

## Cortico-Steroid APIs

Abiraterone Acetate

Beclomethasone Dipropionate

Betamethasone

Betamethasone Acetate

Betamethasone Dipropionate

Betamethasone Sodium Phosphate

Betamethasone Valerate

Budesonide

Clobetasone Butyrate

Clobetasol Propionate

Cloprednol

Clocortolone Pivalate

Deflazacort

Desonide

Desoximethasone

Dexamethasone

Dexamethasone Sodium Phosphate

Difluprednate

Fluocinolone Acetonide

Flumethasone

Fluorometholone

Flurandrenolide

Fluticasone Furoate

Fluticasone Propionate

Halobetasol Propionate

Halometasone Monohydrate

Hydrocortisone

Hydrocortisone Acetate

Hydrocortisone Butyrate

Hydrocortisone Hemisuccinate

Hydrocortisone Sodium Succinate  
(Buffered 5%)

Hydrocortisone Valerate

Methylprednisolone

Methylprednisolone Aceponate

Methylprednisolone Acetate

Methylprednisolone Hemisuccinate

Methylprednisolone Sodium Succinate  
(Buffered 3%)

Mometasone Furoate

Mometasone Furoate Monohydrate

Prednisone

Prednisolone

Prednisolone Acetate

Prednisolone Hemisuccinate

Prednisolone Sodium Phosphate

Triamcinolone Acetonide



### Technical Services

- Process Development at Lab Scale
- Scale Up on Kilo capacity under GMP conditions
- Process Validation
- Analytical Method development and Validation
- Impurities and Working Std. Synthesis
- Commercial Scale Production

### Operating Range

- Capable of operating and controlling temperatures from -70°C to +130°C
- Capable of handling variety of Strong Alkalis and Acids including HF

### Laboratory

HPLCs, Preparatory HPLC, GCs (Head Space), TOCs, UVs, FT-IR, Particle Size Analyzer (Malvern) and complete Microbiology Set-up

### Reaction Capabilities

6- $\alpha$  and 9- $\alpha$  Fluorination

6- $\alpha$  Methylation

Grignard Reactions

Dehydrogenation (Chemical / Microbial)

Epoxydation

Iodination & Substitution

Bromination & Debromination

Reduction

Chlorination

Esterification

Phosphorylation

Oxidation Reaction

Mannich Reaction

Cyanation Reaction

Bromination & Substitution Reaction

Ethynylation Reaction

Enolation Reaction

Deprotonation Reaction

Suzuki Coupling Reaction

Simmon Smith Reaction

Lactonization

N-butyl Lithium Reaction

## Regulatory Filing Cortico-Steroid APIs

Products	CEP/ASMF obtained	US DMF obtained
Abiraterone Acetate	To be filed	To be filed
Beclomethasone Dipropionate Anhydrous	R1-CEP-2005-062-Rev 01	US DMF No. 28137
Betamethasone	R1-CEP 2011-285-Rev 01	US DMF No. 25197
Betamethasone Dipropionate	R1-CEP 2012-079-Rev 00	US DMF No. 25798
Betamethasone Valerate	R1-CEP-2008-307-Rev 00	US DMF No. 22062
Clobetasol Propionate	R1-CEP-2007-263-Rev 02	US DMF No. 20821
Clobetasone Butyrate	R0-CEP-2012-282-Rev 02	To be filed
Cloprednol	ASMF Filed	To be filed
Clocortolone Pivalate	To be filed	To be filed
Deflazacort	ASMF Filed	US DMF No. 24691
Desonide	To be filed	To be filed
Desoximetasone	To be filed	US DMF No. 22400
Dexamethasone	To be filed	To be filed
Dexamethasone Sodium Phosphate	To be filed	To be filed
Fluandrenolide	To be filed	To be filed
Flumethasone	To be filed	US DMF No. 25547
Fluorometholone	To be filed	To be filed
Fluocinolone Acetonide	To be filed	To be filed
Fluticasone Furoate	To be filed	To be filed
Fluticasone Propionate	To be filed	To be filed
Halobetasol Propionate	To be filed	US DMF No. 19402
Hydrocortisone	CEP 2018 - 054	US DMF No. 31349
Hydrocortisone Acetate	CEP-2016-228	US DMF No. 30820
Hydrocortisone Hemisuccinate	R0-CEP 2014-120-Rev 00	US DMF No. 29221
Hydrocortisone Sodium Succinate 5% (Buffered Sterile Lyophilized)	ASMF filed	To be filed
Hydrocortisone Valerate	To be filed	To be filed
Methylprednisolone	R0-CEP 2014-015-Rev 02	US DMF No. 27783
Methylprednisolone Acetate	R1-CEP 2011-063-Rev 00	US DMF No. 24611
Methylprednisolone Hemisuccinate	R1-CEP 2009-187-Rev 02	US DMF No. 22904
Methylprednisolone Sodium Succinate 3% (Buffered Sterile Lyophilized)	ASMF filed	To be filed
Mometasone Furoate	R1-CEP 2007-194-Rev 02	US DMF No. 20684
Mometasone Furoate Monohydrate	To be filed	US DMF No. 25448
Prednisolone	To be filed	To be filed
Prednisone	To be filed	To be filed
Prednisolone Acetate	CEP 2018-089	US DMF No. 032728
Prednisolone Hemisuccinate	ASMF Filed	US DMF No. 24630
Prednisolone Sodium Phosphate	R1-CEP 2011-149-Rev 00	US DMF No. 023899
Prednisolone Sodium Phosphate (Process-2)	R0-CEP 2016-205-Rev 00	To be filed
Triamcinolone Acetonide	R1-CEP 2008-032-Rev 03	US DMF No. 21263
16- $\alpha$ Hydroxy Prednisolone	To be filed	US DMF No. 29224

