



Offers a comprehensive range of Corticosteroid and Steroidal-Hormone APIs, supported by US Drug Master Files (USDMF) and Ph. Eur. Certificates of Suitability (CEP)

US Drug Master Filing (USDMF)

RAU FACILITY - STEROIDS

PRODUCT NAME	DMF
Beclomethasone Dipropionate USP (Micronized & Non-micronized)	028137
Betamethasone Dipropionate	025798
Betamethasone Valerate, USP (Micronized)	022062
Clobetasol Propionate USP	020821
Deflazacort (Micronized)	024691
Desoximetasone USP (Micronized)	022400
Halobetasol Propionate	019402
Hydrocortisone Hemisuccinate USP	029221
Methylprednisolone Acetate USP	024611
Methylprednisolone Hemisuccinate	022904
Mometasone Furoate Monohydrate	025448
Mometasone Furoate Usp (Micronised)	020684
Prednisolone Hemisuccinate	024630
Prednisolone Sodium Phosphate USP	023899
Triamcinolone Acetonide Usp	021263
Betamethasone Acetate Usp	036086
Betamethasone Sodium Phosphate USP	037466
Dexamethasone USP	038162
16 Alpha-hydroxyprednisolone (Intermediate)	029224
Dexamethasone Sodium Phosphate	042465

SEZ FACILITY - STEROIDS

PRODUCT NAME	DMF
Betamethasone Usp (Micronized)	025197
Flumethasone	025547
Methylprednisolone Usp (Micronized)	027783
Hydrocortisone Acetate USP	030820
Hydrocortisone USP	031349
Prednisolone Acetate USP	032728
Prednisolone USP	034505
Methylprednisolone USP (Process 2)	034637



US Drug Master Filing (USDMF)

SEZ FACILITY - HORMONES

PRODUCT NAME	DMF
17alpha-hydroxy Progesterone (Intermediate)	029030
Dehydroepiandrosterone (Intermediate)	029004
Desogestrel Ep/bp (Micronized)	028124
Esterified Estrogens USP	027920
Ethinyl Estradiol Usp (Micronized)	026020
Levonorgestrel EP/USP (Micronized)	027867
Testosterone USP (Micronized)	029869
Testosterone Cypionate USP	029023
Testosterone Enanthate USP	026166
Testosterone Propionate USP (Micronized)	025535
Testosterone Undecanoate	025534
Hydroxyprogesterone Caproate USP	030747
Progesterone USP	032709
Drospirenone	032885
Estradiol Hemihydrate USP	034147

Ph. Eur. Certification of Suitability (CEP)

RAU FACILITY - STEROIDS

PRODUCT NAME

Beclometasone Dipropionate, (Micronised, Non-micronised)
 Betamethasone Dipropionate (Micronised)
 Betamethasone Valerate (Micronised)
 Clobetasone Butyrate (micronised)
 Clobetasol Propionate Micronised, Non-micronised
 Methylprednisolone Acetate (Micronised)
 Methylprednisolone Hydrogen Succinate
 Mometasone Furoate (Micronised)
 Prednisolone Sodium Phosphate
 Triamcinolone Acetonide (Micronised)
 Hydrocortisone Hydrogen Succinate
 Dexamethasone (Micronised)

CEP

R1-CEP 2005-062-Rev 02
 R1-CEP 2012-079-Rev 00
 R1-CEP 2008-307-Rev 00
 R1-CEP 2012-282-Rev 00
 R1-CEP 2007-263-Rev 02
 R1-CEP 2011-063-Rev 01
 R1-CEP 2009-187-Rev 04
 CEP 2007-194-Rev 04
 R1-CEP 2011-149-Rev 01
 R1-CEP 2008-032-Rev 04
 R1-CEP 2014-120-Rev 01
 CEP 2023-083-Rev 00

SEZ FACILITY - STEROIDS

PRODUCT NAME

Betamethasone Micronised
 Methylprednisolone Micronised
 Prednisolone Sodium Phosphate (process 2)
 Hydrocortisone Acetate)Micronised (Grades I And II)
 Hydrocortisone (Micronised)
 Prednisolone Acetate (Micronised)
 Prednisolone (Micronised)

CEP

R1-CEP 2011-285-Rev 01
 R1-CEP 2014-015-Rev 01
 R1-CEP 2016-205-Rev 01
 CEP 2016-228-Rev 03
 CEP 2018-054-Rev 02
 CEP 2018-089-Rev 02
 CEP 2020-194-Rev 01

SEZ FACILITY - HORMONES

PRODUCT NAME

Testosterone (Micronised)
 Drospirenone (Micronised, Non-micronised)
 Ethinyl Estradiol (Micronised)
 Estradiol Hemihydrate (Micronised)

CEP

R1-CEP 2015-314-Rev 01
 CEP 2018-118-Rev 01
 Ro-CEP 2020-029-Rev 00
 Ro-CEP 2020-067-Rev 00