



RCD REGULATORY & CERTIFICATION DATABASE



KEY FEATURES

- > Find the highest quality API producers worldwide
- > Quickly see their regulatory approvals for each active ingredient. **For example:**
 - DMFs
 - VMFs
 - COSs
 - Japanese DMFs
 - Korean DMFs
- > Quickly see the GMP Certification status for each company. **For example:**
 - FDA inspections
 - European GMP
 - Indian GMP
 - Indian approved foreign mfg
 - Chinese GMP
 - WHO GMP



WHO WILL BENEFIT

- > Manufacturers of intermediates
- > Sellers of Intermediates
- > Purchasing Agents at Producers of Dosage from Drugs
- > Marketing Personnel at Active Ingredient Producers

AVAILABLE FORMATS

Online access as single user or site license accounts, updated daily



SUBSCRIBER ADVANTAGES



- Annual subscription with unlimited searching
- Access to more than 28,000 active ingredient and excipient names including synonyms
- Access to more than 12,000 pharmaceutical companies worldwide

All active ingredients manufactured using the intermediate 7-ACA

| Nomenclature | | 7-aminocephalosporanic acid | |
|---------------------------------|-------------------|-----------------------------|---|
| Intermediate | Active Ingredient | RCD | |
| ACTIVE INGREDIENTS 58 result(s) | | | |
| Name | CAS Number | Originator | Market Status Uses |
| Cefacetrile | 10206-21-0 | Ciba-Geigy (Novartis) | Launched Antibacterial |
| Cefaclor | 70356-03-5 | Eli Lilly | Launched Antibacterial |
| Cefalexin | 15686-71-2 | Eli Lilly | Launched Antibacterial |
| Cefaloglycin | 22202-75-1 | Eli Lilly | Launched Antibacterial |
| Cefaloridine | 50-59-9 | Glaxo (GSK) | Launched Antibacterial |
| Cefalotin | 153-61-7 | Eli Lilly | Launched Antibacterial |
| Cefamandole | 34444-01-4 | Eli Lilly | Launched Antibacterial |
| Cefapirin | 21593-23-7 | Bristol-Myers Squibb (BMS) | Launched Antibacterial ; Antibacterial (veterinary) |
| Cefatrizine | 51627-14-6 | SmithKline French (GSK) | Launched Antibacterial |
| Cefazedone | 56187-47-4 | E. Merck KGaA | Launched Antibacterial |
| Cefazolin | 25953-19-9 | Fujisawa | Launched Antibacterial |
| Cefbuparazone | 76610-84-9 | Toyama | Launched Antibacterial |
| Cefdinir | 91832-40-5 | Fujisawa | Launched Antibacterial |

Users of the intermediate 7-ACA and the active ingredients they produce with it (sorted by Company)

| Nomenclature | | | | | | | | | | | | |
|-------------------|-----------------------------------|-----|--|-----|------|------|------|------|------|------|-----|--|
| Intermediate | Active Ingredients | RCD | | | | | | | | | | |
| RCD 194 result(s) | | | <div><input checked="" type="radio"/> Order by Company, AI <input type="radio"/> Order by AI, Company Export</div> | | | | | | | | | |
| Company | AI | DMF | VMF | COS | JDMF | KDMF | FDAL | EGMP | CGMP | IGMP | WHO | |
| ACS Dobfar S.p.A. | Cefaclor | ✓ | | ✓ | ✓ | | ✓ | ✓ | ✓ | ✓ | | |
| ACS Dobfar S.p.A. | Cefalexin | ✓ | | ✓ | ✓ | | ✓ | ✓ | ✓ | ✓ | | |
| ACS Dobfar S.p.A. | Cefatrizine with propylene glycol | ✓ | | ✓ | ✓ | | ✓ | ✓ | ✓ | ✓ | | |
| ACS Dobfar S.p.A. | Cefazolin sodium | ✓ | | ✓ | ✓ | | ✓ | ✓ | ✓ | ✓ | | |
| ACS Dobfar S.p.A. | Cefepime | ✓ | | ✓ | ✓ | | ✓ | ✓ | ✓ | ✓ | | |
| ACS Dobfar S.p.A. | Cefepime hydrochloride | ✓ | | ✓ | ✓ | | ✓ | ✓ | ✓ | ✓ | | |
| ACS Dobfar S.p.A. | Cefoperazone sodium | ✓ | | ✓ | ✓ | | ✓ | ✓ | ✓ | ✓ | | |
| ACS Dobfar S.p.A. | Cefotaxime | ✓ | | ✓ | ✓ | | ✓ | ✓ | ✓ | ✓ | | |
| ACS Dobfar S.p.A. | Cefotaxime sodium | ✓ | | ✓ | ✓ | | ✓ | ✓ | ✓ | ✓ | | |
| ACS Dobfar S.p.A. | Cefotetan disodium | ✓ | | ✓ | ✓ | | ✓ | ✓ | ✓ | ✓ | | |
| ACS Dobfar S.p.A. | Cefoxitin | ✓ | | ✓ | ✓ | | ✓ | ✓ | ✓ | ✓ | | |
| ACS Dobfar S.p.A. | Cefoxitin sodium | ✓ | | ✓ | ✓ | | ✓ | ✓ | ✓ | ✓ | | |

