



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 RIFAMPICIN 150MG CAPSULES 100'S

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

- **Rifampicin 150mg Capsules 100's**

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.

Section 21 Authorisation re Rifampicin 150mg Capsules 26082025-2

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 **26 February 2026**.

Table 1: Provincial estimates

Province	Six Months Estimate
Correctional Services	0
EC-MT	1800
EC-PE	7000
FS	900
GP	2100
KZN	2400
LP	600
MP	286
NC	300
NW	530
SAMHS	80
WC	4800
Total	20 796

Yours sincerely


KHADIJA JAMALOODIEN
CHIEF DIRECTOR: SECTOR WIDE PROCUREMENT
DATE: 27/8/2025

Department of Health • Lefapha la Pholo • Lefapha la Bophelo • uMnyango wezeMpilo • Muhasho wa Mutakalo • Departement van Gesondheid • Kgoro ya Maphelo • Ndzawulo ya Rihanyo • LiTiko le Thempilo • ISebe lezeMpilo • UmNyango WezamaPhilo

Section 21 Outcome Letter

2025-08-26

Ms Buhle Mbongo

National Department Of Health

Pretoria

buhle.mbongo@health.gov.za

Dear Ms Buhle Mbongo

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 **2025-08-26** refers

- A. STATUS: Approved**
- B. APPLICANT: Ms Buhle Mbongo**
- C. IMPORTING COMPANY: EQUITY PHARMACEUTICAL (PTY) LTD**
- D. NUMBER OF PATIENT/(S) INTENDED TO BE TREATED: 22222**
- E. UNREGISTERED MEDICINES: GENERIC NAME: No Data**
- F. TRADE NAME: Rifampicin Capsules 150 mg**
- G. QUANTITY: 20000 Packs (100)**

H. LETTER NUMBER: S2100010516

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:

Yours faithfully,

Dr S Munbodh

Manager: Section 21 Category A Medicines



Mahlodi Maropa

Final Approver

S2100010516



SAHPRA Head Office
Building A, Loftus Park
2nd Floor
Kirkness Str
Arcadia
0083

A rectangular box containing a handwritten signature in black ink. The signature is stylized and appears to be 'M. P. C.' or similar, with a large loop at the beginning.



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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	S21RFQ157
QUOTE ENQUIRY DATE	29/07/2025	QUOTE CLOSING DATE	07/08/2025	
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	RIFAMPICIN 150MG CAPSULES 100'S			
TRADE DESCRIPTION	Rifampicin 150mg Capsules			
UNIT OF MEASURE	100'S	PACK or BOX (SIZE/ QUANTITY)	1 X 100'S	
QUANTITY REQUIRED	1900 Packs of 100's			
TO BE COMPLETED BY THE SUPPLIER/ SERVICE PROVIDER				
SUPPLIER CONTACT DETAILS (as per CSD)				
COMPANY NAME	Equity Pharmaceuticals (Pty) Ltd			
SUPPLIER NUMBER	MAAA007480			
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	ehrdard@equitypharma.co.za		
CONTACT PERSON 2	NAME	Jaco Schoeman		
	PHONE	012 345 1747		

	MOBILE	076 734 0080	
	E-MAIL	jacos@equityharma.co.za	
<u>QUOTE DETAILS</u>			
PRICE PER UNIT (INCL. VAT)	R 167.90	TOTAL PRICE (INCL. DELIVERY & VAT)	R 319 010.00
*STOCK'S EXPIRY DATE(SHELF-LIFE)	36 months		
VOLUMES AVAILABLE – 7DAYS			
VOLUMES AVAILABLE – 14DAYS			
VOLUMES AVAILABLE – 21DAYS			
VOLUMES AVAILABLE – 28DAYS			
VOLUMES AVAILABLE – 35DAYS	1 900		
VOLUMES AVAILABLE - 42DAYS			
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	07/08/2025		
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
- Central Supplier Database Summary Report (CSD), updated for the current month
- Medicine Registration Certificate (Only for Locally Registered Products)
- *Artwork/Labelling
- *Package Insert: (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 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 with 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 bOPV must be provided
- 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.
- **Email subject line for responses with quotes must be kept unchanged from the originally sent RFQ email.**

SUBMIT BOTH COMPLETED RFQ FORM AND QUOTATION (ON AN OFFICIAL COMPANY LETTERHEAD)

07/08/2025



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 # 20250807

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
	Rifampicin 150mg Capsules	100's	1	R 146.00	R 167.90
			1 900	R 277 400.00	R 319 010.00
			1 900	R 277 400.00	R 319 010.00

Valid for 180 days

Employee Signature: _____

Date: 07/08/2025

Approved by: Ehrard van Zyl / Carel Bouwer

07/08/2025



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

National Department of Health

Directorate: Affordable Medicines

E-mail: Section21Quotes@health.gov.za

Attention: Ms Buhle Mbongo

Dear Ms Mbongo

Re: Request for quotation – Rifampicin 150mg Capsules – Section 21 Supply

Trust you are well. Please find below our quotation for *Rifampicin 150mg Capsules* supplied under section 21 terms.

