华北制药

中　国　制　药

CHINA PHARMACEUTICAL

以绿色制造为宗旨　实现可持续发展

Green Manufacturing Oriented to Realize Sustainable Development

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一、中国制药企业发展现状

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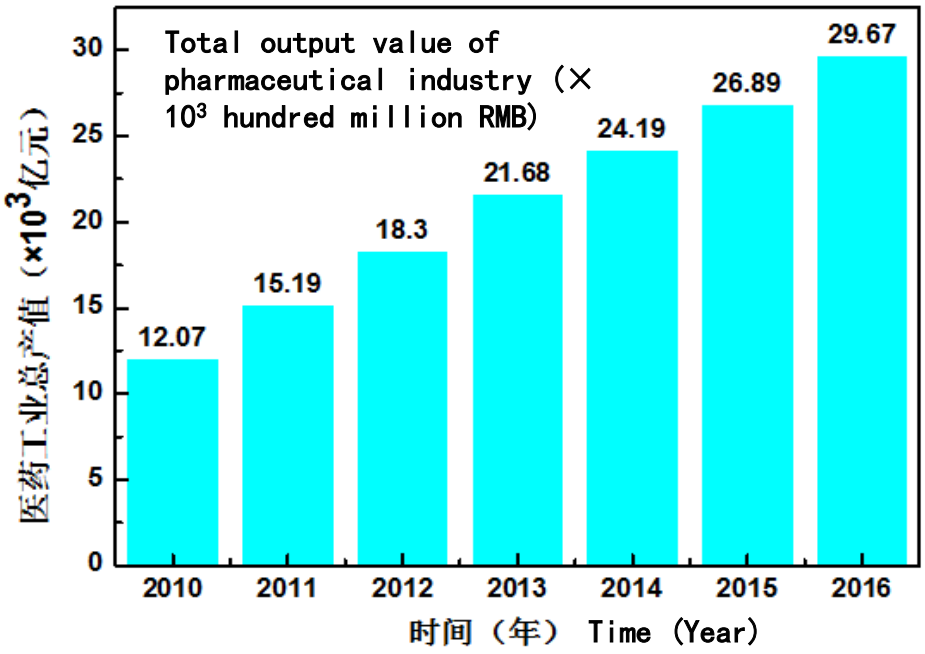
Ⅰ. Development Status of Chinese Pharmaceutical Enterprises

- **中国是全球第一大化学原料药生产国，抗生素产量约占全球80%市场** 。China is the world's largest producer of chemical APIs, and its antibiotic production accounts for approximately 80% of the global market.
- **制药工业是中国的重点发展的战略产业。**The pharmaceutical industry is China's key development strategic industry.
- **生物医药为“十三五”规划十大重点促进产业之一。**Biomedicine is one of the ten key promotion industries for the “Thirteenth Five-Year Plan”.



工信部统计数据：

Data from Ministry of Industry and Information Technology

医药工业总产值

Pharmaceutical industry total output value

2016年：29670亿元

2016: 2.9670 trillion

一、中国制药企业发展现状

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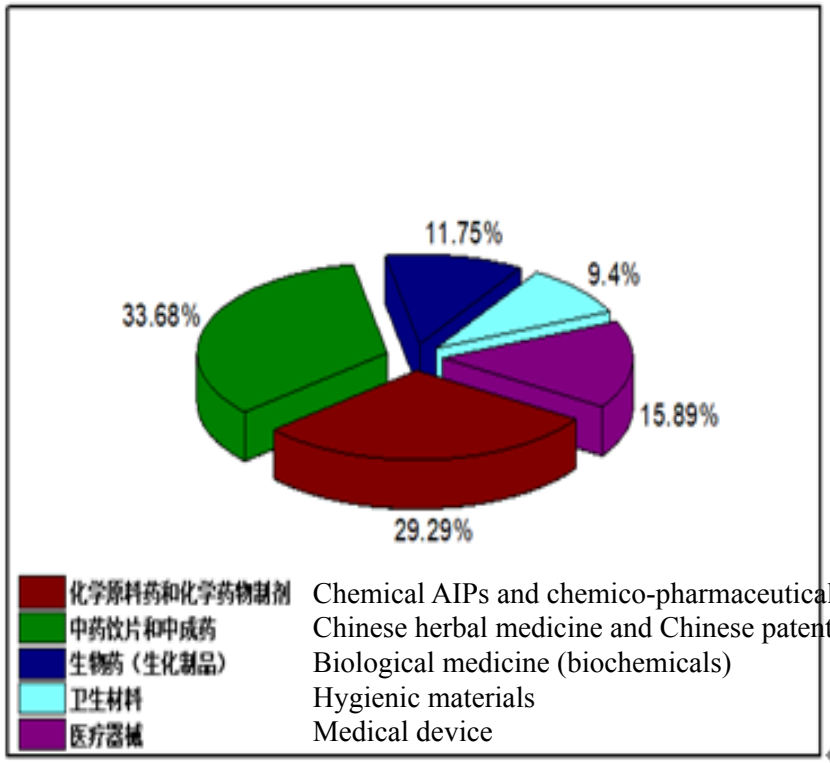
Ⅰ. Development Status of Chinese Pharmaceutical Enterprises

