



health

Department:
Health
REPUBLIC OF SOUTH AFRICA



Private Bag X828, PRETORIA, 0001 Dr AB Xuma Building 1112 Voortrekker Road, Pretoria Townlands 351-JR,
PRETORIA, 0187 Tel (012) 395 8000, Fax (012) 395 8918

Mr E van Zyl
Equity Pharmaceuticals (Pty) Ltd
100 Sovereign Road
Route 21 Corporate Park
Nellmapius Drive
Irene
Pretoria

Dear Mr van Zyl

Section 21 Authorization for FLUOROURACIL 1000MG INJECTION 20ML

Attached, please find the Authorization for exemption under Section 21 of the Medicines and Related Substances Act by SAHPRA granted for:

- **Fluorouracil 1000mg/20mL Injection 20mL**

The quantities for which approval was granted are only estimates based on procurement by provinces over the last 6 months. Please note that the National Department of Health (NDOH) cannot guarantee the procurement of these quantities, as NDOH has no control over orders being placed by provincial depots, and current stock holding might influence estimated quantities.

The following process will be followed to ensure the quality of the product being brought in:

1. Manufacturer will submit an assay and identification of every batch imported.
2. An additional assay of every batch will be done by a quality control laboratory.
3. A random sample will be assayed during the authorized period by a quality control laboratory.
4. Aggregate statistics to be submitted to NDOH in the first week of each month of all orders received and quantities supplied per province.
5. The NDOH needs to be advised of the quantities and date of arrival of stocks in terms of this authorization within 7 days after arrival.
6. The supplier will provide monthly reports, by the 7th of each month, using the attached format of orders received and issues done.
7. Participating Authorities (PAs) will provide a consolidated close out report of usage using the attached format on the date when an authorization lapses.

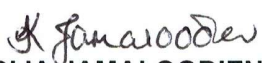
8. The full quantities imported in terms of this Section 21 authorisation must be accounted for.
9. Note that this authorization DOES NOT cover supplies to the private sector.
10. Where this authorization is obtained to provide security of supply due to supply challenges from the contracted supplier, PAs are requested to buy out against contracted suppliers and ensure that related orders are cancelled accordingly to prevent overstocking once the contracted supplier gets back into stock.

It should be noted this authorization applies only for use of the product in the public sector with estimated usage quantities for a period of one month. The authorization is expected to expire on **06 April 2027**.

Table 1: Provincial uptake

Province	Six Months Estimate
Correctional Services	0
EC-MT	300
EC-PE	660
FS	300
GP	1 600
KZN	1 200
LP	600
MP	240
NC	1 000
NW	1 170
SAMHS	796
WC	1 000
Total	8 866

Yours sincerely


KHADIJA JAMALOODIEN
CHIEF DIRECTOR: HEALTH PRODUCTS PROCUREMENT
DATE: 8/10/2026

Section 21 Outcome Letter

2026-10-06

Ms Khadija Jamaloodien

Voortrekker Road, First, Dr AB Xuma, Voortrekker Road, National Department Of Health,
Voortrekker Road, Pretoria Townlands 351-Jr, Pretoria, South Africa, Voortrekker Road, Pretoria,
Gauteng, Pretoria, Gauteng, South Africa, 0157, Voortrekker Road, Pretoria, Gauteng, Pretoria,
Gauteng, Gauteng, South Africa, 0157

Pretoria, Gauteng

buhle.mbongo@health.gov.za

Dear Ms Khadija Jamaloodien

REQUEST TO USE UNREGISTERED MEDICINE IN TERMS OF SECTION 21 OF THE MEDICINES AND CONTROLLED SUBSTANCES ACT, 1965 (ACT 101 of 1965):

Your application dated **2026-10-02** refers

- A. STATUS: Approved**
- B. APPLICANT: Ms Khadija Jamaloodien**
- C. IMPORTING COMPANY: EQUITY PHARMACEUTICAL (PTY) LTD**
- D. NUMBER OF PATIENT/(S) INTENDED TO BE TREATED: 1**
- E. UNREGISTERED MEDICINES: GENERIC NAME (INN / ACTIVE INGREDIENT):
Fluorouracil**
- F. TRADE NAME: Fluorouracil Injection 50 mg/mL**

G. QUANTITY: 8800 Packs (1)

H. LETTER NUMBER: S2100038821

Section 21 authorization letters are valid for a period of 6 months from the letter date, unless otherwise specified.

