

Medicines and Healthcare products Regulatory Agency

CERTIFICATE NUMBER : UK API 42785 Insp GMP 42785/13455310-0007

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER(1),(2)

Part 1

Issued following an inspection in accordance with :
Regulation 331A of The Human Medicines Regulations 2012 (SI 2012/1916)

The competent authority of United Kingdom confirms the following :

The Manufacturer : ACTIVE PHARMA SUPPLIES LIMITED

Site address : ACTIVE PHARMA SUPPLIES LIMITED, UNIT 2, FORWARD INDUSTRIAL ESTATE, TALBOT ROAD, LEYLAND, PR25 2ZJ, UNITED KINGDOM

Is an active substance manufacturer that has been inspected in accordance with Regulation 327 of The Human Medicines Regulations 2012 (SI 2012/1916).

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 20/01/2025 , it is considered that it complies with

- The principles of GMP for active substances referred to in Regulation B17 and C17 of the Human Medicines Regulations 2012 (SI 2012/1916)

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. This certificate is valid only when presented with all pages and both Parts 1 and 2. The authenticity of this certificate may be verified in MHRA-GMDP. If it does not appear, please contact the issuing authority.

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- (1) *Guidance on the interpretation of this template can be found in the Help menu of MHRA-GMDP database.*
 - (2) *These requirements fulfil the GMP recommendations of WHO.*

Part 2

Human Medicinal Products

Manufacture of active substance. Names of substances subject to inspection :

- [2000007846] DEXAMETHASONE ACETATE
- [1000008714] MAGNESIUM STEARATE
- [2000007324] HYOSCINE BUTYLBROMIDE
- [1000008566] LOPERAMIDE
- [1000011976] METHOTREXATE
- [2000006954] SILDENAFIL CITRATE

- [1000009733] RESORCINOL
- [4000007351] CHLORHEXIDINE DIACETATE
- [2000008494] LOPERAMIDE HYDROCHLORIDE
- [1000009821] POTASSIUM BROMIDE
- [1000009143] BENZOIC ACID
- [1000002416] TEMOZOLOMIDE
- [4000010992] METHYLCOBALAMIN
- [1000013818] LEVOMEPRMAZINE
- [1000009436] SPIRONOLACTONE
- [1000008584] SODIUM PROPIONATE
- [2000013061] SODIUM BENZOATE
- [2000008252] MIDAZOLAM HYDROCHLORIDE
- [2000007843] DEXAMETHASONE SODIUM PHOSPHATE
- [1000004660] CHLOROCRESOL
- [1000000270] PREGABALIN
- [1000013957] PENTOXIFYLLINE
- [4000010502] TOCOPHERYL ACETATE
- [3000010308] HYDROCORTISONE MICRONISED
- [3000016930] L-CITRULLINE
- [1000003843] ALLOPURINOL
- [4000009250] GLUCOSE ANHYDROUS
- [1000000391] NADOLOL
- [1000000859] MESALAZINE
- [4000007498] CALCIUM CARBONATE HEAVY
- [2000008780] HYDROGEN PEROXIDE SOLUTION 6%
- [1000009710] SALICYLIC ACID
- [1000012475] TETRACAINE
- [1000007341] LANSOPRAZOLE
- [1000009903] ASCORBIC ACID
- [2000008091] PAPAVERINE HYDROCHLORIDE
- [4000009638] ESOMEPRAZOLE MAGNESIUM TRIHYDRATE
- [1000006286] CETRIMIDE
- [2000013094] SODIUM OXYBATE
- [1000009817] POTASSIUM CITRATE
- [1000004182] CLIOQUINOL
- [4000014216] COAL TAR SOLUTION STRONG
- [1000007415] FINASTERIDE
- [2000008277] BUPRENORPHINE HYDROCHLORIDE
- [2000007323] HYOSCINE HYDROBROMIDE
- [4000009924] MAGNESIUM SULPHATE HEPTAHYDRATE
- [2000008016] CLINDAMYCIN PHOSPHATE
- [1000007071] TRICHLOROACETIC ACID
- [3000006207] ALIMEMAZINE
- [1000009849] ATENOLOL
- [2000008411] MEDROXYPROGESTERONE ACETATE
- [4000010937] THIAMINE HYDROCHLORIDE
- [1000009119] AMLODIPINE
- [2000011380] COAL TAR SOLUTION
- [2000013292] LEVOTHYROXINE SODIUM
- [4000006570] CODEINE PHOSPHATE HEMIHYDRATE