医药企业分布在全国29个省，2016年中国医药工业规模以上企业8246家。

Pharmaceutical companies are located in 29 provinces across the country. In 2016, there are 8,246 large-scale enterprises in China's pharmaceutical industry.



- **化学原料药和化学药物制剂生产企业2415家。**
  2,415 chemical AIPs and chemico-pharmaceutical preparations manufacturers
- **中药饮片和中成药生产企业2777家。**
  2,777 Chinese herbal medicine and Chinese patent medicine manufacturers
- **生物药（生化制品）969家 。**
  969 biological medicine (biochemicals) manufacturers
- **卫生材料生产企业775家。**
  775 hygienic materials manufacturers
- **医疗器械生产企业1310家。**
  1,310 medical device manufacturers

一、中国制药企业发展现状

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Ⅰ. Development Status of Chinese Pharmaceutical Enterprises

化学原料药企业排污特点

Characteristics of Sewage Disposal of Chemical APIs Manufacturers

- **化学药品原料药排污量大，污染物种类多，毒性大。**

  Large pollution discharge, many types of pollutants, high toxicity.

- **原料药生产能源、资源消耗高，生产工艺复杂，反应步骤多。**

  High energy and sources consumption, complicated production process, many reaction steps.

- **原料药生产投入的原辅料种类数量多，投入的物料成品转化率低。**

  There are many types of raw materials and excipients used in the production of APIs, but the conversion rate between fed materials and finished products is low.

- **原料药生产挥发性有机物的排放量约占全国人为源排放总量的4%。**

  The amount of volatile organic compounds produced by APIs accounts for about 4% of the country's total anthropogenic emissions.

在中国，原料药企业是国家环保重点监管的十三个行业之一，原料药企业面临的环保压力和风险更大。

一、中国制药企业发展现状

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Ⅰ. Development Status of Chinese Pharmaceutical Enterprises

制药行业减污控排发展趋势

Development trend of pollution abatement and emission control in the pharmaceutical industry

20世纪80年代—— 环保治理起步，单纯依赖末端生物降解无害化处理 。

1980s--- Environmental management started, relying solely on the end biodegradation innocent treatment.

↓

21世纪初 —— 企业开始关注生产全过程控制、实施清洁生产、源头减污，发展壮大生物制药产业，强化末端治理中的预处理和后处理技术。

At the beginning of 21st century--- Enterprises start to pay attention to the production process control, implement cleaner production and source decontamination, develop and expand biopharmaceutical industry, and strengthen the pretreatment and post-treatment technology for end treatment.

↓

21世纪20年代 —— 产业集聚区发展、园区循环经济，形成全产品链技术集成、全过程减排控污、清洁生产与治污一体化。

2020s---The development of industrial agglomerations and the circular economy of industrial parks will form the integration of the entire product chain technology, emission reduction and pollution control, cleaner production and pollution control in the whole process.

二、绿色制药—源头减排措施

II. Green Pharmacy-Reducing Pollution at Sources

- **政府—政策推动企业实施绿色制药**

  Government---Promote pharmaceutical enterprises to implement green pharmaceuticals through policies.

- **医药行业协会—推动药企实施绿色制药**

  Pharmaceutical profession association---Promote pharmaceutical enterprises to implement green pharmaceuticals.

- **企业—主动实施绿色制药、源头减污**

  Enterprises---Take the initiative to implement green pharmaceuticals and source pollution reduction.