A progress report must be submitted once treatment is completed or on a reauthorization request

Comments:

No Data

Yours faithfully,

Shyamli Munbodh

Manager: Section 21 Category A Medicines





health

Department:
Health
REPUBLIC OF SOUTH AFRICA



Private Bag X828, PRETORIA, 0001 Dr AB Xuma Building 1112 Voortrekker Road, Pretoria Townlands 351-JR, PRETORIA,
0187 Tel (012) 395 8000, Fax (012) 395 8918

REQUEST FOR QUOTATION FORM

- Instruction to complete this Request for Quotation (RFQ)**
PLEASE PROVIDE A QUOTE FOR THE FOLLOWING PRODUCT(S).
PLEASE QUOTE ON THIS RFQ FORM AND ATTACH YOUR QUOTE WITH THE REQUESTED DETAILS.
THE SECTIONS HIGHLIGHTED IN YELLOW MUST BE COMPLETED BY THE SUPPLIER.
- THIS DOES NOT CONSTITUTE ANY OBLIGATION TO PROCURE THE ITEM AS THIS WILL BE SUBMITTED FOR CONSIDERATION TO PROVINCIAL PROCUREMENT UNITS TO SERVE AS A BUY OUT AGAINST CURRENT NON-COMPLIANT SUPPLIERS.**

ONLY RESPONSES FROM DULY REGISTERED SUPPLIERS WILL BE EVALUATED

REFERENCE NUMBER:	NORMAL	SECTION 21	X	S21RFQ189/2026
QUOTE ENQUIRY DATE	22/09/2026	QUOTE CLOSING DATE	30/09/2026	
FOR CRITICAL DELIVERY, DELIVERY REQUESTED ON/BEFORE (SCM Practitioner to Specify if applicable)				
REQUESTING INSTITUTION CONTACT DETAILS				
NAME OF REQUESTOR	Buhle Mbongo			
EMAIL ADDRESS	Buhle.Mbongo@health.gov.za			
PHONE No.	012 395 9539	FAX No.	N/A	
PRODUCT INFORMATION				
DESCRIPTION PER MPC	5-Fluorouracil 1000mg/20mL INJ			
TRADE DESCRIPTION	5-Fluorouracil 1000mg/20ml			
UNIT OF MEASURE	1's	PACK or BOX (SIZE/ QUANTITY)	1	
QUANTITY REQUIRED	8 200			
TO BE COMPLETED BY THE SUPPLIER/ SERVICE PROVIDER				
SUPPLIER CONTACT DETAILS (as per CSD)				
DID YOU BID ITEM FOR TENDER	YES	NO	X	IF NO, WHY <u>Section 21</u>
COMPANY NAME	Equity Pharmaceuticals (Pty) Ltd.			
SUPPLIER NUMBER	MAAA0007480			
SECURITY CODE				
SUPPLIER CODE (NDoH)				
CONTACT PERSON 1	NAME	Ehrard van Zyl		
	PHONE	012 345 1747	FAX	012 345 1412
	MOBILE	072 040 8511		
	E-MAIL	ehrd@equitypharma.co.za		
CONTACT PERSON 2	NAME	Ruzanne van Zyl		
	PHONE	012 345 1747		

