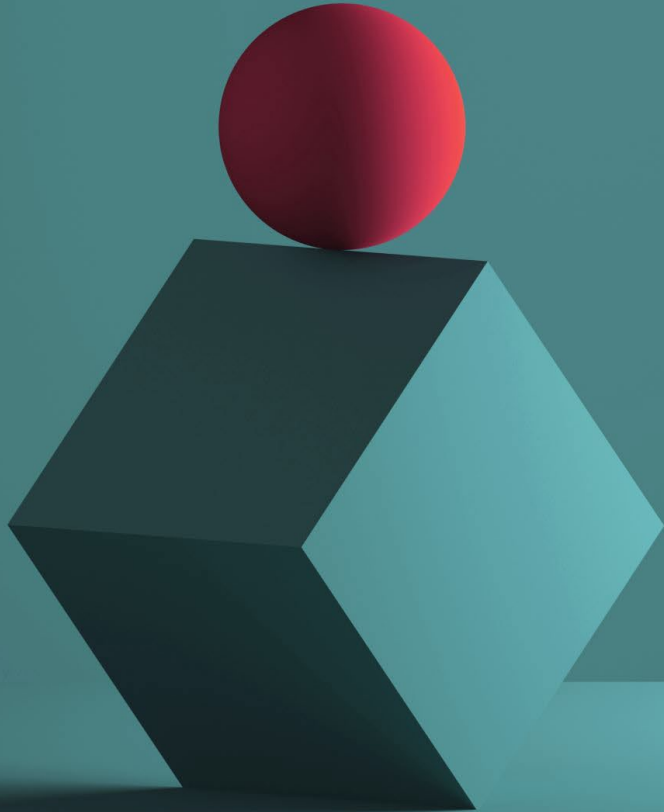


THE - PRODUCTS



BIOMEDICAL EXPERTS PVT LTD.

CYCLOTRON CONSUMABLES

Biomedical Expert has full range of cyclotron consumables package which includes:

O-18 water 98 % atoms

Mannose Triflate

LAL Water

Glass Vials

Sterile Filters

Needles

Reagent Kits

PET Precursor

HUAYI ISOTOPES – THE MANUFACTURER

Huayi Isotopes Co.(HIC), the subsidiary of Huayi Technology Co., Ltd., was established in summer 2002. At present, HIC is a leading Oxygen-18 manufacturer with an annual production capacity of over 150 kilograms. HIC also supplies total solution for the production of PET imaging agent, including precursor, reagent kits, cassettes, sterile vacuum vials and accessories for most of the existing synthesizers.

HUAYI ISOTOPES – THE MANUFACTURER

98% Oxygen-18 Enriched Water

HIC has been one of the leading manufacturers globally with the highest quality; manufactured according to cGMP, ISO-9001:2008 and ISO-14001:2004 standards.

WT-98

^{18}O enriched water (98 atom%) GMP Grade

Application

FDG and other F-18 labelling biomarker production

Standard Packing

WT-98-0050 50 g / vial

WT-98-0020 20 g / vial

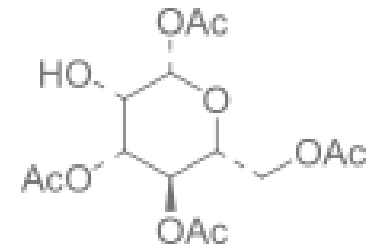
WT-98-0010 10 g / vial



HUAYI ISOTOPES – THE MANUFACTURER

PET Precursors

Development and production, with fully cGMP compliant. Mannose Triflate – continuous production



HUAYI ISOTOPES – THE MANUFACTURER

Sterile Vial:

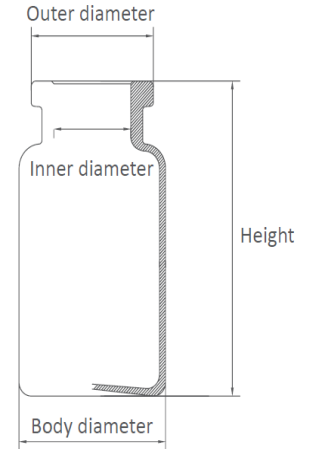
HIC's sterile vials are ISO 13485, ISO9001, CE and GMP-certified. Our facility finishes the sterilization on the final product, allowing us to limit endotoxic level to meet strict specifications.