## Hormone APIs

Boldenone  
 Conjugated Estrogens  
 Desogestrel  
 Dihydrotestosterone (Stanolone)  
 Drospirenone  
 Esterified Estrogens  
 Estradiol  
 Estradiol Hemihydrate  
 Ethinyl Estradiol  
 Ethisterone  
 Ethynodiol Diacetate  
 Gestodene  
 Hydroxyprogesterone  
 Caproate  
 Levonorgestrel

Nandrolone  
 Nandrolone Decanoate  
 Nandrolone Phenyl Propionate  
 Norethindrone Base & Acetate  
 Progesterone  
 Testosterone  
 Testosterone Cypionate  
 Testosterone Decanoate  
 Testosterone Enanthate  
 Testosterone Isocaproate  
 Testosterone Phenylpropionate  
 Testosterone Propionate  
 Testosterone Undecanoate

**Others**  
 Exemestane  
 Rocuronium Bromide

## Intermediates

11-OH Canrenone  
 16- $\alpha$  Hydroxyprednisolone  
 16- $\alpha$  Methyl Epoxide (8DM)  
 16- $\beta$  Methyl Epoxide (DBXI)  
 17- $\alpha$  Hydroxyprogesterone  
 Estrone  
 Ethisterone  
 Prasterone (DHEA) & more ...

## Under Development

Gestonorone Acetate  
 Medrogestone  
 Medroxyprogesterone Acetate  
 Megestrol Acetate  
 Nomigestrol Acetate  
 Spironolactone  
 Ulipristal Acetate  
 Ursodeoxycholic Acid

## Regulatory Filing- Hormone APIs

Products	CEP/ASMF obtained	US DMF obtained
Conjugated Estrogen (Synthetic)	To be filed	To be filed
Dehydroepiandrosterone (DHEA/Prasteron)	To be filed	US DMF No. 29004
Desogestrel	To be filed	US DMF No. 28124
Drospirenone	CEP 2018-118	US DMF No. 032885
Estradiol Hemihydrate	To be filed	To be filed
Estradiol Valerate	To be filed	To be filed
Esterified Estrogens	To be filed	US DMF No. 27920
Estrone	To be filed	To be filed
Ethinyl Estradiol	To be filed	US DMF No. 26020
Ethynodiol Diacetate	To be filed	US DMF No. 26021
17- $\alpha$ - Hydroxyprogesterone	To be filed	US DMF No. 29030
Hydroxyprogesterone Caproate	To be filed	US DMF No. 30747
Levonorgestrel	To be filed	US DMF No. 27867
Medroxyprogesterone acetate	To be filed	To be filed
Nandrolone Decanoate	To be filed	To be filed
Nandrolone Phenylpropionate	To be filed	To be filed
Norethisterone Base	To be filed	To be filed
Testosterone	RO-CEP-2015-314-Rev 00	US DMF No. 29869
Testosterone Cypionate	To be filed	US DMF No. 29023
Testosterone Decanoate	To be filed	To be filed
Testosterone Enanthate	To be filed	US DMF No. 26166
Testosterone Propionate	To be filed	US DMF No. 25535
Testosterone Undecanoate	To be filed	US DMF No. 25534
Progesterone	To be filed	US DMF No. 032709
Stanolone	ASMF filed	To be filed

## Regulatory Filing- Other APIs

Products	CEP/ASMF obtained	US DMF obtained
Exemestane	To be filed	To be filed
Rocuronium Bromide	To be filed	To be filed