Establishment and Progress of the Standard System of Pharmaceutical Excipient in ChP

Chinese Pharmacopoeia Commission

Comprehensive Division
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ChP-EDQM Workshop on Pharmaceutical Excipients
18 September 2018 Strasbourg, France

Main Contents

- Overall Planning
- Work Progress
- Challenges
- Next Step……
General Notices and General Chapters of Chinese Pharmacopoeia (ChP) shall have the same effects on drug products specification unlisted in ChP but issued by other competent authority.

Standards System of Chinese Pharmacopoeia

Compilation Plan of ChP2020 Edition Vol. IV

To establish a scientific, comprehensive, verifiable and enforceable standard system.
Establish and improve standard system of ChP 2020 edition

Improve standard system of ChP
Improve overall quality control level
Strengthen drug standard system with ChP as the core

Systematic and normative, gaps filled in, international harmonized, features highlighted

Pharmacopoeia standards and technical information platform

Platform construction already completed
- Construction of standard nucleic acid sequence information service platform
- Construction of standard database of pharmaceutical excipients in various countries
- Pharmaceutical excipient standard information service material information platform
- Establishment of drug standard open database
- Design and planning of the new official website of the Pharmacopoeia
- Design of the World Pharmacopoeia English Website
- Construction of drug standard database

Planning . . . .
- Database of genotoxic impurities
- Safety evaluation database for inhaled pharmaceutical packaging materials
- Test results data analysis service platform
- Identification infrared map database of pharmaceutical excipients and pharmaceutical packaging materials
Strengthen supervision of pharmaceutical excipients and packaging materials

- Explore and establish a system for reviewing and approving the examination and approval of pharmaceutical excipients, pharmaceutical packaging materials and pharmaceuticals with key quality risk control as the core and filing management as the means.
- Further clarify the main responsibility of the pharmaceutical production enterprise, supervise and perform the auditing duties on the supplier.
- Carry out extended supervision on manufacturers of pharmaceutical excipients and pharmaceutical packaging materials.
- According to the degree of risk, the pharmaceutical products and pharmaceutical packaging materials are classified and managed to strengthen risk control.
- Improve the standard system of pharmaceutical excipients and pharmaceutical packaging materials.

Related regulations and technical documents on pharmaceutical excipients in China

- Article 4 of the Drug Administration Law: Raw materials, excipients, additives and agricultural inputs used by producers to produce products shall comply with the provisions of laws and administrative regulations and national compulsory standards.
- In June 2004, the "Decision of the State Council on Establishing Administrative Licensing for Administrative Approval Items Needed to Be Reserved" (Order No. 412 of the State Council) clearly reserved the "Registration of Pharmaceutical Excipients" and set it as an administrative licensing project.
- In 2004, SFDA issued a draft for the "Quality Management Regulations for the Production of Pharmaceutical Excipients".
- In 2006, the GMP of Pharmaceutical Excipients was officially promulgated and used as a guiding document, requiring the industry to refer to implement, which is not mandatory.
- On June 21st, 2005, SFDA issued the "Regulations on the Registration of Pharmaceutical Excipients" (provisional documents).
- In September 2005, SFDA issued the "Administrative Measures for Pharmaceutical Excipients" (discussion draft).
- In September 2010, SFDA issued the "Regulations on the Filing of Pharmaceutical Raw and Auxiliary Materials" (draft for comment). In November 2011, it was again publicly solicited for opinions, but it has not been officially released.
- On June 1st, 2012, SFDA issued the "Regulations on Strengthening the Supervision and Management of Pharmaceutical Excipients" (Draft for Comment), which was officially implemented on February 1st, 2013.
- On January 12th, 2016, requirements for the approval of the examination and approval of pharmaceutical packaging materials for medicinal materials (draft for comments).
- On May 22nd, 2017, Announcement was issued on the examination and approval of the evaluation of pharmaceutical excipients, pharmaceutical packaging materials and pharmaceuticals (draft for comments).
- On August 10th, 2016, the announcement on the association evaluation of pharmaceutical excipients, pharmaceutical packaging materials and pharmaceuticals was officially released.
- On May 11th, 2017, Notice of SFDA on the "Relevant Policies on Encouraging Drug and Medical Device Innovation to Accelerate the Examination and Approval of New Drugs for Medical Device Listing" (draft for comment) (No. 52, 2017).
- On March 14th, 2018, Announcement on publicly soliciting on matters relating to the import and customs clearance of raw and auxiliary materials (draft for comments).
- On June 5th, 2018, Comments on the Public Solicitation of "Requirements for Registration of Pharmaceutical Excipients" (draft for comment) and Requirements for Registration of Pharmaceutical Packaging Materials (draft for comment).
- On July 19th, 2018, The API, excipients, packaging materials registration system is online (CDE).
Pharmaceutical excipients and pharmaceutical packaging materials play an increasingly prominent role in preparations