	MOBILE	082 616 1954	
	E-MAIL	ruzanne@equitypharma.co.za	
<u>QUOTE DETAILS</u>			
PRICE PER UNIT (INCL. VAT)	R 23.00	TOTAL PRICE (INCL. DELIVERY & VAT)	R 188 600.00
VOLUMES AVAILABLE – 14DAYS			
VOLUMES AVAILABLE – 21DAYS			
VOLUMES AVAILABLE – 28DAYS			
VOLUMES AVAILABLE – 35DAYS			
VOLUMES AVAILABLE – 42DAYS	8200		
VOLUMES AVAILABLE – 49DAYS			
VOLUMES AVAILABLE – 56DAYS			
VOLUMES AVAILABLE – 112DAYS			
QUOTE VALIDITY PERIOD	180 DAYS		
NORMAL LEAD/DELIVERY TIME	3 DAYS		
<u>DEVIATION TO SPECIFICATION</u>			
COMMENTS:			
<u>DECLARATION BY SUPPLIER</u>			
I hereby declare that in submitting this bid, there has been no consultation, communication, agreement or arrangement with any competitor/supplier regarding the price, quality, quantity, specifications and conditions or delivery particulars of the products or services to which this bid invitation relates.			
NAME	Ehrard van Zyl		
CAPACITY	Business Unit Manager: Specialist Medicine		
SIGNATURE (OF A DULY AUTHORISED REPRESENTATIVE OF THE SUPPLIER)			
DATE	2026/09/30		
<u>PROVINCIAL ESTIMATES</u>			
Province	Six Months Estimate		
DCS	0		
EC-MT	300		
EC-PE	0		
FS	300		
GP	1 600		
KZN	1 200		
LP	600		

MP	240
NC	1 000
NW	1 170
SAMHS	796
WC	1 000
Please submit quotations to Section21Quotes@health.gov.za	

Please ensure that you include the following as part of the Quotation:

- Delivery Time (Weeks)
- Price (Vat Inclusive)
- Generic Name
- Trade Name
- Quotation on Official Company Letterhead
- Central Supplier Database Summary Report (CSD)
- Medicine Registration Certificate (Only for Locally Registered Products)
- *Artwork/Labelling
- *Package Insert/ Professional Information/Summary of Product Characteristics: (Please attach)
- *Manufacturer Certificate: (Please attach)
- *Country of Origin: (Please indicate)

*Additional items required when submitting a quote for a Section 21 Item (Unregistered Medicine)
All of the above is required to expedite the process in considering the quotation.

Please **SUBMIT COMPLETED RFQ FORM AND QUOTATIONS ON AN OFFICIAL COMPANY LETTERHEAD**

NB:

- The supplier submitting the quotation must be the same entity which the provinces will place their orders
- The size of each individual attachment must not be more than 2MB (you may attach multiple files in one email but collectively they should not be more than 2MB in size).
- Please ensure that you provide all prescribed documentation that is outlined on page two of this RFQ.
- The confirmation letter from manufacturer to Supply South Africa with Bivalent oral Poliomyelitis Vaccine (bOPV) must be provided (only in cases of Bivalent oral Poliomyelitis Vaccine RFQ)
- Kindly be advised that a picture format of an Artwork shall not be accepted. Artwork must be in pdf or word format only.
- All prices must please be submitted in two decimals and in ZAR.
- If submitting more than one quotation, please make sure that your subject line includes e.g., 1 of 2 or 1 of 3 etc.
- Any submission with missing documentation shall not be considered.
- Any submission with blurry relevant documents shall not be considered.
- The only electronic GMP Certificate considered is that from EUDRA
- CSD must be updated for the current month of the RFQ date.
- **Email subject line for responses with quotes must be kept unchanged from the originally sent RFQ email.**

Please **SUBMIT COMPLETED RFQ FORM AND QUOTATIONS ON AN OFFICIAL COMPANY LETTERHEAD**

30/09/2026



Equity Pharmaceuticals (Pty) Ltd.
1997/009942/07

+27 12 345 1747
+27 12 345 1412
equity@equitypharma.co.za

www.clinigengroup.com
www.equitypharma.co.za

QUOTATION # 20260930

TO: National Department of Health

TEL : 012 395 9539

FAX :