- [2000007395] SULPHACETAMIDE SODIUM
- [3000020819] TRETINOIN MICRONISED
- [2000008378] SERTRALINE HYDROCHLORIDE
- [2000008175] NEOMYCIN SULPHATE
- [2000008319] PAROXETINE HYDROCHLORIDE
- [1000009751] PYRAZINAMIDE
- [2000012211] MAGNESIUM GLYCEROPHOSPHATE
- [1000009347] THEOPHYLLINE
- [1000009411] SUCRALFATE
- [2000011773] GLYCOPYRRONIUM BROMIDE
- [1000009324] BACLOFEN
- [1000005193] CHLORAL HYDRATE
- [2000008543] ADRENALINE ACID TARTRATE
- [3000011086] MENTHOL CRYSTALS
- [4000013814] BETAMETHASONE DIPROPIONATE MICRONISED
- [2000008238] NALOXONE HYDROCHLORIDE
- [2000008360] BETAMETHASONE DIPROPIONATE
- [2000007824] PYRIDOSTIGMINE BROMIDE
- [3000010908] TRISODIUM CITRATE
- [2000008022] CITRIC ACID MONOHYDRATE
- [1000006787] CAPTOPRIL
- [2000007855] DANTROLENE SODIUM
- [1000001561] GRAMICIDIN
- [1000014570] SODIUM CARBONATE
- [2000016304] DAPOXETINE HYDROCHLORIDE
- [2000016109] ESTRADIOL VALERATE
- [2000007599] ETHAMBUTOL HYDROCHLORIDE
- [2000007870] VENLAFAXINE HYDROCHLORIDE
- [2000007814] QUININE SULPHATE
- [1000003257] LATANOPROST
- [1000014071] PHENOBARBITAL
- [4000003578] NORADRENALINE TARTRATE
- [3000010904] CICLOSPORIN
- [2000007522] FEXOFENADINE HYDROCHLORIDE
- [1000008543] LORAZEPAM
- [1000013004] COAL TAR
- [1000008715] SODIUM CYCLAMATE
- [3000004673] L-ARGININE
- [1000002932] TOPIRAMATE
- [1000009383] SULPHUR
- [4000004550] MAGNESIUM SULPHATE EXSICCATED
- [2000008425] MAGNESIUM OXIDE HEAVY
- [1000000832] MINOXIDIL
- [2000008257] MEXILETINE HYDROCHLORIDE
- [1000003204] DIAZOXIDE
- [2000008522] AMITRIPTYLINE HYDROCHLORIDE
- [2000007914] PREDNISOLONE SODIUM PHOSPHATE
- [1000009500] BENZYL BENZOATE
- [1000008764] HYDROCHLOROTHIAZIDE
- [1000001131] METRONIDAZOLE

- [2000008290] BISOPROLOL FUMARATE
- [2000007425] GLACIAL ACETIC ACID
- [1000009091] ZOPICLONE
- [4000011216] CLOPIDOGREL BISULFATE
- [2000008446] ATROPINE SULPHATE
- [1000007496] CALAMINE
- [1000001769] GLICLAZIDE
- [2000008271] CAFFEINE CITRATE
- [1000006699] CARBIMAZOLE
- [2000008484] VERAPAMIL HYDROCHLORIDE
- [1000009303] TRETINOIN
- [1000009387] SULPHASALAZINE
- [1000006766] CARBACHOL
- [2000008003] PILOCARPINE NITRATE
- [1000009291] ACRIFLAVINE
- [1000009902] PHENOL
- [2000008338] METFORMIN HYDROCHLORIDE
- [1000000731] MELATONIN
- [1000008354] ISOPROPYL MYRISTATE
- [2000016108] ESTRADIOL HEMIHYDRATE
- [2000007475] SODIUM VALPROATE
- [3000006909] DISODIUM PHOSPHATE ANHYDROUS
- [1000009822] POTASSIUM BICARBONATE
- [2000008429] MAGNESIUM CARBONATE LIGHT
- [3000006351] ACETYLSALICYLIC ACID
- [1000007380] GABAPENTIN
- [2000013668] CLOPIDOGREL BESILATE
- [1000009354] TESTOSTERONE
- [1000007507] CAFFEINE
- [1000002293] ADAPALENE
- [2000018959] MAGNESIUM HYDROXIDE, LIGHT
- [4000009826] FERROUS SULPHATE HEPTAHYDRATE
- [1000009810] POTASSIUM IODIDE
- [2000007515] FLECAINIDE ACETATE
- [4000003169] CHLORHEXIDINE DIGLUCONATE SOLUTION 20%
- [1000009101] OMEPRAZOLE
- [2000007338] HYDROCORTISONE ACETATE
- [2000006127] CALCIUM CARBONATE LIGHT
- [1000007791] DUTASTERIDE
- [3000005943] FUROSEMIDE
- [2000008103] CHLORHEXIDINE ACETATE
- [1000009812] POTASSIUM HYDROXIDE
- [1000007908] LEVODOPA
- [2000007490] GENTAMICIN SULPHATE
- [2000007877] LOSARTAN POTASSIUM
- [2000007893] PROPANTHELINE BROMIDE
- [1000009788] PRIMIDONE
- [1000008740] AMIODARONE
- [1000009160] BENZOCAINE
- [4000002915] 5-AMINOLEVULINIC ACID HYDROCHLORIDE