- Most of the pharmaceutical production of excipients, pharmaceutical packaging materials are of source confusion.
- The registration of pharmaceutical excipients and medicines is subject to multiple management, and the use of pharmaceutical excipients and materials is highly dependent on the registration and approval results of the drug regulatory authorities.
- The responsibility subject is unclear.
- A comprehensive and dynamic related association of pharmaceutical excipients and drug packaging materials has not been established.

Issued by the General Office of the State Council

Opinions on reforming and improving the policy of supply and use of generic drugs

A few days ago, the General Office of the State Council issued a circular on reforming and improving the policy of supply and use of generic drugs.

The Opinion puts forward that it is necessary to promote the research and development of generic drugs and focus on solving the shortage of high-quality generic drugs.

The opinion puts forward that it is necessary to highlight the problem orientation and improve the quality and efficacy of generic drugs.

Accelerate the evaluation of the consistency of quality and efficacy of generic drugs, and refine the implementation of policy measures to encourage enterprises to conduct consistent evaluation.

Improve the quality of raw materials and packaging materials, carry out relevant standardization revisions, strengthen research and development, and break through key technologies such as purification and quality control.

Improve the level of process manufacturing and promote the solution of bottlenecks that restrict product quality.

Deepen drug review and approval system reform, optimize the review and approval process, improve registration application standards, improve the quality and safety of generic drugs and the efficiency of listing review and approval.

Strengthen drug quality supervision, speed up the establishment of quality management and quality traceability system covering the whole life cycle of generic drugs, and seriously investigate and punish data violations, cut corners, doping and falsehood.

The Opinion puts forward that We must improve the supporting policies and promote high-quality generic drugs to be implemented in clinical use as soon as possible.

The Opinion puts forward that.

Concepts change of standard proposed by general notices in ChP

Verification of analytical methods
- The suitability of the method shall be verified when the method is prescribed by pharmacopoeia.

Suitability of excipients
- Administration route
- use of the drug preparation, composition, dosage, applicable population
- Safety, stability, risk level

Suitability of packaging material
- Nature of the packaging material, composition, use of drug preparation, features of drug preparation
- Safety, stability, risk level
Project establishment of pharmaceutical excipients standards

2009-2018 Project tasks of drug standards

- Traditional Chinese Medicine
- Chemical drugs
- Biologicals
- Pharmaceutical excipients
- Packaging materials
- Methodology

Pharmaceutical excipients standard system planning

- High risk preparation use
- General rules for pharmaceutical excipients
- General preparation use
- Chemical synthesis, semi-synthesis
- Natural mineral
- Animal sources
- Plant sources
- Processing excipients
- Polymer
- Macromolecular
- Total processing
- Premixing

Whole-process management

- Production raw materials
- Technological processes
- Finished product
- Packaging
- Storage and transportation
- Use

