



**KWALITY
PHARMACEUTICALS LTD.**

Quality you can Trust

GLOBAL

Dossier List



BETTER ACCESS | WIDER REACH | HEALTHIER TOMMOROW



KWALITY PHARMACEUTICALS LTD.

GENERAL ORAL SOLID



(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 (Macrocrystals)	YES
14.	Sodium Valproate Gastro-resistant Tablets 500 mg	YES
15.	Raltegravir Tablets 400mg	YES
16.	Dapagliflozin Metformin Extended Release Tablet 10mg / 1gm	YES
17.	Empagliflozin Linagliptin Metformin Extended Release Tablet 10mg / 5mg / 1000mg	YES

GENERAL INJECTABLE



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

Sl. No.	PRODUCTS	DOSSIER READINESS
1.	Propofol Injectable Emulsion 10mg/ml / 20mg/ml	YES



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GENERAL INJECTABLE



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

Sl. No.	PRODUCTS	DOSSIER READINESS
2.	Betamethasone (as Dipropionate) 10 mg / 2 ml and Betamethasone (as Sodium Phosphate) 4 mg / 2 ml) Suspension (BE ongoing)	YES
3.	Amphotericin B Liposomal Injection 50 mg (BE ongoing)	YES
4.	Enoxaparin Sodium 100mg/ml (BE ongoing)	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.	Colistimethate Sodium For Injection 2 MIU (150 mg)	YES
9.	Multivitamin for Injection (Lyophilized) (Adults)	YES
10.	Multivitamin for Injection (Lyophilized) (Children)	YES
11.	Labetalol Hydrochloride Injection 5mg/ml	YES
12.	Omeprazole For Injection 40 mg/Vial	YES
13.	Tenoxicam For Injection 20mg (Lyophilized)	YES
14.	Aprotinin Injection 10000KIU (Lyophilized)	YES
15.	Lidocaine hydrochloride Injection 2%	YES
16.	Bupivacaine Injection 2%	YES
17.	Betamethasone Sodium Phosphate Injection 4mg/1ml	YES
18.	Paracetamol Infusion I.V 500mg/50ml, 1000mg/100ml	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 50mg	YES
24.	Hydralazine Injection 20mg/ml	YES
25.	Paricalcitol Injection 5mcg/ml	YES
26.	Isosorbide Injection 1mg/ml	YES



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

Sl. No.	PRODUCTS	DOSSIER READINESS
27.	Ferric CarboxyMaltose Injection 50mg/ml	YES
28.	Nitroglycerin Injection 5mg/ml	YES
29.	Nicardipine Injection 1 mg/ml & 2.5 mg/ml, 2mg/ml	YES
30.	Norepinephrine Injection 1mg/ml & 2mg/ml	YES

Narcotic Drugs and Psychotropic Substances (Control Substances)



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

Sl. No.	PRODUCTS	DOSSIER READINESS
1.	Ketamine Hydrochloride Injection 10 mg/ml	YES
2.	Morphine Sulphate Injection 10mg/ml	YES
3.	Fentanyl Citrate Injection 50mcg/ml	YES
4.	Midazolam Injection 5mg/ml	YES
5.	Remifentanyl Hydrochloride For Injection 1mg/2mg/5mg	YES
6.	Sufentanyl Citrate Injection 5mcg/ml	YES
7.	Pentazocine Injection 30 mg / ml	YES
8.	Phenobarbitone Injection 200mg/ml	YES

DENTAL CARTRIDGES



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

Sl. No.	PRODUCTS	DOSSIER READINESS
1.	Lidocaine and Epinephrine Injection 1%w/v and 1:200000	YES
2.	Mepivacaine Hydrochloride Injection 2% / 3 %	YES
3.	Articaine and Epinephrine Injection 40mg + 1:100000 / ml	YES



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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 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

GENERAL LIQUID ORALS

(ANVISA UNDER PLAN)

Sl. No.	PRODUCTS	DOSSIER READINESS
1.	Carbamazepine Oral Suspension 100mg/5ml	YES



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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
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 1g	YES
8.	Piperacillin+Tazobactam 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

ONCOLOGY – INJECTABLE



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

Sl. No.	PRODUCTS	DOSSIER READINESS
1.	Azacitidine for Injection 100 mg	YES
2.	Zoledronic Acid for Injection 4mg	YES
3.	Leucovorin Calcium 50/100mg	YES
4.	Irinotecan 100mg	YES
5.	Idarubicin 5 mg	YES
6.	Bleomycin 15 EU	YES



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ONCOLOGY – INJECTABLE



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

Sl. No.	PRODUCTS	DOSSIER READINESS
7.	Doxorubicin Hydrochloride Liposomal Injection 20mg	YES
8.	Docetaxel 80mg/2ml	YES
9.	Paclitaxel (Protein Bound) 100mg	YES
10.	Flurouracil Injection 100mg/ml	YES
11.	Triptorelin Pamoate 11.25mg	YES
12.	Leuprolide Acetate Depot for Injection 3.75mg/7.5mg/11.25mg/22.5 mg (Lyophilized)	YES
13.	Octreotide Acetate Long Acting Release Injection 20mg/30 mg (Lyophilized)	YES

ONCOLOGY – ORAL SOLIDS



(PIC/S/EU-GMP APPROVED)

Sl. No.	PRODUCTS	DOSSIER READINESS
1.	Abiraterone Acetate Tablets 250 mg, 500 mg	YES
2.	Tamoxifen 20 mg	YES
3.	Sunitinib Capsule 50mg	YES
4.	Hydroxycarbamide Capsules 500 mg	YES
5.	Nilotinib Capsules 150 mg, 200 mg	YES
6.	Vandetanib Tablet 100mg, 300 mg	YES
7.	Palbociclib Tablet 75mg, 100mg, 125 mg	YES
8.	Enzalutamide Tablets 40mg, 80mg, 160mg	YES

CEPHALOSPORINS – INJECTABLE



(PIC/S/EU-GMP APPROVED)

Sl. No.	PRODUCTS	DOSSIER READINESS
1.	Ceftriaxone for Injection 1 g	YES
2.	Cefixime for Injection 1g	YES
3.	Cephalothin Injection 1g	YES



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