二、绿色制药—源头减排措施

华北制药

II. Green Pharmacy-Reducing Pollution at Sources

1、政府—政策推动企业实施绿色制药

1. Government---Promote pharmaceutical enterprises to implement green pharmaceuticals through policies.

在21世纪初，中国政府意识到制药工业产业结构不尽合理，低端产品多，化学原料药污染难治理等问题，政府从制药行业结构调整、制药工业污染防治技术和行业排放标准、环保税及企业绿色评定等方面，陆续出台了相关支持性政策和行业排放标准，督促、鼓励企业加大转型升级、实施清洁生产和环保治理工作。

At the beginning of the 21st century, the Chinese government realized that the pharmaceutical industry's industrial structure was not rational, there were many low-end products, and the pollution of chemical APIs was difficult to control. The government has successively issued relevant supporting policies and industry discharge standards on the aspects of the pharmaceutical industry structure adjustment, pollution prevention and control technology, industry emission standards, environmental protection taxes and corporate green rating, to urges and encourages enterprises to transformation and upgrade and implement cleaner production and environmental protection.

二、绿色制药—源头减排措施

华北制药

II. Green Pharmacy-Reducing Pollution at Sources

国家相关产业政策引导企业实施源头减污

Using related national industrial policies to guide enterprises to implement source reduction

- **《产业结构调整目录》，限制新增大宗原料药产能。**

  “Industrial Structure Adjustment Catalogue” stipulates that constrain the capacity of additional bulk APIs.

- **《关于加快医药行业结构调整的指导意见》，指出国家重点推进生物医药技术创新与产业化，淘汰制药中高耗能、高耗水、污染大、效率低的落后工艺和设备。**

  “Guidance on Accelerating the Structural Adjustment of the Pharmaceutical Industry” pointed out that the state has focused on promoting the innovation and industrialization of biomedical technology and eliminated outdated technologies and equipment that are high in energy consumption, high in water consumption, polluting, and inefficient in pharmaceuticals.

- **国家工业和信息化部公布《中国制造2025》，鼓励开展绿色制造评选工作，截止2017年底已有26家制药企业被评定为绿色工厂 。**

  “Made in China 2025”that announced by the Ministry of Industry and Information Technology of the People's Republic of China encourages the selection of green manufacturing. By the end of 2017, 26 pharmaceutical enterprises had been assessed as green factories.

二、绿色制药—源头减排措施

II. Green Pharmacy-Reducing Pollution at Sources

国家环保政策督促强化企业末端治理

National environmental protection policy urges enterprises to implement end treatment.

- **《制药工业污水排放标准》，规定了发酵、化学合成、混装制剂、生物制药、中药、提取等6类制药工业污水排放标准，同时规定了单位产品基准排水量。**The "Pharmaceutical Industry Sewage Discharge Standard" stipulates sewage discharge standards of 6 pharmaceutical types in pharmaceutical industry, such as fermentation, chemical synthesis, mixed preparations, biopharmaceuticals, Traditional Chinese Medicine and extraction; it also stipulates the benchmark effluent volume per unit product.
- **《 制药工业污染防治技术政策》，对制药企业清洁生产、三废排放管理、治理设施运行管理、生物安全性风险防范等提出了要求。**The "Pharmaceutical Industry Pollution Prevention and Control Technology Policy " puts forward requirements for the clean production of pharmaceutical enterprises, the management of three wastes discharge (waste gas, waste water, industrial residue), the management and operation of treatment facilities, and the biosafety risk prevention.
- **《“十三五”挥发性有机物污染防治工作方案》、《制药工业大气污染物排放标准》，对制药企业挥发性有机物废气的排放提出了更严的标准。** The “13th Five-Year Plan: Prevention and Control of Volatile Organic Compounds Pollution” and the “Emission Standard of Air Pollutants for the Pharmaceutical Industry” put forward stringent standards for the emission of volatile organic compounds from pharmaceutical enterprises.
- **国家《环境保护税法》2018年1月1日实施，督促企业主动实施减排。**The national "Environmental Protection Tax Law" was implemented on January 1, 2018, and urged enterprises to actively implement emission reductions.