- Audit on the supplier
- Animal source material safety and risk control
- Plant source material safety and risk control
- Stability of source of raw material
- External factor control
- Process stability intermediate quality control
- Virus inactivation verification
- Impurities
- About the material
- Partial requirements
- Process stability
- Process consistency
- Standard of pharmaceutical excipients
- Names of pharmaceutical excipients
- Terminology
- Infrared discriminant spectrum
- Stability evaluation
- Functional evaluation
- Safety evaluation
- Impurities and related substances

- Packaging materials
- Package integrity
- Sterile, non-sterile packaging
- Environment
- Temperature
- Humidity
- Applicability
- Biocompatibility
- Compatibility
- Stability
Technical system for joint quality evaluation of pharmaceutical excipients and packaging materials and preparations

- Applicability of pharmaceutical packaging materials
- Stability of pharmaceutical packaging materials
- Material safety of pharmaceutical packaging materials

API

Compatiblity of drug and pharmaceutical excipients
The applicability of pharmaceutical excipients

drug packaging materials

- The applicability of pharmaceutical excipients and pharmaceutical packaging materials
- Compatibility of pharmaceutical excipients and pharmaceutical packaging materials

Technical association

excipients

Key Work of National Pharmacopoeia Commission
- Establish and improve the standard system for pharmaceutical excipients
- Comprehensively regulate the source and process control requirements of pharmaceutical excipients
- Strengthen the safety control requirements of excipients
- Production, packaging, storage, transportation management specifications

The quality control system of pharmaceutical excipients and pharmaceutical packaging materials was established to ensure the quality of final products
Provide standard technical support to the implementation of the related review and approval system

Framework of standard system of pharmaceutical excipients in ChP

Identification spectrum
Functional evaluation methods
Safety evaluation method

General Notices

Guidelines for the preparation and quality control of animal-derived pharmaceutical excipients
Guidelines for the preparation and quality control of plant-derived pharmaceutical excipients

General requirements for pharmaceutical excipients

Nomenclature of pharmaceutical excipients

Safety evaluation of pharmaceutical excipients
Functional evaluation of pharmaceutical excipients
Compatibility of pharmaceutical excipients
Stability of pharmaceutical excipients

Suitability of pharmaceutical excipients

Manufacturing process, strength, package, storage, transportation
Nomenclature of pharmaceutical excipients (public)

Basic principle:
Chinese Approved Drug Name, Chinese Nomenclature in Polymer Chemistry, INN

Nomenclature of pharmaceutical excipients

- Excipients of small molecule
exciipients
- Excipients of glycoside
- Starch excipients
- Excipients of oil and fat
- Animal-derived excipients
- Compound excipients
- Synthetic or semi-synthetic polymer excipients

Guideline draft for suitability of excipients (drafted)

Use of drug preparation

Manufacturing process

Stability

Compatibility

Safety

Strength

- Composition differences
- Impurities differences
- Structural consistency
- Microbial contamination
- Batch consistency

- Functional stability
- Effects on stability of drug preparation
- Batch stability

- Physical compatibility
- Chemical compatibility
- Biocompatibility

- Biosafety
- Dosage incompatibility of drugs in preion

- Povidone series
- Polyethylene glycol (PEG)
- PLGA
- HPMC
Finished the draft on general chapter of hollow capsules

- Animal sources
  - cow source
  - pig source
  - pig/cow source
- Non-animal source
  - Hydroxypropyl methylcellulose
  - Hydroxypropyl starch
  - Prouan polysaccharides
- Production environment
  - Class D clean area
- Batch by batch principle
- Sterilization process
  - Bacteriostatic agent
- Use of pigment
- Printing ink

Adventitious agents
- The residual solvents
- Pesticide residues, heavy metal, pesticides

- Serial No. 1
  - Taurine
  - Source: Separated from bezoar; Terrestrial mammals have higher levels of liver and bile; marine animals such as cuttlefish, octopus, fish, and shellfish such as oysters and clams

