KWALITY
PHARMACEUTICALS LTD.

Quality you can Trust

READY
Dossier List



BETTER ACCESS | WIDER REACH | HEALTHIER TOMMOROW

KWALITY PHARMACEUTICALS LTD.

GENERAL ORAL SOLID

EU GMP

(EU-GMP APPROVED)

Sl. No.	PRODUCTS	DOSSIER READINESS
1.	Tadalafil Tablet 5mg	YES
2.	Ondansetron Tablet 8 mg	YES
3.	Deflazacort Tablet 6mg, 18mg, 30mg	YES
4.	Pioglitazone Metformin Tablet 15mg / 850mg	YES
5.	Empagliflozin Metformin Tablet 5mg / 1000mg	YES
6.	Empagliflozin Metformin Tablet 12.5mg / 1000mg	YES
7.	Telmisartan Hydrochlorothiazide Tablet 80 mg /12.5 mg	YES
8.	Atorvastatin Ezetimibe Tablet 10mg /10 mg ; 10mg /20 mg ; 10mg /40 mg	YES
9.	Dapagliflozin Tablets 5mg, 10 mg	YES
10.	Linagliptin Metformin Tablet 2.5mg, 850mg	YES
11.	Tamsulosin Dutasteride Capsule 0.4mg/0.5mg	YES
12.	Sacubitril Valsartan Tablet 100mg, 200mg	YES
13.	Nitrofurantoin Retard Capsule 100 mg	YES
14.	Sodium Valproate Gastro-resistant Tablets 500 mg Raltegravir Tablets 400mg	YES
15.	Dapagliflozin Metformin Extended Release Tablet 10mg / 1gm	YES
16.	Empagliflozin Linagliptin Metformin Extended Release Tablet 10mg , 5mg , 1000mg	YES
17.	Carbamazepine Prolonged-release Tablet 200mg, 400mg	YES
18.	Phenytoin Sodium 100 mg	YES
19.	Levetiracetam Tablet 500 mg / 1000 mg	YES
20.	Naproxen Tablet 500 mg	YES
21.	Naproxen sodium, Paracetamol Tablet 275 mg, 300 mg	YES
22.	Hyoscine Butylbromide, Ibuprofen Tablet 20 mg , 400 mg	YES
23.	Paracetamol, Ibuprofen Tablet 325 mg , 200 mg	YES
24.	Ibuprofen Tablet 400mg, 600 mg, 800mg	YES

KWALITY PHARMACEUTICALS LTD.

GENERAL ORAL SOLID

EU GMP

(EU-GMP APPROVED)

Sl. No.	PRODUCTS	DOSSIER READINESS
25.	Diosmin, Hesperidin Tablet 450mg , 50mg	YES
26.	Mesalazine Tablet 500 mg	YES
27.	Metformin Hydrochloride ER Tablets 500 mg, 850 mg, 1000 mg	YES
28.	Metformin Hydrochloride + Glibenclamide Tablets 500mg + 5mg	YES
29.	Metformin Hydrochloride + Glimepiride Tablets	YES
30.	Metformin Hydrochloride + Linagliptin Tablets 850mg + 2.5mg	YES
31.	Metformin Hydrochloride and Empagliflozin Tablets 1000mg + 12.5mg	YES
32.	Metformin Hydrochloride and Glimepiride Tablets 500mg + 2mg, 1000mg + 2mg, 850mg + 4mg	YES
33.	Metformin Hydrochloride Extended Release + Glimepiride Tablets 500mg + 1mg, 500mg + 2mg	YES
34.	Metformin HCl + Linagliptin + Empagliflozin Extended-Release Tablets 1000mg + 2.5mg + 12.5mg	YES
35.	Metformin HCl + Linagliptin + Empagliflozin Extended-Release Tablets 1000mg + 5mg + 10mg	YES
36.	Metformin + Glibenclamide Tablets 1000 mg + 5 mg	YES
37.	Metformin + Pioglitazone Hydrochloride Tablets 500 mg + 15 mg	YES
38.	Metformin + Sitagliptin Phosphate Tablets 500 mg + 50 mg , 1000 mg + 50 mg	YES
39.	Metformin and Pioglitazone Hydrochloride Tablets 850mg +15mg	YES
40.	Empagliflozin Tablets 10 mg, 25 mg	YES
41.	Dapagliflozin and Metformin HCl Extended Release Tablets 10mg + 1gm, 5mg + 1gm	YES
42.	Dapagliflozin and Metformin HCl Extended Release Tablets	YES

KWALITY PHARMACEUTICALS LTD.