Vial Size

A selection of vials with all USP type I glass, with volumes ranging from 5ml to 100ml, is available. Please request detailed information from our sales department.

Vial No.	Vol.(ml)	Height	Outer diameter	Inner diameter	Body diameter
5A	5.2ml	53.0±0.5mm	12.8±0.2mm	6.7±0.2mm	14.8±0.2mm
5B	8.5ml	36.0±0.5mm	19.8±0.2mm	12.6±0.2mm	22.0±0.2mm
10A	11.4ml	47.0±0.5mm	19.8±0.2mm	12.6±0.2mm	22.0±0.2mm
10B	12.4ml	45.0±0.5mm	19.8±0.2mm	12.6±0.2mm	24.0±0.2mm
10C	12.0ml	49.5±0.5mm	19.8±0.2mm	12.6±0.2mm	22.0±0.2mm
10D	12.2ml	52.0±0.5mm	19.8±0.2mm	12.6±0.2mm	22.0±0.2mm
10E	12.0ml	45.0±0.5mm	19.8±0.2mm	12.6±0.2mm	24.0±0.2mm
15A	17.6ml	52.5±0.5mm	19.8±0.2mm	12.6±0.2mm	25.5±0.25mm
15B	17.3ml	52.0±0.5mm	19.8±0.2mm	12.6±0.2mm	25.0±0.2mm
15C	17.6ml	53.3±0.3mm	20.0±0.2mm	12.6±0.2mm	25.5±0.25mm
20A	25.0ml	58.0±0.5mm	19.8±0.2mm	12.6±0.2mm	31.8±0.3mm
20B,25A	23.0ml	55.0±0.5mm	19.8±0.2mm	12.6±0.2mm	30.0±0.3mm
30A	35.0ml	66.0±0.5mm	19.8±0.2mm	12.6±0.2mm	32.0±0.3mm
30B	39.0ml	70.0±0.5mm	19.8±0.2mm	12.6±0.2mm	32.0±0.3mm
30C	34.0ml	62.7±0.5mm	19.8±0.2mm	12.6±0.2mm	35.8±0.3mm
30F	36.5ml	67.0±0.5mm	19.8±0.2mm	12.6±0.2mm	32.0±0.3mm
30G	33.0ml	68.0±0.5mm	19.8±0.2mm	12.6±0.2mm	30.0±0.3mm
50A	60.0ml	72.5±0.5mm	19.8±0.2mm	12.6±0.2mm	42.5±0.4mm
100A	139.0ml	110.0±1.0mm	28.1±0.2mm	16.6±0.2mm	52.5±0.6mm
100B	117.0ml	95.0.0±1.0mm	19.8±0.2mm	12.6±0.2mm	51.5±0.6mm



Conventional Inventory

Cat. No.	Packaging	Minimum Inventory
NSV-10C	100/Tray	●
SV-10E	100/Tray	●
SV-30C	50/Tray	●
SVV-10A	100/Tray	●
SVV-10C	100/Tray	●
SVV-10D	100/Tray	●
SVV-15A	100/Tray	●
SVV-20A	50/Tray	●
SVV-20B	50/Tray	●
SVV-25A	50/Tray	●
SVV-30A	50/Tray	●
SVV-30C	50/Tray	●

● 5000pcs ● 1000pcs ● 500pcs

QUALITY CERTIFICATION

CERTIFICATE OF REGISTRATION

This is to certify that the quality management system of:

Huayi Isotopes Co.