- Serial No. 2
  - Lanolin-free lanolin
  - Source: Wool

- Serial No. 3
  - shellac
  - Source: Animal-derived fatty resin

- Serial No. 11
  - shellac
  - Source: Animal-derived fatty resin

- Serial No. 12
  - Sodium caseinate
  - Source: Cow, sheep

- Serial No. 13
  - Sulfuric acid fish egg
  - Source: Fish

- Serial No. 14
  - Lactose for inhalation
  - Source: Animal milk

- Serial No. 16
  - glycerin
  - Source: Natural animal and vegetable fat refining

- Serial No. 17
  - Lactic acid
  - Source: Fermentation

- Serial No. 18
  - Capsule gelatin
  - Source: Bovine bone, pork bone

- Serial No. 19
  - Squalane
  - Source: Shark liver (botanical)

- Serial No. 20
  - Human albumin
  - Source: Human plasma

Animal source materials and accessories contained in the ChP 2015 edition

2018/9/19
General rules for the production and preparation of pharmaceutical excipients of animal sources

**Starting materials control**
- Animal species, population health status
- Feeding facilities and environment, pathogen monitoring
- Organs extraction, collection, storage and transportation
- Screening before putting into production
- Exogenous factor screening
- Strengthen auditing of suppliers

**Technical process control**
- Process validation, stability, batch-to-batch consistency
- Determine process parameters and process effects
- Strengthen the inspection of exogenous factors pollution of intermediate products
- Production process trend analysis
- Good Manufacturing Practice (GMP) for Excipients
- Prevention and control of pollution, external pollution factors

**Virus inactivation process**
- Virus inactivation verification
- Evaluation of virus inactivation effect
- Establishment of evaluation method for virus inactivation effect
- The effect of virus elimination process on ingredients

**Composition control**
- Import, residual substances, residual reagents
- Prohibition of addition of toxic and hazardous substances
- Control of risky substances
- Safety limit

**Stability control**
- Packaging, storage, transportation
- Use period
- Possible impact assessment during use
- Batch stability and consistency

**Test method**
- Method validation
- Applicability
- Sensitivity
- Specificity
- Comprehensive evaluation

**Variety and use of plant-derived pharmaceutical excipients contained in the ChP 2015 edition**

<table>
<thead>
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<th>Serial No.</th>
<th>Use</th>
<th>Serial No.</th>
<th>Use</th>
<th>Serial No.</th>
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<td>Thioglycolate</td>
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<td>Hypromellose phthalate</td>
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<td>Gum arabic</td>
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<td>Fraction cellulose</td>
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<td>Peccin</td>
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<td>Starch hydroxypropyl</td>
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<td>Hydroxypropyl cellulose</td>
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<td>Hydroxypropyl starch/hamlet complex</td>
<td>Potato starch</td>
<td>47</td>
<td>Ager</td>
<td>Potato starch</td>
<td>63</td>
<td>Glycose</td>
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<tr>
<td>16</td>
<td>Cassava starch</td>
<td>32</td>
<td>Cyclodextrin</td>
<td>Cassava starch</td>
<td>48</td>
<td>Microcrystalline cellulose</td>
<td>Cassava starch</td>
<td>64</td>
<td>Glycose</td>
</tr>
</tbody>
</table>
Raw material sources for pharmaceutical excipients production

Proportion of excipients from different sources

- Animal sources
- Plant sources
- Chemical synthesis

Quality control considerations for excipients derived from plants

Source control
Process control
Quality control

Packaging, storage and transportation

Excipients derived from plants

Species
Source
Security checks

Process validation
Stability
Control link
Records management

Specification, functionality
Impurities, related substances
External pollution
Chinese herbal medicine processing excipients

Chinese herbal medicine processing is considered to change the drug effect

- Yellow wine, white wine, vinegar, salt water, refined honey, ginger juice, licorice juice, black bean juice, evodia rutaecarpa juice, sesame oil, rice bran water, radish juice, Chinese honeylocust fruit juice
- Lime water, river sand, talcum powder, sulfur, cinnabar, terra flava usta (focal subsoil)
- Bile, sheep fat, animal blood, cow’s milk, wheat bran, rice, white peony, glutinous rice, tofu, pollen typhae

General rules of excipients for processing

**Definition:**
The excipients for processing Chinese herbal medicines refer to the additional materials added in addition to the main medicine in the process of processing Chinese herbal medicines, which have the effect of supporting the main medicine to achieve the purpose of processing. After excipients are added to the Chinese herbal medicine and processed, they can play a role in alleviating or changing the performance of the drug, reducing or eliminating the toxic side effects of the drug, enhancing the curative effect, flavoring and odor, and introducing the drug into the menstruation.