GENERAL ORAL SOLID

EU GMP

(EU-GMP APPROVED)

Sl. No.	PRODUCTS	DOSSIER READINESS
43.	Amlodipine besilate tablets 10mg, 20mg, 40mg	YES
44.	Azithromycin Tablets 500 mg	YES
45.	Captopril Tablets 50 mg	YES
46.	Diclofenac Potassium Tablets 50 mg	YES
47.	Digoxin Tablets 0.25 mg	YES
48.	Levothyroxine Sodium Tablets 50 mcg	YES
49.	Metformin Hydrochloride Tablets 500 mg	YES
50.	Losartan Potassium Tablets 50mg	YES
51.	Nifedipine Extended-Release Tablets 30mg	YES
52.	Prednisone Tablet 5mg	YES
53.	Secnidazole Tablets 1gm	YES
54.	Valsartan Tablets 80mg	YES
55.	Ranitidine Tablets 150mg	YES
56.	Metoclopramide hydrochloride Tablets 10mg	YES
57.	Hydrochlorothiazide Tablets 50 mg	YES
58.	Enalapril maleate Tablets 10 mg	YES
59.	Mycophenolate Mofetil Tablets 500mg	YES
60.	Aciclovir Tablets 200mg	YES
61.	Amlodipine Tablets 5 mg	YES
62.	Azithromycin Tablets 500mg	YES
63.	Carbamazepine Tablets 200mg	YES
64.	Ciprofloxacin Tablets 500mg	YES
65.	Clarithromycin Tablets 500mg	YES
66.	Diclofenac potassium Tablets 50mg	YES
67.	Esomeprazole Tablets 20mg	YES
68.	Ibandronic acid Tablets 150mg	YES
69.	Ibuprofen Tablets 400 mg, 600 mg, 800 mg	YES
70.	Irbesartan Tablets 150 mg, 300 mg	YES
71.	Levothyroxine Tablets 25 mcg, 100 mcg	YES
72.	Loratadine Tablets 10 mg	YES
73.	Pentoxifylline Tablets 400mg	YES

KWALITY PHARMACEUTICALS LTD.

GENERAL ORAL SOLID

EU GMP

(EU-GMP APPROVED)

Sl. No.	PRODUCTS	DOSSIER READINESS
74.	Pentoxifylline Tablets 400mg	YES
75.	Prednisone Tablets 5mg , 50 mg	YES
76.	Verapamil Tablets 80mg	YES
77.	Dexamethasone Tablets 8 mg	YES
78.	Ondasetron Tablet 4 mg, 8 mg	YES
79.	Metronidazole vaginal Tablets 500 mg	YES
80.	Nystatin vaginal Tablets 100000 IU	YES
81.	Verapamil hydrochloride Tablets 80mg	YES
82.	Nitrofurantoin Capsules 50 mg, 100 mg	YES
83.	Itraconazole + Secnidazole Capsules 33.33mg + 166.66mg	YES
84.	Rabeprazole Sodium & Domperidone Capsules 20mg + 10mg , 20mg + 30mg	YES
85.	Rabeprazole Sodium (EC) and Levosulpiride (SR) Capsules 20mg + 75mg	YES
86.	Fluconazole Capsules 150 mg	YES
87.	Tramadol Capsules 100 mg	YES
88.	Chloramphenicol Capsules 500 mg	YES
89.	Pregabalin Capsule 75mg	YES
90.	Ciprofloxacin Capsules 500 mg	YES
91.	Tramadol Capsules 50 mg	YES
92.	Omeprazole Capsules 40 mg	YES
93.	Fluoxetine Capsules 20 mg	YES
94.	Tamsulosin Extended Release Capsules 0.4mg	YES
95.	Itraconazole Capsules 100 mg	YES
96.	Tretinoin capsules 10 mg	YES
97.	Phenazopyridine Tablet 100 mg	YES
98.	Hydroxychloroquine Tablet 200 mg	YES

KWALITY PHARMACEUTICALS LTD.