**a division of Jiangsu Huayi Technology
Co., Ltd.**

Registered Address: Fluorin Chemistry Industrial Park, Changshu
Economic Technological Development Zone, Changshu City, Suzhou City,
Jiangsu Province, China

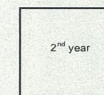
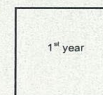
Manufacturing address: No.18, Fuyu Road, Advanced Material Park,
Haiyu Town, Changshu City,

has been assessed by Intertek as conforming to the requirements of:

**CURRENT GOOD MANUFACTURING PRACTICE BASED ON
21 CFR PART 211 (2017) PUBLISHED BY U.S. FOOD AND
DRUG ADMINISTRATION**

The scope of activities:

Manufacturing of Reagents kits for P.E.T., MX Cassette, IFP (Synthera
Integrated Fluidic Processor TM), Sterile Vial, Oxygen-18 enriched
Water, Mannose Triflate, 18F-FDG and PET Precursor (DOTA-TATE,
DOTA-NOC, DOTA-TOC, PSMA-11, PSMA I&T, HDT)



This certificate is valid as long as it bears a proper and authentic Intertek's Laser Logo
dedicated for the year of initial certification and after satisfactory annual surveillance.



Intertek

Certificate Number:
SZ1810D1

Initial Audit Date:
21-22 Sep, 2015

Certificate Issue Date:
23 Oct, 2018

Certificate Expiry Date:
22 Oct, 2021

Certification Administration Centre
Intertek Testing Services

Helen Xue
General Manager
Chemicals & Pharmaceuticals Division



US – FDA GMP CERTIFIED



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

DMF ACKNOWLEDGEMENT LETTER

HUAYI ISOTOPES COMPANY
Attn: ZHIMING JIN, GENERAL MANAGER
JIANGSU ADVANCED MATERIALS INDUSTRIAL PARK, 18 FUYU ROAD
HAIYU TOWN, CHANGSHU CITY, JIANGSU PROVINCE, CHINA 215522

Dear: ZHIMING JIN

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

DMF Number Assigned: 25469
Date of Submission: 10/10/2011
DMF Type: II
Subject: OXYGEN-18 WATER as manufactured in JIANGSU PROVINCE, CHINA
Holder: HUAYI ISOTOPES COMPANY
Submitted by: HUAYI ISOTOPES COMPANY
Agent: GOLDEN SHINE INTERNATIONAL GROUP INC.

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

Your DMF will be reviewed only in connection with a New Drug Applications, Abbreviated New Drug Application, Investigational New Drug Application, Biological License Application, New Animal Drug Application, Abbreviated New Animal Drug Application, Investigational New Animal Drug Application, or DMF it is intended to support.

You are responsible for compliance with the Regulation Title 21 Code of Federal Regulations Part 314.420 as interpreted in "The Guideline for Drug Master Files" [HEW (FDA) 79-3072.

See

<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/DrugMasterFilesDMFs/default.htm>.

You are expected to:

- Adhere to the statement of commitment you have provided.
- Provide to the FDA by submission to the DMF in two copies.

ISO – CERTIFIED PRODUCT

Certificate of Registration



This is to certify that the Quality Management System of

**Huayi Isotopes Co. (a division of Jiangsu Huayi
Technology Co., Ltd.)**

Unified Social Credit Code : 913205817658986684

Operation Address : No.18, Fuyu Road, (New Materials Industrial Park), Haiyu Town, Changshu City, Jiangsu Province, China

Registered Address : Fluorine Chemical Industrial Park, Changshu Economic Development Zone, Changshu City, Jiangsu Province, China

applicable to

Manufacturing of Reagents Kits for P.E.T., Cold Kits, Oxygen-18 Enriched Water, Mannose Triflate; Processing of Sterile Vial, MX Cassette, IFP(Synthera Integrated Fluidic Processor)

has been assessed and registered by NQA against the provisions of

ISO 9001:2015

This registration is subject to the company maintaining a quality management system, to the above standard, which will be monitored by NQA.

Certified Clients shall accept regular surveillance assessments, the validity of certificates shall be maintained for the positive result of audit.