- [2000007383] TERBUTALINE SULPHATE
- [2000008318] OXYBUTYNIN HYDROCHLORIDE
- [2000008500] LISINAPRIL DIHYDRATE
- [2000008376] BECLOMETHASONE DIPROPIONATE
- [4000010954] RIBOFLAVIN
- [1000004605] CHLOROTHIAZIDE
- [4000006254] GLUCOSE MONOHYDRATE
- [1000007419] SODIUM THIOSULPHATE
- [2000007511] FLUCINOLONE ACETONIDE
- [1000008377] IODINE
- [1000009540] SODIUM BICARBONATE
- [2000007906] PROCAINE HYDROCHLORIDE
- [1000008346] KETOPROFEN
- [2000008358] BETAMETHASONE VALERATE
- [1000006709] CARBIDOPA
- [2000008485] VANCOMYCIN HYDROCHLORIDE
- [2000008414] MEBEVERINE HYDROCHLORIDE
- [2000007900] PROFLAVINE HEMISULPHATE
- [2000008095] CHLORPHENIRAMINE MALEATE
- [2000008337] METHADONE HYDROCHLORIDE
- [3000017598] PHENYTOIN POWDER
- [4000011052] SODIUM GLYCEROPHOSPHATE HYDRATE
- [1000000458] MANNITOL
- [1000003230] ZONISAMIDE
- [1000009818] POTASSIUM CHLORIDE
- [3000010012] SODIUM HYDROGEN CARBONATE
- [2000008399] ZINC OXIDE
- [2000010983] BENZALKONIUM CHLORIDE
- [1000005173] CHLORAMPHENICOL
- [1000008348] ATORVASTATIN
- [1000009080] RAMIPRIL
- [1000009441] SORBITOL
- [4000006807] ZINC SULPHATE HEPTAHYDRATE
- [1000007411] AZELAIC ACID
- [1000009308] TRANEXAMIC ACID
- [2000007672] ENALAPRIL MALEATE
- [1000009661] NYSTATIN
- [1000000947] MERCAPTOPYRIMIDINE
- [2000006529] FLUDROCORTISONE ACETATE
- [2000007753] DISODIUM EDTATE
- [1000009531] SODIUM HYDROXIDE
- [2000008529] AMILORIDE HYDROCHLORIDE
- [1000007745] ISONIAZID
- [1000007367] BISOPROLOL
- [1000004479] CHOLESTEROL
- [2000008004] PILOCARPINE HYDROCHLORIDE
- [1000009790] PRILOCAINE
- [1000008469] SIROLIMUS
- [2000008586] TRIAMCINOLONE ACETONIDE
- [2000008064] PHENYTOIN SODIUM

- [100000149] METHYL SALICYLATE
- [3000004479] CITRIC ACID ANHYDROUS
- [1000009680] NIFEDIPINE
- [1000009800] POVIDONE-IODINE
- [2000008504] LIOTHYRONINE SODIUM
- [2000012207] MAGNESIUM CHLORIDE
- [2000008390] FLUOXETINE HYDROCHLORIDE
- [1000008905] ICHTHAMMOL
- [3000004664] OXETACAINE
- [1000008752] HYDROQUINONE
- [1000002937] DITHRANOL
- [1000003208] DIAZEPAM
- [2000007496] FORMALDEHYDE SOLUTION
- [3000021667] ESTRADIOL (17-ALPHA)
- [2000008014] CLOBETASOL PROPIONATE
- [3000017596] BISACODYL POWDER
- [3000010117] SODIUM DIHYDROGEN PHOSPHATE
- [2000008278] BUPIVACAINE HYDROCHLORIDE
- [1000000183] EXEMESTANE
- [1000015338] LIDOCAINE
- [2000008199] CAPSICUM TINCTURE
- [1000007337] BORIC ACID
- [1000009887] PHENYTOIN
- [2000008067] PHENYLEPHRINE HYDROCHLORIDE
- [3000011974] BETAINE ANHYDROUS
- [4000007084] SODIUM CROMOGLICATE
- [2000016490] TACROLIMUS MONOHYDRATE
- [1000009536] SODIUM CHLORIDE
- [1000000162] TADALAFIL
- [2000008609] KETAMINE HYDROCHLORIDE
- [2000007992] PODOPHYLLUM RESIN
- [1000009551] SILVER NITRATE
- [1000000894] MAGNESIUM HYDROXIDE
- [4000000347] CAMPHOR RACEMIC
- [1000003322] DEXPANTHENOL
- [1000009262] UREA
- [3000010996] ALUMINIUM OXIDE HYDRATED
- [2000008097] CHLOROQUINE PHOSPHATE
- [1000009653] OLEIC ACID
- [2000007763] DILTIAZEM HYDROCHLORIDE
- [1000002962] DIPYRIDAMOLE
- [1000009535] SODIUM CITRATE
- [2000006346] DULOXETINE HYDROCHLORIDE
- [1000009609] PARACETAMOL
- [2000007813] RANITIDINE HYDROCHLORIDE
- [2000007815] QUININE HYDROCHLORIDE
- [1000008918] IBUPROFEN
- [1000003125] ALUM
- [4000010966] PYRIDOXINE HYDROCHLORIDE
- [2000014083] LIDOCAINE HYDROCHLORIDE

- [1000001953] GRISEOFULVIN

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

DEXAMETHASONE ACETATE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 Other
- Only re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

MAGNESIUM STEARATE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 Other
- Only re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

HYOSCINE BUTYLBROMIDE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 Other
- Only re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

LOPERAMIDE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 Other
- Only re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

METHOTREXATE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 Other
- Only re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

SILDENAFIL CITRATE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
- 3.1.4 Other
Only re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
- 3.5.2 Primary Packaging
- 3.5.3 Secondary Packaging

RESORCINOL

- 3.1 Manufacture of Active Substance by Chemical Synthesis
- 3.1.4 Other
Only re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
- 3.5.2 Primary Packaging
- 3.5.3 Secondary Packaging

CHLORHEXIDINE DIACETATE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
- 3.1.4 Other
Only re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
- 3.5.2 Primary Packaging
- 3.5.3 Secondary Packaging

LOPERAMIDE HYDROCHLORIDE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
- 3.1.4 Other
Only re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
- 3.5.2 Primary Packaging
- 3.5.3 Secondary Packaging

POTASSIUM BROMIDE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
- 3.1.4 Other
Only re packaging option required, none of the above applicable.

- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

BENZOIC ACID

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

TEMOZOLOMIDE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

METHYLCOBALAMIN

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

LEVOMEPRMAZINE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

SPIRONOLACTONE

- 3.1 Manufacture of Active Substance by Chemical Synthesis

3.1.4 Other
Only re packaging option required, none of the above applicable.

3.5 General Finishing Steps
3.5.2 Primary Packaging

3.5.3 Secondary Packaging

SODIUM PROPIONATE

3.1 Manufacture of Active Substance by Chemical Synthesis
3.1.4 Other
Only re packaging option required, none of the above applicable.

3.5 General Finishing Steps
3.5.2 Primary Packaging

3.5.3 Secondary Packaging

SODIUM BENZOATE

3.1 Manufacture of Active Substance by Chemical Synthesis
3.1.4 Other
Only re packaging option required, none of the above applicable.

3.5 General Finishing Steps
3.5.2 Primary Packaging

3.5.3 Secondary Packaging

MIDAZOLAM HYDROCHLORIDE

3.1 Manufacture of Active Substance by Chemical Synthesis
3.1.4 Other
Only re packaging option required, none of the above applicable.

3.5 General Finishing Steps
3.5.2 Primary Packaging

3.5.3 Secondary Packaging

DEXAMETHASONE SODIUM PHOSPHATE

3.1 Manufacture of Active Substance by Chemical Synthesis
3.1.4 Other
Only re packaging option required, none of the above applicable.

3.5 General Finishing Steps
3.5.2 Primary Packaging

3.5.3 Secondary Packaging

CHLOROCRESOL

- 3.1 Manufacture of Active Substance by Chemical Synthesis
3.1.4 Other
Only re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
3.5.2 Primary Packaging
3.5.3 Secondary Packaging

PREGABALIN

- 3.1 Manufacture of Active Substance by Chemical Synthesis
3.1.4 Other
Only re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
3.5.2 Primary Packaging
3.5.3 Secondary Packaging

PENTOXIFYLLINE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
3.1.4 Other
Only re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
3.5.2 Primary Packaging
3.5.3 Secondary Packaging

TOCOPHERYL ACETATE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
3.1.4 Other
Only re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
3.5.2 Primary Packaging
3.5.3 Secondary Packaging

HYDROCORTISONE MICRONISED

- 3.1 Manufacture of Active Substance by Chemical Synthesis
3.1.4 Other
Only re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
3.5.2 Primary Packaging
3.5.3 Secondary Packaging

L-CITRULLINE

- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

ALLOPURINOL

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

GLUCOSE ANHYDROUS

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

NADOLOL

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

MESALAZINE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

CALCIUM CARBONATE HEAVY

- 3.1 Manufacture of Active Substance by Chemical Synthesis

3.1.4 Other
Only re packaging option required, none of the above applicable.

3.5 General Finishing Steps

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

HYDROGEN PEROXIDE SOLUTION 6%

3.1 Manufacture of Active Substance by Chemical Synthesis

3.1.4 Other
Only re packaging option required, none of the above applicable.

3.5 General Finishing Steps

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

SALICYLIC ACID

3.1 Manufacture of Active Substance by Chemical Synthesis

3.1.4 Other
Only re packaging option required, none of the above applicable.

3.5 General Finishing Steps

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

TETRACAINE

3.1 Manufacture of Active Substance by Chemical Synthesis

3.1.4 Other
Only re packaging option required, none of the above applicable.

3.5 General Finishing Steps

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

LANSOPRAZOLE

3.1 Manufacture of Active Substance by Chemical Synthesis

3.1.4 Other
Only re packaging option required, none of the above applicable.

3.5 General Finishing Steps

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

ASCORBIC ACID

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

PAPAVERINE HYDROCHLORIDE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

ESOMEPRAZOLE MAGNESIUM TRIHYDRATE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

CETRIMIDE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

SODIUM OXYBATE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

POTASSIUM CITRATE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 Other
- Only re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

CLIOQUINOL

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 Other
- Only re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

COAL TAR SOLUTION STRONG

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 Other
- Only re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

FINASTERIDE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 Other
- Only re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

BUPRENORPHINE HYDROCHLORIDE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 Other
- Only re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging

3.5.3 Secondary Packaging

HYOSCINE HYDROBROMIDE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
3.1.4 Other
Only re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
3.5.2 Primary Packaging
3.5.3 Secondary Packaging

MAGNESIUM SULPHATE HEPTAHYDRATE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
3.1.4 Other
Only re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
3.5.2 Primary Packaging
3.5.3 Secondary Packaging

CLINDAMYCIN PHOSPHATE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
3.1.4 Other
Only re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
3.5.2 Primary Packaging
3.5.3 Secondary Packaging

TRICHLOROACETIC ACID

- 3.1 Manufacture of Active Substance by Chemical Synthesis
3.1.4 Other
Only re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
3.5.2 Primary Packaging
3.5.3 Secondary Packaging

ALIMEMAZINE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
3.1.4 Other
Only re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

ATENOLOL

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

MEDROXYPROGESTERONE ACETATE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

THIAMINE HYDROCHLORIDE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

AMLODIPINE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

COAL TAR SOLUTION

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.

- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

LEVOTHYROXINE SODIUM

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

CODEINE PHOSPHATE HEMIHYDRATE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

SULPHACETAMIDE SODIUM

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

TRETINOIN MICRONISED

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

SERTRALINE HYDROCHLORIDE

- 3.5 General Finishing Steps

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

3.5.4 Other

Only re packaging option required, none of the above applicable.