GENERAL INJECTABLE

(EU-GMP/SFDA/ANVISA/INVIMA/PIC/S APPROVED)

Sl. No.	PRODUCTS	DOSSIER READINESS
1.	Propofol Injectable Emulsion 10mg/ml / 20mg/ml	YES
2.	Betamethasone (as Dipropionate) 10 mg / 2 ml and Betamethasone (as Sodium Phosphate) 4 mg / 2 ml) Suspension	YES
3.	Amphotericin B Liposomal Injection 50 mg	YES
4.	Enoxaparin Sodium 100mg/ml	YES
5.	Hydrocortisone Sodium Succinate for Injection 100mg/Vial	YES
6.	Sodium Bicarbonate Injection 8.4%	YES
7.	Alprostadil for Injection 10mcg , 20mcg	YES
8.	Labetalol Hydrochloride Injection 5mg/ml	YES
9.	Omeprazole For Injection 40 mg/Vial	YES
10.	Tenoxicam For Injection 20mg (Lyophilized)	YES
11.	Aprotinin Injection 10000KIU (Lyophilized)	YES
12.	Lidocaine hydrochloride Injection 2%	YES
13.	Bupivacaine Injection 2%	YES
14.	Betamethasone Sodium Phosphate Injection 4mg/1ml	YES
15.	Colistimethate Sodium For Injection 2 MIU (150 mg)	YES
16.	Multivitamin for Injection (Lyophilized) (Adults)	YES
17.	Multivitamin for Injection (Lyophilized) (Children)	YES
18.	Paracetamol Injection 500mg	YES
19.	Dobutamine Injection 12.5 mg,ml	YES
20.	Acyclovir Injection 250 mg / 500 mg / 1 g	YES
21.	Phloroglucinol Injection 10mg / ml	YES
22.	Ketorolac Tromethamine Injection 30 mg/ml	YES
23.	Diclofenac Injection 50 mg	YES
24.	Hydralazine Injection 20 mg/ml	YES
25.	Paricalcitol Injection 5 mcg/ml	YES
26.	Isosorbide Injection 1 mg/ml	YES
27.	Ferric CarboxyMaltose Injection 50mg/ml	YES

KWALITY PHARMACEUTICALS LTD.

GENERAL INJECTABLE

(EU-GMP/SFDA/ANVISA/INVIMA/PIC/S APPROVED)

Sl. No.	PRODUCTS	DOSSIER READINESS
28.	Nitroglycerin Injection 5mg/ml	YES
29.	Nicardipine Injection 1 mg/ml & 2.5 mg/ml, 2mg/ml	YES
30.	Norepinpehrine Injection 1mg/ml & 2mg/ml	YES
31.	Lidocaine Hydrochloride Injection 1%w/v	YES
32.	Neostigmine Injection 2.5mg/ml	YES
33.	Fluconazole Injection 2mg/ml	YES
34.	Voriconazole Injection 200mg	YES
35.	Ganciclovir for injection 500mg	YES
36.	Nitroglycerin Injection 1mg/ml	YES
37.	Hydralazine Hydrochloride Injection 5mg/ml	YES
38.	Nicardipine Hydrochloride Injection 2.5mg/ml	YES
39.	Adrenaline Injection 0.1mg/ml	YES
40.	Epinephrine Injection 1mg/ml	YES
41.	Digoxin Injection 0.25mg./ml	YES
42.	Dobutamine Injection 12.5mg/ml	YES
43.	Acyclovir For Injection 250mg / 500mg	YES
44.	Bupivacaine and Adrenaline Injection 5 mg+9mcg/ml	YES
45.	Bupivacaine and Adrenaline Injection 5mg/ml + 5mcg (1:200000)/ml	YES
46.	Bupivacaine HCl. In Dextrose Injection USP 5 mg+ 80 mg/ml	YES
47.	Bupivacaine Injection 10 mg/ml	YES
48.	Lignocaine Hydrochloride and Dextrose Injection 50 mg + 75 mg / ml	YES
49.	Bupivacaine Injection 5mg/ml (Single Dose)	YES
50.	Lidocaine and Adrenaline Injection 20 mg+18mcg	YES
51.	Bupivacaine Injection 2.5mg/ml	YES
52.	Bupivacaine HCL and Adrenaline Injection 5 mg+ 1:80000	YES
53.	Lignocaine Hydrochloride and Dextrose Injection 53.5 mg + 75 mg / ml	YES

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GENERAL INJECTABLE

(EU-GMP/SFDA/ANVISA/INVIMA/PIC/S APPROVED)