二、绿色制药—源头减排措施

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Ⅱ. Green Pharmacy-Reducing Pollution at Sources

2、医药行业协会—推动药企实施绿色制药

2. Pharmaceutical profession association---Promote pharmaceutical enterprises to implement green pharmaceuticals.

中国化学制药工业协会是政府推进绿色发展的排头兵，积极参与推进行业健康、良性、可持续发展，积极推进绿色制药工艺的认证与认可，组织各类绿色环保发展论坛，为政府、制药会员企业、环保节能产业企业搭建交流、学习、推进平台；起到了提高行业企业绿色发展认识，扩大眼界，促进进步的作用。

The China Chemical Pharmaceutical Industry Association is the pioneer in promoting green development. It actively participates in the promotion of healthy, benign and sustainable development in pharmaceutical industry, actively promotes the certification and recognition of green pharmaceutical processes, and organizes various types of green environmental protection development forums to build communication, learning and promotion platforms for governments, pharmaceutical member enterprises and environmental-friendly and energy-saving industry and enterprises; they have played a role in raising awareness of green development, expanding their horizons and promoting progress in pharmaceutical industry and enterprises.

近年来已将13个重污染与环境友好工艺、12个具有高污染、高环境风险的药物列入国家《高污染、高环境风险产品名录》、《重污染工艺名录》、《环境友好工艺名录》和《环境友好产品名录》。

In recent years, 13 heavily polluted and environmentally friendly processes, 12 drugs with high pollution and high environmental risks have been included in the national “Catalogue of High-Pollution and High-Environmental Risk Products”, “Heavy Pollution Technology List”, “Environmental Friendly Technology List” and “Environmental Friendly Products List”.

二、绿色制药—源头减排措施

华北制药

Ⅱ. Green Pharmacy-Reducing Pollution at Sources

3、企业主动实施绿色制药、源头减污

3. Enterprises---Take the initiative to implement green pharmaceuticals and source pollution reduction.

在源头减排措施中，企业从产业结构调整、原辅材料替代、工艺优化升级、新装备的应用、废物综合利用等多方面采取措施，实施清洁生产，实现节能、降耗、减污、增效。

Following the policy of sources reduction, enterprises adopt measures in various aspects such as industrial restructuring, replacement of raw materials and excipients, optimization and upgrading of processes, application of new equipment, and comprehensive utilization of waste, etc. to implement cleaner production and achieve energy conservation, consumption reduction, pollution reduction, and efficiency improvement.

产业结构调整
Adjustment of industrial structure

- **限制大宗传统、高污染的原料药**
  Constrain traditional and high polluting bulk APIs;
- **发展生物制药、制剂**
  Develop biopharmaceuticals and preparations.
- **例：华北制药实施以上措施，近年来污染物减排50%；制剂药与原料药收入比例由2011年的3:7提高到6.7:3.3。**

二、绿色制药—源头减排措施

华北制药

Ⅱ. Green Pharmacy-Reducing Pollution at Sources

3、企业主动实施绿色制药、源头减污

3. Enterprises---Take the initiative to implement green pharmaceuticals and source pollution reduction.

原辅材料替代
Replacement of raw materials and excipients

- **无毒无害或低毒低害的原料替代高毒和难以去除高度的原料**
  Non-toxic or low-toxic raw materials replace raw materials of high toxicity and hard-to-remove high toxicity.
- **例：水质洗涤液取代其他溶剂、溶液；选择毒性低的或活性保持时间长的、不易流失的催化剂；维生素B12原料中氰化钠的替代。**

废物综合利用
Comprehensive utilization of waste

- **生产过程废物经运处理后回用于生产**
  Wastefrom the production process is returned to production after being treated.
- **例：污水处理产生的沼气、污泥和菌渣气化热解产生的可燃气体，转化热能蒸汽回用于生产。**

二、绿色制药—源头减排措施

华北制药

Ⅱ. Green Pharmacy-Reducing Pollution at Sources

3、企业主动实施绿色制药、源头减污

3. Enterprises---Take the initiative to implement green pharmaceuticals and source pollution reduction.

工艺优化升级
Optimization and upgrading of processes

- **绿色技术应用：如酶法、生物转化、膜技术、结晶技术、手性技术等。**
  Green technology applications: enzymic method, biotransformation, membrane technology, crystallization technology, chirotechnology, etc.
- **例：6-APA、7-ADCA直通工艺的实施，可以实现减污40%，酶法阿莫西林不再使用溶媒，酶法头孢氨苄减少溶媒90%。**

设备替代与更新
Replacement and update of devices.