The information of this certificate can be checked on CNCA's website (www.cnca.gov.cn)

SNQA's website : www.snqa.com.cn

Managing Director

Certificate Number

46207

Date:

25 March 2019

Valid Until:

25 March 2022

EAC Code:

12/14/15



The use of the UKAS Accreditation Mark indicates accreditation in respect of those activities covered by the accreditation certificate number 015 held by NQA.

NQA is a trading name of NQA Certification Limited, Registration No 09351758. Registered Office: Warwick House, Houghton Hall Park, Houghton Regis, Dunstable, LU5 5ZX, UK.

This certificate is the property of NQA and must be returned on request.

IMI – THE MANUFACTURER

50 YEARS OF AMERICAN INNOVATION

We believe that our customers and the patients they serve deserve only the highest level of quality and security. For 50 years, we have committed ourselves to delivering high-quality American made compounding devices, customer satisfaction, and service. When you partner with us, you not only receive superior devices from the industry leader in Tamper Evident Cap Technology, you also receive a dedicated team of support professionals available to you when you need them. Our mission is to build long-lasting relationships with pharmaceutical and compounding professionals to continuously advance our devices to serve the healthcare industry.

IMI – CYLOTRON PRODUCT

Filtered Venting Needles



IMI – CYLOTRON PRODUCT

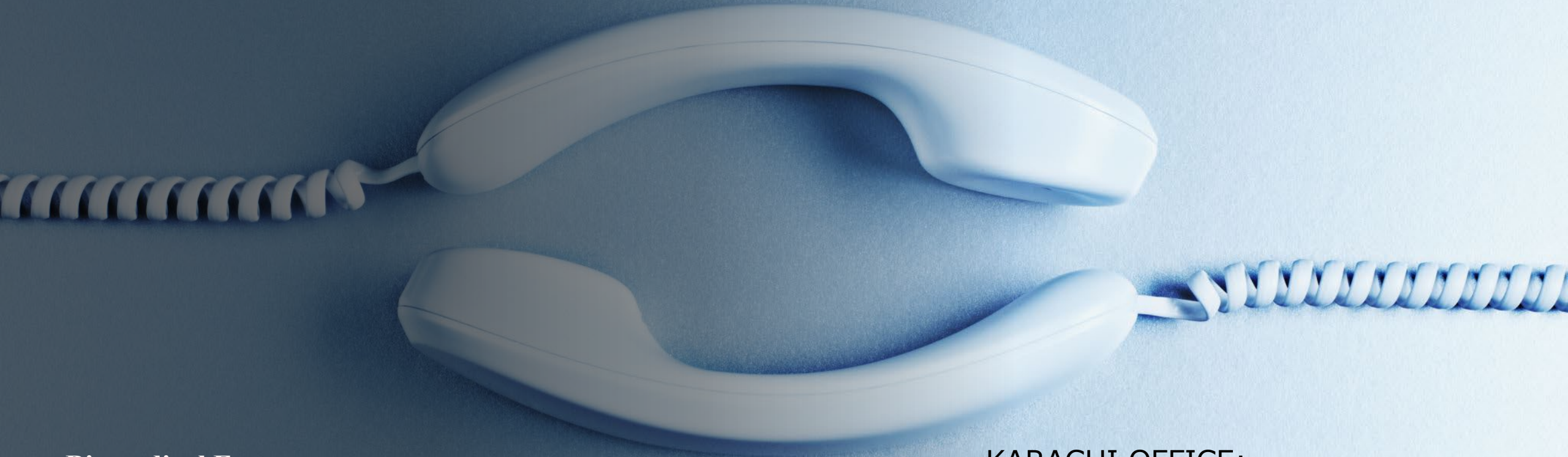
Aspirating Needle 3" Sharp Canula





OUR PARTNERS

CONTACT



Biomedical Experts
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Punjab Co-Operative Housing Society, Ghazi Road,
0092333-0276327
support@biomedical-experts.com
www.biomedical-Experts.com

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Tel: +966500136265