Sl. No.	PRODUCTS	DOSSIER READINESS
54.	Bupivacaine Hydrochloride with Glucose Solution Injection 0.25% + 7.5%	YES
55.	Ropivacaine Hydrochloride Injection 0.75%	YES
56.	Bupivacaine Hydrochloride Injection 0.25%	YES
57.	Thiopental Sodium for Injection 500 mg / 1 gm	YES
58.	Etomidate Injection 2mg/ml	YES
59.	Neostigmine Injection 2.5mg/ml / 0.5 mg/ml	YES
60.	Heparin Sodium Injection 1000 I.U/ml / 5000 I.U/ml	YES
61.	Aprotinin Injection 100000 KIU / 200000 KIU	YES
62.	Caspofungin Acetate Injection 50mg	YES
63.	Ribavirin Injection 50mg/ml	YES
64.	Zidovudine Injection 10 mg/ml	YES
65.	Ephedrine HCl 100 mcg/ml	YES
66.	Salbutamol Injection 0.5mg/ml / 1 mg/ml	YES
67.	Aminophylline Injection	YES
68.	Enalapril Maleate Injection 1.25mg/ml	YES
69.	Clonidine Injection 150mcg/ml Methyldopa Hydrochloride Injection 50 mg/ml	YES
70.	Verapamil Hydrochloride Injection 2.5 mg/ml	YES
71.	Phentolamine Mesylate for Injection 1mg/ml, 10mg/ml	YES
72.	Hydralazine Hydrochloride Injection 5mg/ml, 10mg/ml, 20mg/ml, 50mg/ml	YES
73.	Reserpine Injection 1mg/ml	YES
74.	Atenolol Injection 5mg/10ml	YES
75.	Glyceryl Trinitrate Injection 5mg/ml, 5ml	YES
76.	Tartrate Metroprolol Injection 1mg/1ml	YES
77.	Dihydralazine Mesilate Injection 5mg/ml	YES
78.	Metoprolol Injection 1mg/1ml, 5mg/ml	YES
79.	Nimodipine Intravenous Infusion 200mcg/ml	YES
80.	Nicardipine Hydrochloride Injection 1mg/ml	YES

KWALITY PHARMACEUTICALS LTD.

GENERAL INJECTABLE

(EU-GMP/SFDA/ANVISA/INVIMA/PIC/S APPROVED)

Sl. No.	PRODUCTS	DOSSIER READINESS
81.	Nicardipine Hydrochloride Injection 2mg/ml	YES
82.	Ephedrine Hydrochloride Injection 40mg/ml	YES
83.	Isosorbide Mononitrate Injection 1mg/ml	YES

GENERAL CREAM, OINTMENT, GEL

(WHO APPROVED)

Sl. No.	PRODUCTS	DOSSIER READINESS
1.	Mupirocin cream 2%	YES
2.	Triamcinolone Acetonide Oral Paste 0.1%	YES
3.	Terbinafine Cream 1%	YES
4.	Clotrimazole Cream 1%w/w	YES
5.	Ketoconazole cream 2%	YES
6.	Gentamicin sulfate cream 0.1% w/w	YES
7.	Aciclovir cream 5%	YES
8.	Hydrocortisone acetate cream 1% w/w	YES
9.	Clobetasol Propionate Cream 0.05%	YES
10.	Tiabendazole ointment 5%	YES
11.	Nitrofurazone ointment 0.2%	YES
12.	Bacitracin Ointment 500 IU/ gm	YES
13.	Clindamycin phosphate gel 1%w/w	YES

KWALITY PHARMACEUTICALS LTD.

GENERAL SUPPOSITORIES

(WHO APPROVED)

Sl. No.	PRODUCTS	DOSSIER READINESS
1.	Metronidazole + Miconazole Vaginal Suppository 500mg + 100mg	YES
2.	Metronidazole + Miconazole Vaginal Suppository 750 mg + 200 mg	YES
3.	Clindamycin + Ketoconazole Vaginal Suppository 100mg + 400mg	YES
4.	Clindamycin and Clotrimazole Vaginal Suppository 100mg + 100mg	YES
5.	Clindamycin Phosphate Vaginal Suppository 100mg	YES
6.	Clotrimazole Vaginal Pessaries 500mg	YES
7.	Diclofenac Sodium Suppositories 100mg	YES
8.	Niflumic Acid Auppository 400 mg / 700 mg	YES
9.	Anti Hemorrhoidal Suppositories 0.5%	YES
10.	Paracetamol Suppositories 125 mg / 250 mg	YES

GENERAL ORAL SOLUTION & SUSPENSION

(PIC/S & GMP PLANNED)

Sl. No.	PRODUCTS	DOSSIER READINESS
1.	Albendazole Oral Suspension 200mg/5ml	YES
2.	Dried Ivy Leaf Extract Syrup 7mg/ml	YES
3.	Levocarnitine Oral Solution 1gm/10ml	YES
4.	Loratadine Oral Solution 5mg per 5ml	YES
5.	Acetaminophen Oral Solution 120mg/5ml	YES
6.	Ferrous Sulphate Oral Solution 125 mg/5ml	YES
7.	Metronidazole Suspension 125mg per 5ml	YES
8.	Ibuprofen oral suspension 100mg per 5ml	YES
9.	Paracetamol oral suspension 125mg/5ml, 250mg/5ml	YES
10.	Trimethoprim + Sulfamethoxazole oral suspension 40mg+200mg/5ml	YES

KWALITY PHARMACEUTICALS LTD.