- **实现节能、节水、减少资源浪费、降噪作用。**
  To achieve the result of energy saving, water saving, waste reduction and noise reduction.
- **例：回收设备结构改造、生产在线检测和监控系统安装、过滤洗涤干燥三合一设备的应用。**

三、绿色制药—末端治理技术

III . Green Pharmacy-End Treatment Technology

1、废水治理技术

1. Treatment technology of wastewater

制药废水特点：

Characteristics of pharmaceutical wastewater:

废水中污染物成分复杂，有机物浓度高、难降解组分多，毒性大，可生化性差。

Complex composition of pollutants in wastewater; high concentration of organic compounds; numerous hard-to-degrade components; high toxicity; poor biodegradability.

目前采取的治理技术：Treatment technology employed currently:

“物化+生物法”、“水解酸化+好氧处理”，近年来随着国家废水排放标准的提高，以“物化预处理+生物法+深度处理”为普遍工艺。

"Physical-chemical + biological method", "hydrolytic acidification + aerobic treatment“; in recent years, with the improvement of national wastewater discharge standards, the "physical-chemical pretreatment + biological method+ advanced treatment" becomes the universal process.

废水治理装置

Wastewater treatment devices

电解预处理

Electrolytic pretreatment

芬顿氧化后处理

Fenton oxidation as post-treatment

MVR高效蒸发

MVR efficient evaporation

CASS生物处理

CASS biotreatment

厌氧生物膜反应器

Anaerobic biofilm reactor

膜生物反应器

Membrane bioreactor

三、绿色制药—末端治理技术

III . Green Pharmacy-End Treatment Technology

2、废气治理技术

2. Treatment technology of waste gas

制药废气特点：废气污染物主要是VOCs和恶臭。

Characteristics of pharmaceutical waste gas: Waste gas pollutants are mainly VOCs and odors.

废气处理技术分为“资源化”和“破坏性”的两类，一般情况下需要采取组合工艺才能达到较好效果。

Waste gas treatment technology is divided into two categories, "resources" and "destructiveness". Normally, combinational processes are needed to achieve better results.

资源化技术
Resources reuse technology

冷凝（冷冻）法、吸收法、吸附法以及近年开始应用的膜分离等。
Condensation (freezing) method, absorption method, adsorbent method, and membrane separation that has been applied in recent years, etc.

破坏性技术
Destructive technology

燃烧法、氧化法、生物法、光催化氧化、低温等离子氧化以及一些情况下的吸收法、吸附法。
Combustion, oxidation, biological, photocatalytic oxidation and low-temperature plasma oxidation methods, and absorbent and absorption methods in some cases.

废气异味治理装置

Waste gas and odors treatment devices

三级碳纤维吸附

Three-steps carbon fiber adsorption

分子筛转轮吸附浓缩

Molecular sieve runner adsorptive enrichment

化学洗涤

Chemical scrub

RTO蓄热焚烧

RTO regenerative thermal oxidizers

生物滤池

Bacteria bed

低温等离子

Low-temperature plasma

三、绿色制药—末端治理技术

III . Green Pharmacy-End Treatment Technology

2、废气治理技术

2. Treatment technology of waste gas

制药废气治理难点：目前异味因子溯源还不到位，部分技术应用缺乏针对性；VOCs及恶臭污染物日常检测方法和仪器亟待完善、推广。

Difficulties in the treatment of pharmaceutical waste gas: At present, the traceability of the odor factor is not yet unfulfilled thoroughly, and some of the technology applications are not targeted; routine detection methods and instruments for VOCs and odor pollutants need to be improved and promoted.

华药大型污水处理厂异味收集装置

Large-scale sewage treatment plant for chemicals--- odor gathering devices

三、绿色制药—末端治理技术

华北制药

III . Green Pharmacy-End Treatment Technology

3、固废综合利用

3. Comprehensive utilization of solid waste

制药固废种类：Types of pharmaceutical solid waste:

制药企业排放的固废包括：菌渣、污泥、釜残、废活性炭、废树脂、废盐、污粉、废溶媒、废包材等废物。

Slag, sludge, distillation residue, waste activated carbon, waste resin, waste salt, waste powder, waste solvent, waste packaging materials and other wastes .

固废综合利用： Comprehensive utilization of solid waste:

无害化技术：热水解、碱解、酶解、水热、热解、焚烧等。

Harmless technology: thermal hydrolysis, alkaline hydrolysis, enzymatic hydrolysis, hydrothermal, pyrolysis, incineration, etc.

资源化技术：企业菌渣肥料化、沼气能源利用、热解气化利用、作生物质燃料、二次发酵生产工业氮源等。

Resources reuse technology: fungi residues transformed into fertilizer, biogas energy utilization, thermal pyrolysis utilization, biomass fuel, and secondary nitrogen to produce industrial nitrogen, etc.

