

Product List

Hovione has developed a range of customized particle engineered APIs with superior powder properties and a suite of innovative, highly specialized Device Platforms that are able to address the challenges in your formulation development.

Inhalation

Particle Engineered/Customized APIs

Corticosteroids

| PRODUCT | ROUTE OF ADMINISTRATION | | CAS NUMBER | CUSTOMIZED PARTICLE SIZE | REGULATORY STATUS |
|--------------------------------|----------------------------|------------------------|---------------|--------------------------|--|
| Fluticasone Furoate | O Inhalation 🔒 N | Nasal | 397864-44-7 | ~ | US DMF |
| Fluticasone Propionate | Onhalation 🔒 | Nasal <u>O</u> Topical | 80474-14-2 | ~ | CEP, US DMF, JP DMF, CN DMF, KR DMF |
| Mometasone Furoate Anhydrous | Onhalation 🔒 N | Nasal <u></u> Topical | 83919-23-7 | ~ | CEP, US DMF, JP DMF |
| Mometasone Furoate Monohydrate | Ø Inhalation 🔒 N | Nasal | 141646-00-6 | ~ | CEP, US DMF, JP DMF, CN DMF |

LABA/LAMA

| PRODUCT | ROUTE OF ADMINISTRATION | CAS NUMBER | CUSTOMIZED PARTICLE SIZE | REGULATORY STATUS |
|------------------------|----------------------------|---------------|--------------------------|----------------------|
| Umeclidinium Bromide | (A) Inhalation | 869113-09-7 | ~ | DEV, TECH PACK |
| Vilanterol Trifenatate | (A) Inhalation | 503070-58-4 | ~ | GMP, TECH PACK |
| Salmeterol Xinafoate | (Inhalation | 94749-08-3 | ~ | CEP, US DMF |

Formulation Services

- Carrier-based, composite and carrier-free formulation development
- Generic deformulation and formulation services
- Novel formulation development
- Spray Drying, Jet Milling and Wet Polishing particle engineering capabilities
- API particle customization to tailor formulation performance
- $\bullet \ {\hbox{Dry powder inhalation drug product manufacturing:}}$
 - High and low shear powder blending
 - · Capsule, reservoir, and blister filling
- Biorelevant analytical formulation testing
- Integrated API, excipient, blending, device and analytical formulation capabilities

Patented Device Platforms

| DEVICE | ROUTE OF ADMINISTRATION | TYPE | DOSING | DOSE RANGE | APPLICATIONS |
|-----------------------|-------------------------|-----------|------------|-------------------|--|
| Nasal Powde Device | r 🚵 Nasal | Capsule | Single-use | Up to 40mg | Acute treatments and Rescue therapies |
| Sunriser® DPI | ⊘ Inhalation | Capsule | Multi-use | Up to 50mg | Asthma, COPD, Cystic Fibrosis and more |
| TwinCaps® DPI | ₽ Inhalation | Reservoir | Single-use | Up to 2 x 30mg | Anti-virals, Vaccines, rescue therapies and more |
| Large Dose DPIs | 0 Inhalation | Reservoir | Single-use | Up to 8 x 50mg | Antibiotics, Biologics, Anti-virals and more |
| PowdAir® DPI | 0 Inhalation | Capsule | Reusable | Up to 50mg | Asthma, COPD, Cystic Fibrosis and more |
| Papillon DPI | ∂ Inhalation | Blister | Reusable | Up to 50mg | Asthma, COPD, Cystic Fibrosis and more |

- Available for integrated formulation-device development, licensing, supply and customization
- Active collaborations with device partners to bring the right dry powder inhalation device for every formulation

From feasibility to commercial







Product List



Oral, Injectable, Topical and Ophthalmic

Security of supply

Hovione provides the peace of mind of a high-quality manufacturer who is a founding member of Rx-360 and has an unblemished regulatory track record.

| | ROUTE OF ADMINISTRATION | CAS NUMBER | CUSTOMIZED PARTICLE SIZE | REGULATORY STATUS |
|----------------------------------|-------------------------|---------------|--------------------------|--------------------------------|
| Doxycycline Hyclate | Oral Injectable | 24390-14-5 | ~ | CEP, US DMF, JP DMF |
| Doxycycline Monohydrate | Oral | 17086-28-1 | ~ | CEP, US DMF |
| Minocycline Base | Oral Injectable | 10118-90-8 | ~ | US DMF |
| Minocycline Hydrochloride | Oral Injectable Oral | 13614-98-7 | ~ | CEP, US DMF, JP DMF, CN DMF |
| Corticosteroids | | | | |
| PRODUCT | ROUTE OF ADMINISTRATION | CAS NUMBER | CUSTOMIZED PARTICLE SIZE | REGULATORY STATUS |
| Betamethasone Acetate | Ophthalmic Injectable | 987-24-6 | 905 | US DMF |
| Betamethasone Disodium Phosphate | Ophthalmic Injectable | 151-73-5 | | US DMF, JP DMF, CA DN |
| Halobetasol Propionate | <u> </u> | 66852-54-8 | ~ | ASMF, US DMF, CA DMF |
| Hydrocortisone Aceponate | <u></u> Topical | 74050-20-7 | ~ | ASMF & VMF |
| Antiparasitic | • | | | |
| PRODUCT | ROUTE OF ADMINISTRATION | CAS NUMBER | CUSTOMIZED PARTICLE SIZE | REGULATORY STATUS |
| Ivermectin | Oral Oral | 70288-86-7 | | CEP, US DMF, JP DMF |
| Excipients | | | | |
| PRODUCT | ROUTE OF ADMINISTRATION | CAS NUMBER | CUSTOMIZED PARTICLE SIZE | REGULATORY STATUS |
| DTPA (Pentetic Acid) | Injectable | 67-43-6 | | GMP, TECH PACK, CN DN |

Drug Delivery Expertise

- Solubility Enhancement Platforms:
 - ASD-HIPROS, Dispersome®
- Sustained Release
- Ophthalmic
- Inhalation and Nasal

Manufacturing Services

- Integrated offer: from chemical synthesis to drug product manufacturing
- Bottom-up and Top-down particle engineering by:
 - Spray drying, Spray congealing, Hot melt extrusion, Co-precipitation, Crystallization and Milling
- · Batch tableting and precision capsule filling
- Continuous Tableting

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