Narcotic Drugs and Psychotropic Substances- INJECTABLE (Control Substances)

(EU-GMP/SFDA/ANVISA/INVIMA/PIC/S APPROVED)

SI. No.	PRODUCTS	DOSSIER READINESS
1.	Fentanyl Citrate Injection 50 mcg / ml	YES
2.	Sufentanil Citrate Injection 50 mcg / ml	YES
3.	Remifentanil Hydrochloride For Injection 1 mg, 2 mg, 3 mg (Lyophilized)	YES
4.	Diazepam Injection 10 mg / ml, 10mg / 2 ml	YES
5.	Ketamine Hydrochloride Injection 10 mg / ml, 50 mg / ml	YES
6.	Morphine Sulphate Injection 10 mg / ml	YES
7.	Pentazocine Injection 30 mg / ml	YES
8.	Phenobarbital Sodium Injection 200 mg / ml	YES
9.	Clonazepam Injection 1 mg / ml	YES
10.	Ephedrine Hydrochloride Injection 30 mg / ml, 50 mg / ml	YES
11.	Ephedrine Injection 1 mg / ml	YES
12.	Ergometrine and Oxytocin Injection 500 mcg + 10 I.U / ml	YES
13.	Ergometrine Injection 0.2 mg / ml, 0.5 mg / ml	YES
14.	Methylergometerine Maleate Injection 0.2 mg / ml	YES
15.	Pethidine Injection 50 mg / ml	YES

Narcotic Drugs and Psychotropic Substances- LIQUID ORAL

(EU-GMP/SFDA/ANVISA/INVIMA/PIC/S APPROVED)

SI. No.	PRODUCTS	DOSSIER READINESS
1.	Morphine Sulphate Syrup 10 mg / 5 ml	YES
2.	Phenobarbital Oral Solution 15 mg / 5 ml	YES
3.	Phenobarbitone Sodium Syrup 20 mg / 5 ml	YES

KWALITY PHARMACEUTICALS LTD.

Narcotic Drugs and Psychotropic Substances- ORAL SOLID

(EU-GMP/SFDA/ANVISA/INVIMA/PIC/S APPROVED)

Sl. No.	PRODUCTS	DOSSIER READINESS
1.	Phenobarbital Sodium Tablets 30 mg, 50 mg, 60 mg, 100 mg	YES
2.	Clomipramine Tablets 10 mg, 25 mg, 50 mg, 75 mg	YES
3.	Morphine Tablets 10 mg, 30 mg, 60 mg	YES
4.	Diazepam Tablet 10mg, 5mg, 2 mg	YES
5.	Lorazepam Tablets 0.5 mg, 1 mg, 2 mg	YES
6.	Buprenorphine Tablets 0.1 mg, 0.2 mg, 0.4 mg	YES

DENTAL CARTRIDGES

(EU-GMP/SFDA/ANVISA/INVIMA/PIC/S APPROVED)

Sl. No.	PRODUCTS	DOSSIER READINESS
1.	Lidocaine Hydrochloride and Epinephrine Injection 20 mg and 1:80000 / ml, 1.8 ml Cartridge	YES
2.	Articaine and Epinephrine Injection 40mg + 1:100000 / ml, 1.8 ml Cartridge	YES
3.	Mepivacaine Hydrochloride Injection 3%, 1.8 ml Cartridge	YES
4.	Pralidoxime Chloride injection 375mg/ml, 5 ml Cartridge	YES
5.	Atropine Sulphate Injection 1.25mg/ml, 5 ml Cartridge	YES

KWALITY PHARMACEUTICALS LTD.