Email : Section21Quotes@health.gov.za

CONTACT PERSON / PATIENT : Buhle Mbongo

NB IMPORTED AND SUPPLIED UNDER SECTION 21 TERMS

PRODUCT CODE	DESCRIPTION	PACK SIZE	QUANTITY	PRICE EXCL	TOTAL INCL
	5-Fluorouracil 1000mg/20ml	1 x 20ml	1	R 20.00	R 23.00
			8 200	R 164 000.00	R 188 600.00
			8 200	R 164 000.00	R 188 600.00

Valid for 180 days

Employee Signature: _____

Date: 30/09/2026

Approved by: Ehrard van Zyl



30/09/2026

National Department of Health

Directorate: Affordable Medicines

E-mail: Buhle.Mbongo@health.gov.za

Attention: Ms Buhle Mbongo

Equity Pharmaceuticals (Pty) Ltd.
1997/009942/07

☎ +27 12 345 1747
📠 +27 12 345 1412
✉ equity@equitypharma.co.za

www.clinigengroup.com
www.equitypharma.co.za

Dear Ms Mbongo

Re: Request for quotation – 5- Fluorouracil 1000mg/20ml – Section 21 Supply

Trust you are well. Please find below our quotation for 5-Fluorouracil 1000mg/20ml supplied under section 21 terms.

- Quantity: **8 200 vials**
- Delivery Time (Weeks): **6 weeks**
- Price (Vat Inclusive): **R 23.00 incl. vat per vial**
- Generic Name: **5-Fluorouracil 1000mg/20ml**
- Trade Name: **5-Fluorouracil 1000mg/20ml**
- Packaging: **1 x 20ml**
- Specifications: **Each vial containing 1000mg Fluorouracil**
- Shelf Life: **36 months**
- Package Insert: **Please find attached**
- Manufacturer: **Kwality Pharmaceuticals Ltd.**
- Country of Origin: **India**

Please note that the immediate availability of the product is conditioned on the manufacturer receiving notice of our order as soon as possible. Unfortunately, the stock cannot be reserved for our purposes for too long.

We look forward to your response.

Please contact me if you require any additional information.

Kind Regards

Ehrhard van Zyl

FLUOROURACIL

INJECTION USP

50 mg/ml

COMPOSITION :

Each ml contains:

Fluorouracil USP 50 mg

(as Fluorouracil Sodium)

Water for Injection USP q.s.

CATEGORY : Anticancer drugs

GENERAL INFORMATION :

It is a pyrimidine analogue antimetabolite which is used as an antineoplastic in the adjuvant and palliative treatment of various malignancies.

MOA : It inhibits thymidylate synthesis, thus DNA synthesis is inhibited.

PHARMACOKINETICS :

Absorption of fluorouracil from the gastrointestinal tract is unpredictable and fluorouracil is usually given intravenously. After intravenous injection fluorouracil is cleared rapidly from plasma with a mean half-life of about 16 minutes. It is distributed throughout body tissues and fluids including crossing the blood-brain barrier to appear in the CSF, and disappears from the plasma within about 3 hours. Within the target cell fluorouracil is converted to 5-fluorouridine monophosphate and floxuridine monophosphate (5-fluorodeoxyuridine monophosphate), the former undergoing conversion to the triphosphate which can be incorporated into RNA while the latter inhibits thymidylate synthetase. About 15% of an intravenous dose is excreted unchanged in the urine within 6 hours. The remainder is inactivated primarily in the liver and is catabolised via dihydropyrimidine dehydrogenase similarly to endogenous uracil. A large amount is excreted as respiratory carbon dioxide, urea and other metabolites are also produced.

INDICATIONS :

Used as an adjuvant to radiotherapy, surgery and in combination with other drugs, Malignant neoplasms of breast, G.I. tract and carcinoma of pancreas, carcinoma of urinary bladder, hepatoma, carcinoma of colon, topical treatment of premalignant keratosis of skin and multiple superficial basal cell carcinomas.