Users of the intermediate 7-ACA and the active ingredients they produce with it (sorted by Active Ingredient)

| Nomenclature | | 7-aminocephalosporanic acid | | | | | | | | | | |
|-------------------|--|-----------------------------|--|-----|------|------|------|------|------|------|-----|--|
| Intermediate | Active Ingredients | RCD | | | | | | | | | | |
| RCD 194 result(s) | | | <input type="radio"/> Order by Company, AI <input checked="" type="radio"/> Order by AI, Company <input type="button" value="Export"/> | | | | | | | | | |
| AI | Company | DMF | VMF | COS | JDMF | KDMF | FDAL | EGMP | CGMP | IGMP | WHO | |
| Cefaclor | ACS Dobfar S.p.A. | ✓ | | ✓ | ✓ | | ✓ | ✓ | ✓ | ✓ | | |
| Cefaclor | Centrient Pharmaceuticals | ✓ | | ✓ | ✓ | | ✓ | ✓ | ✓ | ✓ | | |
| Cefaclor | Lupin Limited | ✓ | | ✓ | ✓ | | ✓ | ✓ | ✓ | ✓ | | |
| Cefaclor | Qilu Antibiotics Pharmaceutical Co., Ltd. | ✓ | | ✓ | ✓ | | ✓ | ✓ | ✓ | ✓ | | |
| Cefaclor | Sun Pharmaceutical Industries Ltd. | ✓ | | ✓ | ✓ | | ✓ | ✓ | ✓ | ✓ | | |
| Cefaclor | Unimark Remedies Limited | ✓ | | ✓ | ✓ | | ✓ | ✓ | ✓ | ✓ | | |
| Cefaclor | Zhejiang Dongbang Pharmaceutical Co., Ltd. | ✓ | | ✓ | ✓ | | ✓ | ✓ | ✓ | ✓ | | |
| Cefalexin | ACS Dobfar S.p.A. | ✓ | | ✓ | ✓ | | ✓ | ✓ | ✓ | ✓ | | |
| Cefalexin | Antibioticos De Leon S.L.U. | ✓ | | ✓ | ✓ | | ✓ | ✓ | ✓ | ✓ | | |
| Cefalexin | Aurobindo Pharma Ltd. | ✓ | | ✓ | ✓ | | ✓ | ✓ | ✓ | ✓ | | |
| Cefalexin | Centrient Pharmaceuticals | ✓ | | ✓ | ✓ | | ✓ | ✓ | ✓ | ✓ | | |
| Cefalexin | Lupin Limited | ✓ | | ✓ | ✓ | | ✓ | ✓ | ✓ | ✓ | | |

The world's highest quality producers of Aciclovir with their DMFs and GMP status