- Safety
- Controllability
- Raw materials
- Production process
- Home made processing excipients
- Plants, animals
- Stable quality
- Species identification
- Stable process
- Guarantee period
Principles for selection of pharmaceutical excipients

- Excipients have been approved domestically and used in preparations
- Commonly used excipients for domestic marketed preparations
- Foreign imported excipients are widely used in domestic preparations and have a long history of use.
- The national drug regulatory authorities consider it necessary to develop national standards for pharmaceutical excipients.

Collection of pharmaceutical excipients samples

- In September 2017, 134 samples of medicinal excipients, 66 companies, more than 400 batches of samples were publicly collected.
- In February 2018, 97 companies provided 768 batches of 103 excipients.
The new excipients monographs developing plan in ChP 2020

![Bar chart showing addition and revision counts for first and second batches]

The list of new excipients monographs under development have been published in the ChP website.

### Publicity Status of Standard for Pharmaceutical Excipients

<table>
<thead>
<tr>
<th>Serial No.</th>
<th>Product name</th>
<th>Serial No.</th>
<th>Product name</th>
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<tbody>
<tr>
<td>1</td>
<td>桉油 Eucalyptus Oil</td>
<td>11</td>
<td>磷酸二氢钠一水合物 Sodium Dihydrogen Phosphate monohydrate</td>
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<tr>
<td>2</td>
<td>八角茴香油 Star Anise Oil</td>
<td>12</td>
<td>磷酸钠 Sodium Sulfate</td>
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<td>3</td>
<td>扁桃仁油 Almond Oil</td>
<td>13</td>
<td>磷酸钠十水合物 Sodium Sulfate Decahydrate</td>
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<tr>
<td>4</td>
<td>冰片约成树脂) Borneolum Syntheticum</td>
<td>14</td>
<td>麦芽糖醇 Maltitol</td>
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<tr>
<td>5</td>
<td>二甲基亚胺 Dimethylformamide</td>
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<td>松节油 Turpenline Oil</td>
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<td>肌醇 Inositol</td>
<td>16</td>
<td>无水磷酸二氢钠 Anhydrous Sodium Dihydrogen Phosphate</td>
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<td>油酸聚氧（5-6）酯 PolyoxylOleate(5-6)</td>
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<td>可可脂 Cocoa Butter</td>
<td>19</td>
<td>油酸聚氧（10）酯 PolyoxylOleate(10)</td>
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<td>10</td>
<td>磷酸二氢钠二水合物 Sodium Dihydrogen Phosphate dihydrate</td>
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<td>月桂酸 Lauric acid</td>
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## Publicity Status of Standard for Pharmaceutic Excipients