OPHTHALMICS

(ANVISA / PIC/s APPROVED)

Sl. No.	PRODUCTS	DOSSIER READINESS
1.	Dorzolamide +Timolol Solution 20mg+5mg/ml	YES
2.	Brimonidine Solution 0.2%	YES
3.	Timolol Solution 0.25% / 0.3%	YES
4.	Ciprofloxacin + Dexamethasone Solution 0.3%+0.1%	YES
5.	Bimatoprost Solution 0.03% / 0.1%	YES
6.	Brimonidine 0.2% Solution	YES
7.	Brinzolamide+ Timolol Solution 2 mg/6.8 mg	YES

MULTI-DOSE PRESERVATIVE-FREE OPHTHALMICS PRODUCTS

(CE / ISO 13485 APPROVED)

8.	Sodium Hyaluronate Eye Drops 0.4%	YES
9.	Sodium Hyaluronate Eye Drops 0.2%	YES
10.	Sodium Hyaluronate Eye Drops 0.15%	YES
11.	Carboxymethylcellulose Sodium Ophthalmic Solution 0.5% w/v	YES
12.	Trehalose and Sodium Hyaluronate Ophthalmic Solution 3% w/v + 0.15% w/v	YES
13.	Hypromellose 0.5% Ophthalmic Solution	YES

BETA LACTAM – INJECTABLE

(EU GMP/ SFDA/ ANVISA/ PIC/S APPROVED)

Sl. No.	PRODUCTS	DOSSIER READINESS
1.	Meropenem for Injection 500mg/1000mg	YES
2.	Amoxicillin for Injection 500mg / 1000mg	YES
3.	Amoxicillin+ Potassium Clavulanate for Injection 500mg + 100mg	YES

KWALITY PHARMACEUTICALS LTD.

BETA LACTAM – INJECTABLE

(EU GMP/ SFDA/ ANVISA/ PIC/S APPROVED)

Sl. No.	PRODUCTS	DOSSIER READINESS
4.	Amoxicillin+Potassium Clavulanate for Injection 1000mg + 200mg	YES
5.	Ertapenem Sodium For Injection 1g	YES
6.	Imipenem + Cilastatin 500+500 mg	YES
7.	Aztreonam Injection 1g	YES
8.	Piperacillin+Tazobactum Injection 4.5g	YES

BETA LACTAM – ORAL SOLIDS

(EU GMP/ANVISA APPROVED)

Sl. No.	PRODUCTS	DOSSIER READINESS
1.	Amoxicillin + Potassium Clavulanate 875+125 mg	YES
2.	Amoxicillin + Potassium Clavulanate 500+125 mg	YES
3.	Sultamicillin Tab 375/750 mg	YES

BETA LACTAM – DRY SYRUP & SUSPESNIONS

(ANVISA APPROVED)

Sl. No.	PRODUCTS	DOSSIER READINESS
1.	Sultamicillin Powder for oral Suspension 250mg/5ml	YES
2.	Amoxicillin for oral suspension 250 mg/5ml	YES
3.	Amoxicillin for oral suspension 125mg	YES
4.	Amoxicillin for oral suspension 250mg	YES
5.	Amoxicillin and Clavulanate Potassium for oral Suspension 250mg + 62.5mg/5ml	YES

KWALITY PHARMACEUTICALS LTD.

BETA LACTAM – DRY SYRUP & SUSPESNIONS

(ANVISA APPROVED)

Sl. No.	PRODUCTS	DOSSIER READINESS
6.	Amoxicillin and Clavulanate Potassium for oral Suspension 200mg + 28.5mg/5ml	YES
7.	Ampicillin and cloxacillin for oral suspension 125mg + 125mg/5ml	YES

ONCOLOGY – INJECTABLE

(EU-GMP / INVIMA APPROVED)

Sl. No.	PRODUCTS	DOSSIER READINESS
1.	Azacitidine Injection 100 mg	YES
2.	Zoledronic Acid Injection 4mg	YES
3.	Leucovorin Calcium Injection 50/100mg	YES
4.	Irinotecan Injection 100mg	YES
5.	Bleomycin for Injection 15 IU	YES
6.	Paclitaxel (Protein Bound) Injection 100mg	YES
7.	Flurouracil Injection 100mg/ml	YES
8.	Triptorelin Pamoate for Injection 11.25mg	YES
9.	Leuprolide Acetate Depot for Injection 3.75mg/ 7.5mg/11.25mg/22.5 mg (Lyophilized)	YES
10.	Octreotide Acetate Long Acting Release Injection 20mg/30 mg (Lyophilized)	YES
11.	Idarubicin Hydrochloride for Injection 5mg (Lyophilized)	YES
12.	Idarubicin Hydrochloride for Injection 10mg (Lyophilized)	YES
13.	Doxorubicin Hydrochloride Liposomal Injection 20mg/10ml	YES
14.	Doxorubicin Hydrochloride for Injection 50mg/Vial (Lyophilized)	YES

KWALITY PHARMACEUTICALS LTD.