NEOMYCIN SULPHATE

3.1 Manufacture of Active Substance by Chemical Synthesis

3.1.4 Other

Only re packaging option required, none of the above applicable.

3.5 General Finishing Steps

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

PAROXETINE HYDROCHLORIDE

3.5 General Finishing Steps

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

PYRAZINAMIDE

3.1 Manufacture of Active Substance by Chemical Synthesis

3.1.4 Other

Only re packaging option required, none of the above applicable.

3.5 General Finishing Steps

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

MAGNESIUM GLYCEROPHOSPHATE

3.1 Manufacture of Active Substance by Chemical Synthesis

3.1.4 Other

Only re packaging option required, none of the above applicable.

3.5 General Finishing Steps

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

THEOPHYLLINE

3.1 Manufacture of Active Substance by Chemical Synthesis

3.1.4 Other

Only re packaging option required, none of the above applicable.

3.5 General Finishing Steps

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

SUCRALFATE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

GLYCOPYRRONIUM BROMIDE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

BACLOFEN

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

CHLORAL HYDRATE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

ADRENALINE ACID TARTRATE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.

- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

MENTHOL CRYSTALS

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

BETAMETHASONE DIPROPIONATE MICRONISED

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

NALOXONE HYDROCHLORIDE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

BETAMETHASONE DIPROPIONATE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

PYRIDOSTIGMINE BROMIDE

- 3.1 Manufacture of Active Substance by Chemical Synthesis

3.1.4 Other
Only re packaging option required, none of the above applicable.

3.5 General Finishing Steps
3.5.2 Primary Packaging

3.5.3 Secondary Packaging

TRISODIUM CITRATE

3.1 Manufacture of Active Substance by Chemical Synthesis
3.1.4 Other
Only re packaging option required, none of the above applicable.

3.5 General Finishing Steps
3.5.2 Primary Packaging

3.5.3 Secondary Packaging

CITRIC ACID MONOHYDRATE

3.1 Manufacture of Active Substance by Chemical Synthesis
3.1.4 Other
Only re packaging option required, none of the above applicable.

3.5 General Finishing Steps
3.5.2 Primary Packaging

3.5.3 Secondary Packaging

CAPTOPRIL

3.1 Manufacture of Active Substance by Chemical Synthesis
3.1.4 Other
Only re packaging option required, none of the above applicable.

3.5 General Finishing Steps
3.5.2 Primary Packaging

3.5.3 Secondary Packaging

DANTROLENE SODIUM

3.1 Manufacture of Active Substance by Chemical Synthesis
3.1.4 Other
Only re packaging option required, none of the above applicable.

3.5 General Finishing Steps
3.5.2 Primary Packaging

3.5.3 Secondary Packaging

GRAMICIDIN

- 3.1 Manufacture of Active Substance by Chemical Synthesis
3.1.4 Other
Only re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
3.5.2 Primary Packaging
3.5.3 Secondary Packaging

SODIUM CARBONATE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
3.1.4 Other
Only re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
3.5.2 Primary Packaging
3.5.3 Secondary Packaging

DAPOXETINE HYDROCHLORIDE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
3.1.4 Other
Only primary and secondary repacking required
- 3.5 General Finishing Steps
3.5.2 Primary Packaging
3.5.3 Secondary Packaging

ESTRADIOL VALERATE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
3.1.4 Other
Only re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
3.5.2 Primary Packaging
3.5.3 Secondary Packaging

ETHAMBUTOL HYDROCHLORIDE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
3.1.4 Other
Only re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
3.5.2 Primary Packaging
3.5.3 Secondary Packaging

VENLAFAXINE HYDROCHLORIDE

- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

QUININE SULPHATE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

LATANOPROST

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

PHENOBARBITAL

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

NORADRENALINE TARTRATE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

CICLOSPORIN

- 3.1 Manufacture of Active Substance by Chemical Synthesis

3.1.4 Other
Only re packaging option required, none of the above applicable.

3.5 General Finishing Steps

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

FEXOFENADINE HYDROCHLORIDE

3.1 Manufacture of Active Substance by Chemical Synthesis

3.1.4 Other
Only re packaging option required, none of the above applicable.

3.5 General Finishing Steps

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

LORAZEPAM

3.1 Manufacture of Active Substance by Chemical Synthesis

3.1.4 Other
Only re packaging option required, none of the above applicable.

3.5 General Finishing Steps

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

COAL TAR

3.1 Manufacture of Active Substance by Chemical Synthesis

3.1.4 Other
Only re packaging option required, none of the above applicable.

3.5 General Finishing Steps

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

SODIUM CYCLAMATE

3.1 Manufacture of Active Substance by Chemical Synthesis

3.1.4 Other
Only re packaging option required, none of the above applicable.

3.5 General Finishing Steps

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

L-ARGININE

- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

TOPIRAMATE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

SULPHUR

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

MAGNESIUM SULPHATE EXSICCATED

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

MAGNESIUM OXIDE HEAVY

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

MINOXIDIL

- 3.1 Manufacture of Active Substance by Chemical Synthesis

3.1.4 Other
Only re packaging option required, none of the above applicable.

3.5 General Finishing Steps

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

MEXILETINE HYDROCHLORIDE

3.1 Manufacture of Active Substance by Chemical Synthesis

3.1.4 Other
Only re packaging option required, none of the above applicable.

3.5 General Finishing Steps

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

DIAZOXIDE

3.1 Manufacture of Active Substance by Chemical Synthesis

3.1.4 Other
Only re packaging option required, none of the above applicable.

3.5 General Finishing Steps

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

AMITRIPTYLINE HYDROCHLORIDE

3.1 Manufacture of Active Substance by Chemical Synthesis

3.1.4 Other
Only re packaging option required, none of the above applicable.

3.5 General Finishing Steps

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

PREDNISOLONE SODIUM PHOSPHATE

3.1 Manufacture of Active Substance by Chemical Synthesis

3.1.4 Other
Only re packaging option required, none of the above applicable.

3.5 General Finishing Steps

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

BENZYL BENZOATE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
3.1.4 Other
Only re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
3.5.2 Primary Packaging
3.5.3 Secondary Packaging