三、绿色制药—末端治理技术

III . Green Pharmacy-End Treatment Technology

3、固废综合利用

3. Comprehensive utilization of solid waste

固废资源化利用
Solid waste recycling utilization

生产废物，经收集、提取、精制、回用于生产
Wastes from production are collected, extracted, refined and recycled for production.
例：青霉素生产过程中的苯乙酸、特戊酸、醋酸钠等原料的回收利用

废物无害化处理后，作为副产物外售综合利用
Wastes after the harmless treatment, they can be treated as by-products for external sales.
例：氯化铵回收、菌渣做肥、华药菌渣加工生物质燃料

企业内部综合利用，热能回用于生产
Internal use, such as thermal energy to be reused to production.
例：菌渣厌氧化产沼气、污泥气化热解

固废综合利用
Comprehensive utilization of solid waste

华药菌渣厌氧发酵设施（5000㎥*3）
Chemicals' bacterial residue anaerobic fermentation devices (5000㎥*3)

菌渣压粒设备
Bacterial residue granulating devices

菌渣生物质燃料
Bacterial residue biomass fuel

四、原料药企业绿色发展方向

Ⅳ. Green Development Direction of API Enterprises

1、提升原料药绿色制造水平

1. Improve APIs' green manufacturing level

利用现代生物技术改进传统生产工艺，大力推广基因工程、生物催化等生物替代技术，积极采用生物发酵方法生产药用活性物质。开发生物转化、高效提取纯化、高产低耗菌种应用等清洁生产技术，从生产过程中减少污染物产生和资源消

耗，推动环境污染源头治理。

Use modern biotechnology to improve the traditional production process, and vigorously promote genetic engineering, biological catalysis and other biological alternative technologies, and actively adopt biological fermentation methods to produce medicinal active substances. Develop clean production technologies such as bio-transformation, high-efficiency extraction and purification, and application of high-yield and low-consumption bacteria, reduce the generation of pollutants and resource consumption from the production process, and promote the pollution management from sources.

四、原料药企业绿色发展方向

Ⅳ. Green Development Direction of API Enterprises

2、推动原料药集约化生产

2. Promote intensive production of APIs

借助“一致性评价”要求，加速提升行业集中度，一致性评价政策的推出对医药行业供给格局产生根本影响，特别是化药仿制药企业会出现大规模去产能状况，龙头企业的市场集中度进一步集中，预计2018年后化药行业的去产能有望超过50%，对行业节能降耗，提高品质将带来显著效果。

Accelerate the promotion of industry concentration by means of "Consistency Evaluation" requirements. The introduction of the consistency evaluation has a fundamental impact on the supply structure of the pharmaceutical industry. In particular, the generic pharmaceutical enterprises of chemical drugs will experience a large-scale capacity reduction, and the market concentration of leading enterprises will be further concentrated. It is expected that after 2018, the capacity reduction of the chemical industry is expected to exceed 50%, which will bring significant results to the industry in terms of energy saving and consumption reduction and quality improvement.