DOSAGE :

Adults: 12mg/kg body-wt. once daily for 4 successive days i.v. Max. daily dose: 800mg. If no toxicity give 6mg/kg on days 6`8`10`12. Discontinue day 12. Maintain dose 10-15mg/kg/week Max dose 1g/week.

CONTRAINDICATIONS : Serious infection, depressed bone marrow function.

ADVERSE EFFECTS : Nausea, vomiting, diarrhoea, alopecia, conjunctivitis, bone marrow depression, angina pectoris, cardiac arrhythmias, oral and G.I. ulcers, hyperpigmentation. Chest pain, breathlessness.

PRECAUTIONS :

Anaemia, leucopenia, skin pigmentation, eruption. Patient should be hospitalised during 1st course of treatment. Hepatic or renal impairment, hypersensitivity.

INTERACTIONS :

Cimetidine: Increased plasma fluorouracil concentration.

Other Bone marrow depressants, Immunosuppressive agents, Irradiation: Additive adverse effects.

Leucovorin calcium: Toxicity of fluorouracil enhanced.

Metronidazole: Enhanced toxicity.

Lab Tests: Elevation in alkaline phosphatase, serum transaminase, serum bilirubin and lactic dehydrogenase may occur.

STORAGE :

Store at a temperature between 20° to 25°C.

Do not freeze. Protect from light.

KEEP OUT OF THE REACH OF CHILDREN

PRESENTATION :

20 ml vial packed in a printed carton.

Manufactured by:

KWALITY PHARMACEUTICALS LTD.

1-A, Industrial Area, Raja Ka Bagh,

Tehsil - Nurpur, Distt.- Kangra,

(H.P.) - 176201, INDIA

Batch: _____
Mfg.: _____
Exp.: _____

FLUOROURACIL
INJECTION USP

50 mg/ml

50 mg/ml

FOR I.V. INJECTION
ONLY

Each ml contains :
 Fluorouracil USP 50 mg
 (as Fluorouracil Sodium)
 Water for Injection USP q.s.

Dosage:
As directed by the Oncologist.

Storage:
Store at a temperature between
20° to 25°C. Do not freeze.
Protect from light.

Keep out of the reach of children.
Do not use the Injection if it is
not clear.

If separation has occurred, the injection should be heated to 60° C, vigorously shaken and allowed to cool to body temperature prior to use.

20 ml

50 mg/ml

FOR I.V. INJECTION
ONLY

Warning: To be supplied against demand from Cancer Hospitals, Institutions and against Prescription of a Cancer Specialist only.

See Package insert for complete
prescribing information

Mfg. Lic. No.: BNZ/08/41

Manufactured by:
**KWALITY
PHARMACEUTICALS LTD.**
1-A, Industrial Area, Raja Ka Bagh,
Tehsil - Nurpur, Distt.- Kangra,
(H.P.) - 176201, INDIA

20ml

COMPOSITION: Each ml contains:

Fluorouracil USP 50 mg

(as Fluorouracil Sodium)

Water for Injection USP q.s.

Contains no antimicrobial preservatives

Dosage: As directed by the Oncologist.

See Package insert for complete
prescribing information

Storage:

Store at a temperature between 20° to
25°C. Do not freeze. Protect from light.

Keep out of the reach of children.

Do not use the Injection if it is not clear.

If separation has occurred, the injection
should be heated to 60°C, vigorously
shaken and allowed to cool to body
temperature prior to use.

FLUOROURACIL

INJECTION USP

50 mg/ml

FOR I.V. INJECTION
ONLY

20 ml

Warning: To be supplied against demand
from Cancer Hospitals, Institutions and against
Prescription of a Cancer Specialist only.

Mfg. Lic. No.: BNZ/08/41

Batch :

Mfg. :

Exp. :

NVZ

Manufactured by:

KWALITY PHARMACEUTICALS LTD.

1-A, Industrial Area, Raja Ka Bagh, Tehsil -
Nurpur, Distt.- Kangra, (H.P.) - 176201, India