| Name | Aciclovir | CAS Number | 59277-89-3 | Originator | Wellcome Foundation (GSK) | Market Status | Launched | Uses | Antiviral | | |
|--|------------------|------------|------------|------------|---------------------------|---------------|----------|------|-----------------|-------------|-------|
| Active Ingredients | Intermediate | Reaction | RCD | DMF | COS | KDMF | Company | SPC | US Paragraph IV | Orange Book | Trial |
| RCD 19 result(s) | | | | | | | | | | | |
| <div><div><div><div><div><div></div><div>Order by Company</div></div><div><div>Order by Company, AI</div><div>Order by AI, Company</div></div></div><div><div>Export</div></div></div></div></div> | | | | | | | | | | | |
| Company | AI | DMF | VMF | COS | JDMF | KDMF | FDAI | EGMP | CGMP | IGMP | WHO |
| Aurore Life Sciences Private Limited | Acyclovir | | | | | | | | | | |
| Excella GmbH & Co. Kg | Acyclovir | | | | | | | | | | |
| Excella GmbH & Co. Kg | Acyclovir sodium | | | | | | | | | | |
| Hainan Poly Pharm Co., Ltd. | Acyclovir sodium | | | | | | | | | | |
| Hetero Drugs Limited | Acyclovir | | | | | | | | | | |
| Hubei Yitai Pharmaceutical Co., Ltd. | Acyclovir | | | | | | | | | | |
| Mylan Laboratories Limited | Acyclovir | | | | | | | | | | |
| Olon S.p.A. | Acyclovir | | | | | | | | | | |
| Piramal Enterprises Ltd. | Acyclovir | | | | | | | | | | |
| Quimica Sintetica | Acyclovir | | | | | | | | | | |
| Recordati S.P.A. | Acyclovir | | | | | | | | | | |
| Signa S.A. de C.V. | Acyclovir | | | | | | | | | | |

| Name | Aciclovir | CAS Number | 59277-89-3 | Originator | Wellcome Foundation (GSK) | Market | | | | | |
|--------------------------------------|--------------|------------|------------|------------|---------------------------|--------|------|---------|------------------|-----------------|---|
| Active Ingredients | Intermediate | Reaction | RCD | DMF | COS | JDMF | KDMF | Company | SPC | US Paragraph IV | O |
| RCD 19 result(s) | | | | | | | | | | | |
| Company | | | | | | | | | AI | | |
| Aurore Life Sciences Private Limited | | | | | | | | | Acyclovir | | |
| Excella GmbH & Co. Kg | | | | | | | | | Acyclovir | | |
| Excella GmbH & Co. Kg | | | | | | | | | Acyclovir sodium | | |
| Hainan Poly Pharm Co., Ltd. | | | | | | | | | Acyclovir sodium | | |
| Hetero Drugs Limited | | | | | | | | | Acyclovir | | |
| Hubei Yitai Pharmaceutical Co., Ltd. | | | | | | | | | Acyclovir | | |
| Mylan Laboratories Limited | | | | | | | | | Acyclovir | | |
| Olon S.p.A. | | | | | | | | | Acyclovir | | |
| Piramal Enterprises Ltd. | | | | | | | | | Acyclovir | | |
| Quimica Sintetica | | | | | | | | | Acyclovir | | |
| Recordati S.P.A. | | | | | | | | | Acyclovir | | |
| Signa S.A. de C.V. | | | | | | | | | Acyclovir | | |

Click on any RCD record to see all the supporting details

| DMF 1 result(s) | | | | | |
|-----------------------------|------------------------------------|--------------------------------|-----------------------------------|---------------|--|
| Number | Type | Submission Date | Holder | Subject | |
| 25587 | II | 13/12/2011 | HETERO DRUGS LTD | ACYCLOVIR | |
| COS 1 result(s) | | | | | |
| Certificate Number | Issue Date | Substance Name | Certificate Holder | | |
| R1-CEP 2012-090-Rev 01 | 05/07/2020 | Aciclovir | HETERO DRUGS LIMITED Hyderabad IN | | |
| FDA INSPECTIONS 7 result(s) | | | | | |
| FEI | Firm Name | Country | Insp End Date | FDA483 Issued | |
| 3009225386 | Hetero Drugs Limited (Unit IX) | India | 10/02/2017 | N | |
| 3009488373 | Hetero Drugs Limited | India | 15/09/2017 | N | |
| 3003510514 | Hetero Drugs Ltd. - Unit 1 | India | 02/03/2018 | Y | |
| 3004378446 | Hetero Labs Limited | India | 14/03/2017 | N | |
| 3004378446 | Hetero Labs Limited | India | 28/09/2018 | Y | |
| 3009093782 | Hetero Labs Ltd. - Unit IX | India | 18/08/2017 | Y | |
| 3009093782 | Hetero Labs Ltd. - Unit IX | India | 14/05/2019 | Y | |
| EUROPE GMP 21 result(s) | | | | | |
| Certificate Number | EudraGMP Document Reference Number | Site Name | | | |
| 19MP007HPT02 | 54929 | HETERO DRUGS LIMITED Unit-I | | | |
| IT/E/API/2/2020 | 79819 | Hetero Drugs Limited, Unit IX. | | | |



VISIT OUR WEBSITE FOR MORE INFORMATION:

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