ONCOLOGY – INJECTABLE

(EU-GMP / INVIMA APPROVED)

Sl. No.	PRODUCTS	DOSSIER READINESS
15.	Ifosfamide for Injection 1000mg (Lyophilized)	YES
16.	Ifosfamide for Injection 2000mg (Lyophilized)	YES
17.	Ifosfamide For Injection USP 1 gm/ Vial(As Lyophilized)3 Amps of Mesna Injection 200mg / 2ml	YES
18.	Ifosfamide For Injection USP 2 gm/ Vial(As Lyophilized)6 Amps of Mesna Injection 200mg / 2ml	YES
19.	Cyclophosphamide for Injection 1000mg (Lyophilized)	YES
20.	Cyclophosphamide for Injection 500mg (Lyophilized)	YES
21.	Cyclophosphamide for Injection 200mg (Lyophilized)	YES
22.	Docetaxel Injection 80mg/2ml	YES
23.	Paclitaxel Injection USP 30mg/5ml	YES
24.	Fluorouracil Injection 50 mg / ml	YES
25.	Zoledronic Acid for Injection 4mg (Lyophilized)	YES
26.	Irinotecan Hydrochloride Injection 20mg/ml	YES
27.	Carboplatin Injection 150mg/15ml	YES
28.	Carboplatin Injection 450mg	YES
29.	Carboplatin Injection 50mg/5ml	YES
30.	Carboplatin Injection 10mg/ml	YES
31.	Cisplatin Injection 0.5mg/ml	YES
32.	Cisplatin Injection 1mg/ml	YES
33.	Cisplatin Injection 10mg/ml	YES
34.	Cisplatin Injection 50mg/ml	YES
35.	Cladribine Injection 1mg/ml	YES
36.	Carmustine Injection 100mg	YES
37.	Cytarabine Injection 1000mg/5ml	YES
38.	Docetaxel Injection 20 mg per 2 ml	YES
39.	Gemcitabine For Injection 200mg/Vial	YES
40.	Gemcitabine For Injection 500mg/Vial	YES
41.	Gemcitabine For Injection 1000mg/Vial	YES
42.	Vinorelbine Injection 50mg / 5ml	YES
43.	Cabazitaxel 60mg/1.5ml	YES

KWALITY PHARMACEUTICALS LTD.

ONCOLOGY – INJECTABLE

(EU-GMP / INVIMA APPROVED)

Sl. No.	PRODUCTS	DOSSIER READINESS
44.	Doxorubicin Hydrochloride Liposome Injection(As Pegylated Liposome) 20mg/ 10ml	YES
45.	Paclitaxel Concentrate solution for injection, 6mg/ml,16.7ml vial (100 mg)	YES
46.	Oxaliplatin Injection, solution for injection, 2mg/ml, 25 ml vial (50mg)	YES
47.	Oxaliplatin Injection, solution for injection, 2mg/ml, 50 ml vial (100mg)	YES
48.	Paclitaxel Injection, concentrate solution for Injection (6mg/ml),5ml(30mg)	YES
49.	Fluorouracil Injection 500mg / 10ml	YES
50.	Vincristine Sulfate Injection 1 mg / 2mg	YES
51.	Etoposide Injection 100mg /5ml	YES
52.	Fluorouracil Injection 250 mg per 5 ml	YES
53.	Methotrexate Injection 1gm inj	YES
54.	Docetaxel Injection 120 mg per 2 ml	YES
55.	Cisplatin Injection 50mg/50ml Vial	YES
56.	Methotrexate Injection 50mg	YES

ONCOLOGY – ORAL SOLIDS

(EU-GMP APPROVED)

Sl. No.	PRODUCTS	DOSSIER READINESS
1.	Abiraterone Acetate Tablets 250mg	YES
2.	Tamoxifen Tablets 20 mg	YES
3.	Sunitinib Capsules 50mg	YES
4.	Hydroxycarbamide Capsules 500 mg	YES
5.	Nilotinib Capsules 150 / 200 mg	YES
6.	Vandetanib Tablet 100mg, 300 mg	YES

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ONCOLOGY – ORAL SOLIDS

(EU-GMP APPROVED)