四、原料药企业绿色发展方向

华北制药

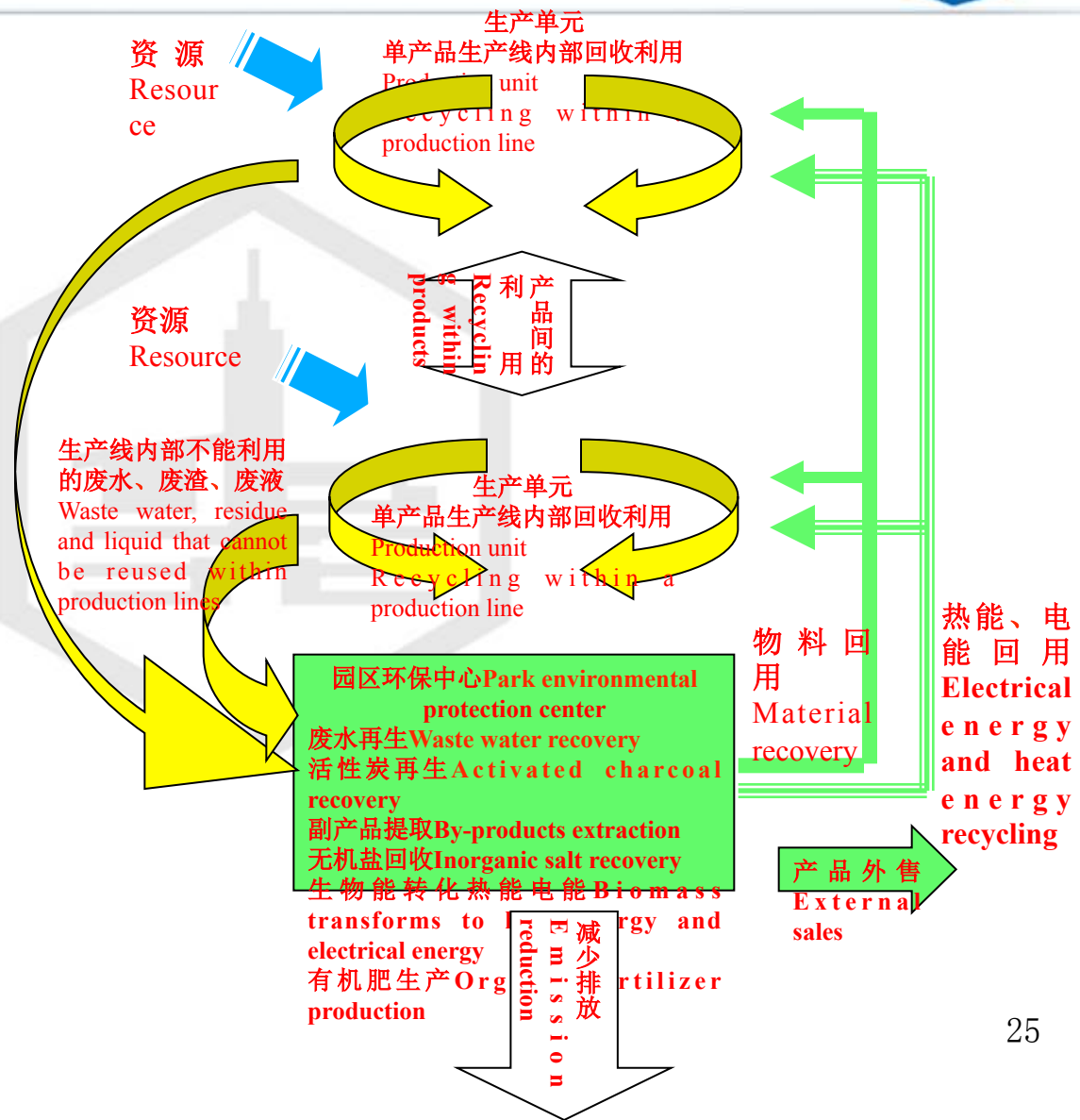
Ⅳ. Green Development Direction of API Enterprises

3、建设高标准集中生产基地

3. Build high standard centralized production base

加快建设绿色工厂和循环经济园区，推动原料互供、资源共享，加强企业内及企业间的副产物循环利用、废弃物无害化处理和污染物综合治理。

Accelerate the construction of green factories and circular economy parks; promote mutual supply of raw materials and resources sharing; and strengthen the recycling of by-products, the harmless disposal of wastes, and the comprehensive treatment of pollutants within and between enterprises.



四、原料药企业绿色发展方向

华北制药

Ⅳ. Green Development Direction of API Enterprises

4、 建立生产过程与末端治理全过程控制示范项目

4. Set up a demonstration project where the production process and the terminal management process are controlled in the whole process.

依托国家重大专项课题《水体污染控制与污染治理技术重大专项重点行业（制药）污染全过程控制技术集成与工程示范项目》—— 进行原料药生产全过程研究，从提高发酵效率、酶法转化工艺、绿色结晶技术、废水抗生素残留强化脱毒、废水高效低成本处理等全过程控制研究，形成指导行业推广应用的技术指南，支撑制药行业可持续发展。

Relying on the national major special project "Pollution Control Integration Technology and Engineering Demonstration Projects in Water Pollution Control and Technology for Major Special Key Industries (Pharmaceutical) "--- the entire process of APIs production should be studied, such as improving the fermentation efficiency, enzymatic conversion process, green crystallization technology, enhanced detoxification of antibiotic residues from wastewater, high-efficiency and low-cost treatment of wastewater, etc., so as to form a technical guide to promote and direct the industry development and support the sustainable development of pharmaceutical industry.

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Thank You