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<td>内京麝香甲酯 Methyl Myristate</td>
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<td>铝酸钙 Aluminum Stearate</td>
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<td>4</td>
<td>丁烷 Butane</td>
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<td>15</td>
<td>内京麝香异丙酯 Isopropyl Myristate</td>
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<td>钙酸钙 Sodium Stearate</td>
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<td>27</td>
<td>月桂醇 Lauryl Alcohol</td>
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<td>异丁烷 Isobutane</td>
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<td>17</td>
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<td>2018-4-8</td>
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<td>甜菊素 Steviosin</td>
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<td>对甲基苯酸 Methyl Palmitic Acid</td>
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</tr>
<tr>
<td>8</td>
<td>对氯苯甲酸 Paracetamol</td>
<td>2018-4-8</td>
<td>19</td>
<td>甜菊素 Steviosin</td>
<td>2018-4-8</td>
<td>31</td>
<td>月桂酸 Calcium Stearate</td>
<td>2018-4-8</td>
</tr>
<tr>
<td>9</td>
<td>丙三醇 Propylene Glycol</td>
<td>2018-4-8</td>
<td>20</td>
<td>甜菊素 Steviosin</td>
<td>2018-4-8</td>
<td>21</td>
<td>小茴香 Oil Bitter-Fennel Fruit Oil</td>
<td>2018-4-8</td>
</tr>
<tr>
<td>10</td>
<td>己二酸 Adipic Acid</td>
<td>2018-4-8</td>
<td>22</td>
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<td>2018-4-8</td>
<td>22</td>
<td>柠檬油 Lemon Oil</td>
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</table>

## Publicity Status of Standard for Pharmaceutic Excipients

<table>
<thead>
<tr>
<th>Serial No.</th>
<th>Product name</th>
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<th>Serial No.</th>
<th>Product name</th>
<th>Time</th>
<th>Serial No.</th>
<th>Product name</th>
<th>Time</th>
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<tbody>
<tr>
<td>1</td>
<td>右旋糖酐 20 Dextran 20</td>
<td>2018-4-27</td>
<td>12</td>
<td>四氯乙烯四氢化碳 Tetrafluoroethane</td>
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<td>23</td>
<td>维生素 C Vitamin C</td>
<td>2018-7-3</td>
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<td>2018-4-27</td>
<td>13</td>
<td>七氟丙烷 Heptafluoropropane</td>
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<td>钙酸钙 Calcium Stearate</td>
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<td>花生油 Peanut Oil</td>
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<td>17</td>
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<td>2018-8-13</td>
<td>28</td>
<td>呋喃苯胺 Furfurylamine</td>
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<td>柠檬酸 Lactic Acid</td>
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<td>19</td>
<td>椰子油 Coconut Oil</td>
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<td>呋喃苯胺 Furfurylamine</td>
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<tr>
<td>9</td>
<td>甘露醇 Mannitol</td>
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<td>20</td>
<td>无水磷酸二氢钠 Anhydrous Sodium Dihydrogen Phosphate</td>
<td>2018-8-13</td>
<td>31</td>
<td>呋喃苯胺 Furfurylamine</td>
<td>2018-7-3</td>
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<tr>
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<td>无水磷酸二氢钠 Anhydrous Sodium Dihydrogen Phosphate</td>
<td>2018-8-13</td>
<td>32</td>
<td>呋喃苯胺 Furfurylamine</td>
<td>2018-7-3</td>
</tr>
</tbody>
</table>
Establishment of standard database for pharmaceutic adjuvant

Challenge

- Industry level is not high
- Weak research base
- Lack exchange of supply and demand information
- Management model needs to be changed
- Establish evaluation criteria
- Product intrinsic quality
- Set up the testing method
- . . . .
Problems with standards development

- Variety (what the industry needs)
- Sample (what industry uses)
- Project (what the industry concerned about)
- Limits (what industry does)
- Process (what is used in the industry)
- Source (what industry uses)
- Specification (what does the enterprise need)

Next steps…

- Clarify positioning, make up the short board, fill the blank, strengthen the association
- Strengthen the establishment of the drug standard system
- It is suggested to review and approve the standard system by using associated evaluation
- Perfect the test method establishment, method transformation, test result analysis and evaluation platform
- Improve the establishment of digital drug standards
- Perfect the establishment of drug standards and resource database
Summary

- Material safety control
- Identification of production materials
- Formulation process control
- Specification of detection method
- Establishment of test items
- Establishment the whole process, life-cycle control system
- Establishment of considerations, strategies, and methods for the study of associations with preparations
- Establishment the whole process, life-cycle control system
- Strengthen the general chapter draft on the compatibility, suitability and stability of the excipients

Thank you for your attention