and modified nucleosides prepared in house in chemoenzymatic way

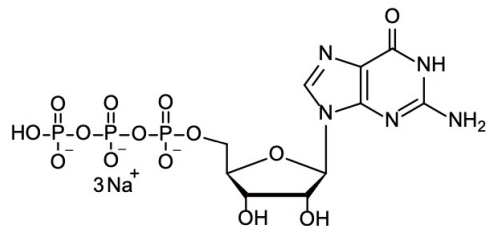
Glycoscience related raw materials

Sugar Nucleotides
Glyco-enzymes
Monosaccharides
ADC linkers

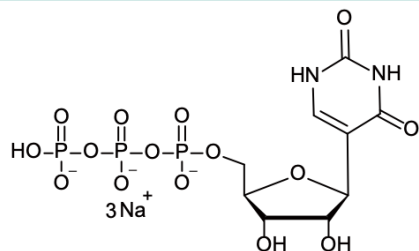
.....

- Comprehensive: around 50 sugar nucleotides; around 200 glycol-enzymes; and around 20 ADC glycan linkers
- Capacity: 100 kg scale for sugar nucleotides (so far world's biggest);
- Technology: Enzyme catalyzed synthesis; Fermentation synthesis; and chemical synthesis; e.g. GalNAc, Fucose
- Custom synthesis: Glycolipid with DSM; Sweetener with Coke

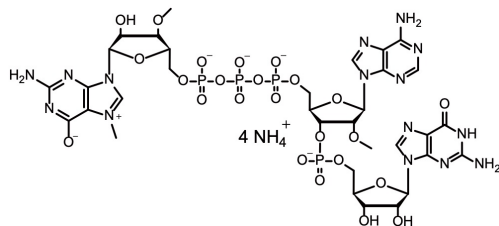
Featured products- mRNA related products



➤ **Natural NTP** different kinds of salt e.g. Na⁺, tris, and *etc.*



➤ **Unnatural NTP**, e.g. pUTP, 5-Me-CTP, and custom synthesis



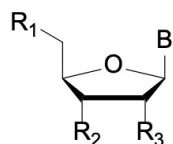
➤ **Natural Cap analog**, e.g. GAG, GAU and novel cap analogs
(patent application in progress)



Featured products- phosphoramidites

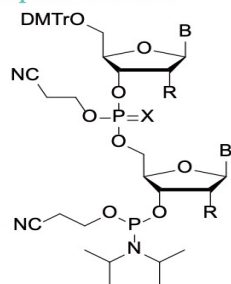


Modified Nucleosides/Phosphoramidites



B = A/C/G/T/U
R₁/R₂/R₃ = required PGs

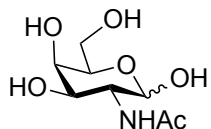
Dimer Phosphoramidites



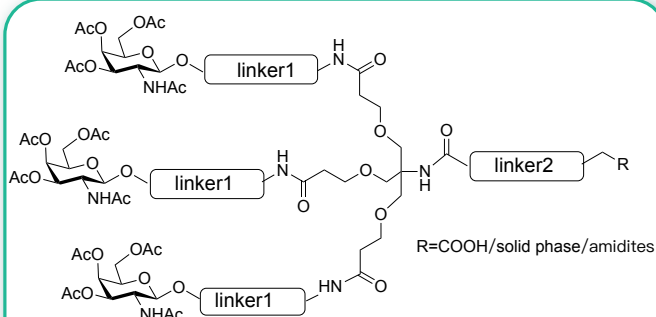
X=O/S
R = H/OMe/F
B = protected A/C/G/T/U

- 8 DMF files to be approved soon
- 3 IND applications using our amidites to be filed
- ICHQ7 & Q11: critical impurities<0.1% non-critical impurities<0.2%
- 3- 5 tons/yr for regular amidites
- GMP or GMP-like grade for 2'-F and 2'-OMe amidites
- Critical SMs, e.g. Nucleosides(2'-F-dA/dG prepared in enzymatic way)
- Phosphorus reagent prepared in house
- Over 100 custom synthesis: dimer, trimer and tetramer
- P=S single chiral center dimers in multiple kg scale
- 16 RNA standard dimers in stock

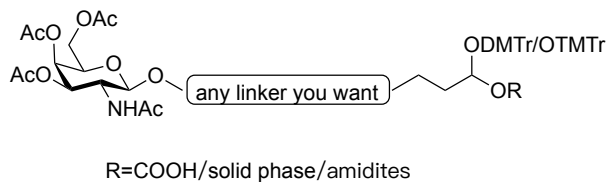
Featured products- GalNAc series



GalNAc monosaccharide: fermentation source, non-animal origin, tons scale/yr



Trimer GalNAc-Succinate/CPG/PS/Amidite: High purity with impurities controlled, 100kg scale/yr



Monomer GalNAc-Succinate/CPG/PS/Amidite: High purity with impurities controlled, 100kg scale/yr