Sl. No.	PRODUCTS	DOSSIER READINESS
7.	Palbociclib Tablet 75mg, 100mg, 125 mg	YES
8.	Enzalutamide Tablets 40mg, 80mg, 160mg	YES
9.	Capecitabine Tablets 500mg	YES
10.	Everolimus Tablets 10 mg	YES
11.	Abiraterone Acetate Tablets 500mg	YES
12.	Anastrozole Tablets 1Mg	YES
13.	Bicalutamide Tablets 50mg	YES
14.	Methotrexate Tablets 2.5mg	YES
15.	Letrozole Tablets 2.5mg	YES
16.	Everolimus Tablets 5 mg	YES
17.	Megestrol Acetate Tablets 160 Mg	YES
18.	Regorafenib Tablets 40 mg	YES
19.	Cyclophosphamide Tablets 200 mg	YES
20.	Cyclophosphamide Tablets 50 mg	YES
21.	Ruxolitinib Tablets 5mg	YES
22.	Ruxolitinib Tablets 15mg	YES
23.	Enzalutamide Tablets 40mg	YES
24.	Enzalutamide Tablets 80mg	YES
25.	Erlotinib Hydrochloride Tablets 100mg	YES
26.	Erlotinib Hydrochloride Tablets 150mg	YES

CEPHALOSPORINS – INJECTABLE

(EU-GMP APPROVED)

Sl. No.	PRODUCTS	DOSSIER READINESS
1.	Ceftazidime + Avibactam for Injection 2000mg + 500mg	YES
2.	Ceftriaxone Injection 1 g	YES

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CEPHALOSPORINS – INJECTABLE

(EU-GMP APPROVED)

Sl. No.	PRODUCTS	DOSSIER READINESS
3.	Ceftriaxone Injection 2 g	YES
4.	Cefixime Injection 1g	YES
5.	Cephalothin Injection 1g	YES
6.	Ceftriaxone+ Sulbactum 1.5g	YES
7.	Cefazolin Sodium Injection 1000mg	YES
8.	Cefazolin Sodium Injection 500mg	YES
9.	Cefepime Injection 2gm	YES
10.	Cefepime Hydrochloride For Injection 1g	YES
11.	Cefoperazone + Sulbactam For Injection 1000mg + 500mg	YES
12.	Cefoperazone + Sulbactam For Injection 250 mg + 125mg	YES
13.	Cefoperazone + Sulbactam For Injection 1000mg + 1000mg	YES
14.	Cefoperazone + Sulbactam For Injection 2000mg + 1000mg	YES
15.	Cefotaxime Sodium Injection 500mg	YES
16.	Cefotaxime sodium and Sulbactam Sodium Injection 1000mg+500mg	YES
17.	Cefotaxime sodium and Sulbactam Sodium Injection 500mg+250mg	YES
18.	Cefotaxime Sodium For Injection 125mg	YES
19.	Cefotaxime Sodium Injection 250mg	YES
20.	Cefotaxime Sodium Injection 3000 mg	YES
21.	Cefotaxime Sodium Injection 500mg	YES
22.	Cefoxitin Sodium Injection 1g	YES
23.	Cefradine For Injection 500mg	YES
24.	Ceftazidime Injection 1000mg	YES
25.	Ceftazidime Injection 2000mg	YES
26.	Ceftazidime Injection 250mg	YES
27.	Ceftazidime Injection 500mg	YES

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CEPHALOSPORINS – INJECTABLE

(EU-GMP APPROVED)

Sl. No.	PRODUCTS	DOSSIER READINESS
28.	Ceftriaxone & Tazobactam for Injection 562.5mg	YES
29.	Ceftriaxone and Tazobactam for Injection 1250mg	YES
30.	Ceftriaxone and Tazobactam for Injection 2250mg	YES
31.	Ceftriaxone + Salbactam For Injection 250mg + 125mg	YES
32.	Ceftriaxone + Salbactam For Injection 500mg+250mg	YES
33.	Cefuroxime for Injection 1.5gm	YES
34.	Cefuroxime for Injection 1gm	YES
35.	Cefuroxime for Injection 750 mg	YES
36.	Cefuroxime Sodium for Injection 250 mg	YES
37.	Cefuroxime Sodium for Injection 500 mg	YES
38.	Cefotaxime for injection 1000mg	YES

CEPHALOSPORINS – ORAL SOLID

(EU-GMP APPROVED)

Sl. No.	PRODUCTS	DOSSIER READINESS
1.	Cefuroxime Axetil Tablets 500 mg	YES
2.	Cefixime Tablets 400mg	YES
3.	Cefprozil Tablets 500mg	YES
4.	Cephalexin Tablets 500 mg	YES
5.	Fosfomycin Sodium for Injection 1 / 4 g	YES

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