HYDROCHLOROTHIAZIDE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
3.1.4 Other
Only re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
3.5.2 Primary Packaging
3.5.3 Secondary Packaging

METRONIDAZOLE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
3.1.4 Other
Only re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
3.5.2 Primary Packaging
3.5.3 Secondary Packaging

BISOPROLOL FUMARATE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
3.1.4 Other
Only re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
3.5.2 Primary Packaging
3.5.3 Secondary Packaging

GLACIAL ACETIC ACID

- 3.1 Manufacture of Active Substance by Chemical Synthesis
3.1.4 Other
Only re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
3.5.2 Primary Packaging
3.5.3 Secondary Packaging

ZOPICLONE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 Other
- Only re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

CLOPIDOGREL BISULFATE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 Other
- Only re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

ATROPINE SULPHATE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 Other
- Only re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

CALAMINE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 Other
- Only re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

GLICLAZIDE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 Other
- Only re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging

3.5.3 Secondary Packaging

CAFFEINE CITRATE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

CARBIMAZOLE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

VERAPAMIL HYDROCHLORIDE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

TRETINOIN

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

SULPHASALAZINE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

CARBACHOL

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

PILOCARPINE NITRATE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

ACRIFLAVINE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

PHENOL

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

METFORMIN HYDROCHLORIDE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.

- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

MELATONIN

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

ISOPROPYL MYRISTATE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

ESTRADIOL HEMIHYDRATE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

SODIUM VALPROATE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

DISODIUM PHOSPHATE ANHYDROUS

- 3.1 Manufacture of Active Substance by Chemical Synthesis

3.1.4 Other
Only re packaging option required, none of the above applicable.

3.5 General Finishing Steps

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

POTASSIUM BICARBONATE

3.1 Manufacture of Active Substance by Chemical Synthesis

3.1.4 Other
Only re packaging option required, none of the above applicable.

3.5 General Finishing Steps

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

MAGNESIUM CARBONATE LIGHT

3.1 Manufacture of Active Substance by Chemical Synthesis

3.1.4 Other
Only re packaging option required, none of the above applicable.

3.5 General Finishing Steps

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

ACETYLSALICYLIC ACID

3.1 Manufacture of Active Substance by Chemical Synthesis

3.1.4 Other
Only re packaging option required, none of the above applicable.

3.5 General Finishing Steps

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

GABAPENTIN

3.1 Manufacture of Active Substance by Chemical Synthesis

3.1.4 Other
Only re packaging option required, none of the above applicable.

3.5 General Finishing Steps

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

CLOPIDOGREL BESILATE

- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging
 - 3.5.4 OtherOnly re packaging option required, none of the above applicable.

TESTOSTERONE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

CAFFEINE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

ADAPALENE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

MAGNESIUM HYDROXIDE, LIGHT

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

FERROUS SULPHATE HEPTAHYDRATE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
3.1.4 Other
Only re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
3.5.2 Primary Packaging
3.5.3 Secondary Packaging

POTASSIUM IODIDE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
3.1.4 Other
Only re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
3.5.2 Primary Packaging
3.5.3 Secondary Packaging

FLECAINIDE ACETATE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
3.1.4 Other
Only re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
3.5.2 Primary Packaging
3.5.3 Secondary Packaging

CHLORHEXIDINE DIGLUCONATE SOLUTION 20%

- 3.1 Manufacture of Active Substance by Chemical Synthesis
3.1.4 Other
Only re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
3.5.2 Primary Packaging
3.5.3 Secondary Packaging

OMEPRAZOLE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
3.1.4 Other
Only re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
3.5.2 Primary Packaging
3.5.3 Secondary Packaging

HYDROCORTISONE ACETATE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 Other
- Only re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

CALCIUM CARBONATE LIGHT

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 Other
- Only re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

DUTASTERIDE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 Other
- Only re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

FUROSEMIDE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 Other
- Only re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

CHLORHEXIDINE ACETATE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 Other
- Only re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging

3.5.3 Secondary Packaging

POTASSIUM HYDROXIDE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
3.1.4 Other
Only re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
3.5.2 Primary Packaging
3.5.3 Secondary Packaging

LEVODOPA

- 3.1 Manufacture of Active Substance by Chemical Synthesis
3.1.4 Other
Only re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
3.5.2 Primary Packaging
3.5.3 Secondary Packaging

GENTAMICIN SULPHATE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
3.1.4 Other
Only re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
3.5.2 Primary Packaging
3.5.3 Secondary Packaging

LOSARTAN POTASSIUM

- 3.1 Manufacture of Active Substance by Chemical Synthesis
3.1.4 Other
Only re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
3.5.2 Primary Packaging
3.5.3 Secondary Packaging

PROPANTHELINE BROMIDE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
3.1.4 Other
Only re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

PRIMIDONE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

AMIODARONE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

BENZOCAINE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

5-AMINOLEVULINIC ACID HYDROCHLORIDE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

TERBUTALINE SULPHATE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.

- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

OXYBUTYNIN HYDROCHLORIDE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

LISINOPRIL DIHYDRATE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

BECLOMETHASONE DIPROPIONATE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

RIBOFLAVIN

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

CHLOROTHIAZIDE

- 3.1 Manufacture of Active Substance by Chemical Synthesis

3.1.4 Other

Only re packaging option required, none of the above applicable.

3.5 General Finishing Steps

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

GLUCOSE MONOHYDRATE

3.1 Manufacture of Active Substance by Chemical Synthesis

3.1.4 Other

Only re packaging option required, none of the above applicable.

3.5 General Finishing Steps

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

SODIUM THIOSULPHATE

3.1 Manufacture of Active Substance by Chemical Synthesis

3.1.4 Other

Only re packaging option required, none of the above applicable.

3.5 General Finishing Steps

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

FLUOCINOLONE ACETONIDE

3.1 Manufacture of Active Substance by Chemical Synthesis

3.1.4 Other

Only re packaging option required, none of the above applicable.

3.5 General Finishing Steps

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

IODINE

3.1 Manufacture of Active Substance by Chemical Synthesis

3.1.4 Other

Only re packaging option required, none of the above applicable.

3.5 General Finishing Steps

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

SODIUM BICARBONATE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
3.1.4 Other
Only re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
3.5.2 Primary Packaging
3.5.3 Secondary Packaging

PROCAINE HYDROCHLORIDE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
3.1.4 Other
Only re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
3.5.2 Primary Packaging
3.5.3 Secondary Packaging

KETOPROFEN

- 3.1 Manufacture of Active Substance by Chemical Synthesis
3.1.4 Other
Only re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
3.5.2 Primary Packaging
3.5.3 Secondary Packaging

BETAMETHASONE VALERATE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
3.1.4 Other
Only re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
3.5.2 Primary Packaging
3.5.3 Secondary Packaging

CARBIDOPA

- 3.1 Manufacture of Active Substance by Chemical Synthesis
3.1.4 Other
Only re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
3.5.2 Primary Packaging
3.5.3 Secondary Packaging

VANCOMYCIN HYDROCHLORIDE

- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

MEBEVERINE HYDROCHLORIDE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

PROFLAVINE HEMISULPHATE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

CHLORPHENIRAMINE MALEATE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherPrimary and Secondary Repackaging only
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

METHADONE HYDROCHLORIDE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

PHENYTOIN POWDER

- 3.1 Manufacture of Active Substance by Chemical Synthesis

3.1.4 Other

Only re packaging option required, none of the above applicable.

3.5 General Finishing Steps

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

SODIUM GLYCEROPHOSPHATE HYDRATE

3.1 Manufacture of Active Substance by Chemical Synthesis

3.1.4 Other

Only re packaging option required, none of the above applicable.

3.5 General Finishing Steps

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

MANNITOL

3.1 Manufacture of Active Substance by Chemical Synthesis

3.1.4 Other

Only re packaging option required, none of the above applicable.

3.5 General Finishing Steps

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

ZONISAMIDE

3.5 General Finishing Steps

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

POTASSIUM CHLORIDE

3.1 Manufacture of Active Substance by Chemical Synthesis

3.1.4 Other

Only re packaging option required, none of the above applicable.

3.5 General Finishing Steps

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

SODIUM HYDROGEN CARBONATE

3.1 Manufacture of Active Substance by Chemical Synthesis

3.1.4 Other

Only re packaging option required, none of the above applicable.

- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

ZINC OXIDE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

BENZALKONIUM CHLORIDE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

CHLORAMPHENICOL

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

ATORVASTATIN

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

RAMIPRIL

- 3.1 Manufacture of Active Substance by Chemical Synthesis

3.1.4 Other
Only re packaging option required, none of the above applicable.

3.5 General Finishing Steps

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

SORBITOL

3.1 Manufacture of Active Substance by Chemical Synthesis

3.1.4 Other
Only re packaging option required, none of the above applicable.

3.5 General Finishing Steps

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

ZINC SULPHATE HEPTAHYDRATE

3.1 Manufacture of Active Substance by Chemical Synthesis

3.1.4 Other
Only re packaging option required, none of the above applicable.

3.5 General Finishing Steps

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

AZELAIC ACID

3.1 Manufacture of Active Substance by Chemical Synthesis

3.1.4 Other
Only re packaging option required, none of the above applicable.

3.5 General Finishing Steps

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

TRANEXAMIC ACID

3.1 Manufacture of Active Substance by Chemical Synthesis

3.1.4 Other
Only re packaging option required, none of the above applicable.

3.5 General Finishing Steps

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

ENALAPRIL MALEATE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
3.1.4 Other
Only re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
3.5.2 Primary Packaging
3.5.3 Secondary Packaging

NYSTATIN

- 3.1 Manufacture of Active Substance by Chemical Synthesis
3.1.4 Other
Only re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
3.5.2 Primary Packaging
3.5.3 Secondary Packaging

MERCAPTOPURINE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
3.1.4 Other
Only re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
3.5.2 Primary Packaging
3.5.3 Secondary Packaging

FLUDROCORTISONE ACETATE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
3.1.4 Other
Only re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
3.5.2 Primary Packaging
3.5.3 Secondary Packaging

DISODIUM EDETATE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
3.1.4 Other
Only re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
3.5.2 Primary Packaging
3.5.3 Secondary Packaging

SODIUM HYDROXIDE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 Other
- Only re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

AMILORIDE HYDROCHLORIDE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 Other
- Only re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

ISONIAZID

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 Other
- Only re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

BISOPROLOL

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 Other
- Only re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

CHOLESTEROL

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 Other
- Only re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging

3.5.3 Secondary Packaging

PILOCARPINE HYDROCHLORIDE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

PRILOCAINE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

SIROLIMUS

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

TRIAMCINOLONE ACETONIDE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

PHENYTOIN SODIUM

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

METHYL SALICYLATE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

CITRIC ACID ANHYDROUS

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

NIFEDIPINE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

POVIDONE-IODINE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

LIOTHYRONINE SODIUM

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.

- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

MAGNESIUM CHLORIDE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

FLUOXETINE HYDROCHLORIDE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

ICHTHAMMOL

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

OXETACAINE

- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

HYDROQUINONE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

DITHRANOL

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

DIAZEPAM

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

FORMALDEHYDE SOLUTION

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

ESTRADIOL (17-ALPHA)

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

CLOBETASOL PROPIONATE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.

- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

BISACODYL POWDER

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

SODIUM DIHYDROGEN PHOSPHATE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

BUPIVACAINE HYDROCHLORIDE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

EXEMESTANE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

LIDOCAINE

- 3.1 Manufacture of Active Substance by Chemical Synthesis

3.1.4 Other
Only re packaging option required, none of the above applicable.

3.5 General Finishing Steps

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

CAPSICUM TINCTURE

3.1 Manufacture of Active Substance by Chemical Synthesis

3.1.4 Other
Only re packaging option required, none of the above applicable.

3.5 General Finishing Steps

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

BORIC ACID

3.1 Manufacture of Active Substance by Chemical Synthesis

3.1.4 Other
Only re packaging option required, none of the above applicable.

3.5 General Finishing Steps

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

PHENYTOIN

3.1 Manufacture of Active Substance by Chemical Synthesis

3.1.4 Other
Only re packaging option required, none of the above applicable.

3.5 General Finishing Steps

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

PHENYLEPHRINE HYDROCHLORIDE

3.1 Manufacture of Active Substance by Chemical Synthesis

3.1.4 Other
Only re packaging option required, none of the above applicable.

3.5 General Finishing Steps

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

BETAINE ANHYDROUS

- 3.1 Manufacture of Active Substance by Chemical Synthesis
3.1.4 Other
Only re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
3.5.2 Primary Packaging
3.5.3 Secondary Packaging

SODIUM CROMOGLICATE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
3.1.4 Other
Only re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
3.5.2 Primary Packaging
3.5.3 Secondary Packaging

TACROLIMUS MONOHYDRATE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
3.1.4 Other
Only re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
3.5.2 Primary Packaging
3.5.3 Secondary Packaging

SODIUM CHLORIDE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
3.1.4 Other
Only re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
3.5.2 Primary Packaging
3.5.3 Secondary Packaging

TADALAFIL

- 3.1 Manufacture of Active Substance by Chemical Synthesis
3.1.4 Other
Only re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
3.5.2 Primary Packaging
3.5.3 Secondary Packaging

KETAMINE HYDROCHLORIDE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 Other
- Only re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

PODOPHYLLUM RESIN

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 Other
- Only re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

SILVER NITRATE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 Other
- Only re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

MAGNESIUM HYDROXIDE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 Other
- Only re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

CAMPHOR RACEMIC

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 Other
- Only re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging

3.5.3 Secondary Packaging

DEXPANTHENOL

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

UREA

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

ALUMINIUM OXIDE HYDRATED

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

CHLOROQUINE PHOSPHATE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

OLEIC ACID

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

DILTIAZEM HYDROCHLORIDE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

DIPYRIDAMOLE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

SODIUM CITRATE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

DULOXETINE HYDROCHLORIDE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

PARACETAMOL

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.

- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

RANITIDINE HYDROCHLORIDE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

QUININE HYDROCHLORIDE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

IBUPROFEN

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

ALUM

- 3.1 Manufacture of Active Substance by Chemical Synthesis
 - 3.1.4 OtherOnly re packaging option required, none of the above applicable.
- 3.5 General Finishing Steps
 - 3.5.2 Primary Packaging
 - 3.5.3 Secondary Packaging

PYRIDOXINE HYDROCHLORIDE

- 3.1 Manufacture of Active Substance by Chemical Synthesis

3.1.4 Other
Only re packaging option required, none of the above applicable.

3.5 General Finishing Steps

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

LIDOCAINE HYDROCHLORIDE

3.1 Manufacture of Active Substance by Chemical Synthesis

3.1.4 Other
Only re packaging option required, none of the above applicable.

3.5 General Finishing Steps

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

GRISEOFULVIN

3.1 Manufacture of Active Substance by Chemical Synthesis

3.1.4 Other
Only re packaging option required, none of the above applicable.

3.5 General Finishing Steps

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

Any restrictions related to the scope of this certificate:

Building	Room Line/equipment	QC Testing	Products
This certificate is issued based on a desk-based assessment of GMP compliance information provided by the manufacturer. This certificate should be used in combination with the relevant authorisation/registration. A risk-based site inspection programme remains in force.			

20/01/2025	Name and signature of the authorised person of the Competent Authority of United Kingdom Confidential Medicines and Healthcare products Regulatory Agency Tel : Confidential
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