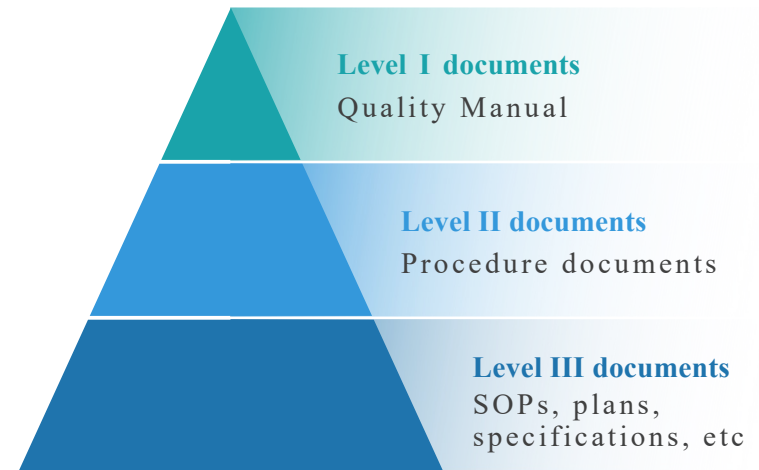
Quality



Quality Assurance and Quality Control



- Quality assurance and quality control standards were built depending on **GMP level and ISO 9001**
- Certifications: ISO 9001 Certificate of Conformity Quality Management System & ISO 13485 Certificate of Conformity Medical Device Quality Management System.
- Glycogene has a quality assurance system which can monitor research, production, storage, shipment, and after sale services.





Multiple DMFs have been filed with FDA



5 DMFs have been filed with FDA, and 10+ more DMFs are in progress.

Product Name	DMF#
ADENOSINE-5'-TRIPHOSPHATE	037895
CYTIDINE-5'-TRIPHOSPHATE	039147
GUANOSINE-5'-TRIPHOSPHATE	039146
URIDINE-5'- TRIPHOSPHATE	039144
M7(3'OMEG)(5')ppp(5')(2'OMEA)PG	039491

Reference ID: 5305331

Reference ID: 5305325

Reference ID: 5305454

Reference ID: 5305454

Reference ID: 5320700

DMF 039491

QINGDAO GLYCOGENE PHARMACEUTICAL TECHNOLOGY CO., LTD.
ATTN: CAO XUEFENG, GENERAL MANAGER
ROOM 201, BUILDING 3, NO. 108 GUANCHANG 2ND ROAD
AOSHANWEI SUB-DISTRICT
JIMO DISTRICT, QINGDAO CITY, SHANDONG PROVINCE - 266216, CHINA

DMF ACKNOWLEDGEMENT

Dear Cao Xuefeng,

The Food and Drug Administration acknowledges receipt of the following Drug Master File (DMF) submission:

DMF NUMBER ASSIGNED: 039491
DATE OF SUBMISSION: FEBRUARY 05, 2024
DMF TYPE: II
DMF TITLE: M7(3'OMEG)(5')PPP(5')(2'OMEA)PG
SUBJECT (TITLE): QINGDAO GLYCOGENE PHARMACEUTICAL TECHNOLOGY CO., LTD.
HOLDER: QINGDAO GLYCOGENE PHARMACEUTICAL TECHNOLOGY CO., LTD.
JENKEM TECHNOLOGY USA INC.

SUBMITTED BY:

AGENT:

All subsequent correspondence to this DMF should be identified with the information as provided above.

Your DMF will be reviewed only in connection to a New Drug Application, Abbreviated New Drug Application, Investigational New Drug Application, Biological License Application, New Animal Drug Application, or DMF it is intended to support when a Letter of Authorization (LOA) is submitted to the DMF and a copy of the LOA is submitted in the application e.g., NDA, that references the DMF.

For information on various DMF submissions, example of letter templates and DMF Guidance for Industry, check the DMF website at <https://www.fda.gov/drugs/drug-master-files-dmf-guideline-drug-master-files-dmf>

The holder of the DMF is responsible for compliance with 21 CFR 314.420 as interpreted in "The Guideline for Drug Master Files" at <https://www.fda.gov/drugs/drug-master-files-dmf-guideline-drug-master-files-dmf>

QC Major instruments



The quality control laboratory is equipped with NMR, HRMS, LC-MS, HPLC, GC, PCR, and *etc.*, to meet the QC needs.



NMR



HRMS



LC-MS



HPLC



GC



PCR



Capacity



mRNA Raw Material Manufacture - NTPs and Cap analogs



annual 4000-5000L for NTPs and 1000L for cap analogs

UP-Water system, DAC purification system, HPLC, UPLC-MS, q-PCR

Nucleoside/amidites/GalNAc Manufacture



Nucleosides: 2T/month

Phosphoramidites: 200kg/month; Kilogram to tons scale under GMP level



Supply Chain, Customer services, and Project Managment



Supply Chain and Customer Services



- **Warehouse and distribution center in US**
- **24/7 available for technical services**
- **Overnight shipment available**
- **US team – sales, business development and technical support**
- **Free sample available upon request**
- **US custom clearance services**
- **Every project will be assigned a project manager. Customers will be updated periodically via email and/or teleconference**



Summary



- **Integrated R&D and Manufacture**
- **Unique chemo-enzymatic synthesis platform**
- **Non-animal origin GalNAc products in large scale**
- **Broad product pipeline, and large scale capacities**
- **Quality Assurance and QC**
- **High Quality products and stability programs**
- **Broad customer base from small biotech to large pharma, domestic and international**
- **Best-in-class supply chain and customer services**
- **Custom synthesis and periodical update via email and teleconference**



Glycogene Inc – Your trusted partner for RNA raw materials and product development

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Thanks for watching

**Your Trusted Partner for Nucleic Acid and
Carbohydrate Raw Materials and Product
Development**