- | | |
|--------------------------|------------------------------------|
| • Quantity: | 1 900 packs |
| • Delivery Time (Weeks): | 5 Weeks |
| • Price (Vat Inclusive): | R 167.90 |
| • Generic Name: | Rifampicin |
| • Trade Name: | Rifampicin 150mg Capsules |
| • Packaging: | 100's |
| • Specifications: | 150mg |
| • Shelf Life: | 36 months |
| • Package Insert: | 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

A handwritten signature in black ink, appearing to read "Ehrard van Zyl", written over a horizontal line.

Ehrard van Zyl

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only

Rifampicin

Capsules

150 mg

COMPOSITION

Each capsule contains:
Rifampicin BP 150 mg
Approved colours used in shell.

CATEGORY

Rifampicin antituberculosis drug.

GENERAL INFORMATION

It is a potent bactericidal drug.

MOA

It acts by inhibiting DNA dependent RNA synthesis.

PHARMACOKINETICS

After oral administration it is distributed to different body tissues and penetrates meninges, caseous masses and placental barrier. It is metabolised in liver to active metabolite and induces the microsomal enzymes of liver.
On Set of Action : Few days.
Duration of Action : Upto 24 hours.

INDICATIONS

Tuberculosis. Other: Neisseria meningitides carriers, Legionellas, Leprosy & prophylaxis of meningitis due to H.influenzae.

DOSAGE AND ADMINISTRATION

Adults: 450-600mg single dose before breakfast.
Children: 10-20mg/kg/day.
Meningococcal Carriers: Same dose as above for 4 days only.

CONTRAINDICATIONS

Liver disease and jaundice.

ADVERSE EFFECTS

Skin rash, drug fever, nausea, vomiting, peripheral neuropathy, fatigue, hepatitis and jaundice. Haemolytic anaemia. Diarrhoea, drowsiness, ataxia, headache, flu like syndrome, stomatitis.

SPECIAL PRECAUTIONS

Liver impairment, imparts orange red colour to urine, saliva, tears, sweat and sputum. Malnourished. Young children. Contact lenses may be irreversibly stained.

INTERACTIONS

Rifampicin by inducing the hepatic microsomal enzymes may reduce the efficacy of the following drugs: Acetaminophen, oral anticoagulants, barbiturates, benzodiazepines, chloramphenicol, clofibrate. Oral contraceptives, corticosteroids, cyclosporine, digitoxin, disopyramide, beta blockers oestrogens, hydantoins, mexiletine, quinidine, sulfones, sulphonylureas, theophylline, verapamil.

Halothane: Hepatotoxicity and hepatic encephalopathy.

Isoniazid: Higher incidence of hepatotoxicity than with either agent alone.

Ketoconazole: Treatment failure of either ketoconazole or rifampicin.

Food: Interferes with absorption of rifampicin, therefore it should be taken on empty stomach.

Lab tests: Inhibits standard assays for serum folate and vitamin B12 (riboflavin). Transient abnormalities in liver function tests, reduced excretion of contrast media used for visualization of gall bladder.

STORAGE:

Store below 25°C. Protect from light and moisture.
Keep out of the reach of children.

PRESENTATION

Blister strip of 10 capsules and 10 strips are packed in a printed box.

Manufactured by :
KWALITY PHARMACEUTICALS LTD.
Nag Kalan, Majitha Road, Amritsar - India



150 mg

Rifampicin Capsules

Component : Carton

Dimension : 85 x 64 x 75 mm

Colour : CMYK

Specification: Cyber XL

Coating : UV Coating

Rifampicin Capsules

150 mg

10 x 10 Capsules

Composition:

Each capsule contains:
Rifampicin BP 150 mg
Approved colours used in shell.

Dosage:

As directed by the Physician.

Storage:

Store below 25°C.
Protect from light and moisture.
Read enclosed leaflet carefully before use.

Rifampicin Capsules

150 mg

10 x 10 Capsules

Keep out of the reach of children.

Mfg. Lic. No. : 1800-OSP

Batch No. :

Mfg. Date :

Exp. Date :

Manufactured by :
KWALITY PHARMACEUTICALS LTD.
Nag Kalan, Majitha Road, Amritsar - India

SHELF LIFE : 36 Months										Checked by Dossier (Rohit)		Checked by Q.C. Department						
Check List For Labeling										Formulation No. :								
Work Order No.	Version	Pharmacop.	Spell.	Compo.	Batch.	Mfg., Exp.	Expiry as per Schedule 'P'	MRP.	Packing	Category	Mfg. Name	Reg. No.	Check Order for Product Volume & Packing	Storage				
14364/4	English																	
Matching all parameters between Box and Label										Country of Export : IRAN					Registered / Not Registration Artwork Status:			
Previous Specimen Artwork										Designed by : DESIGNER 3					Registered <input type="checkbox"/> Not Registered <input type="checkbox"/>			
Checked By.										Approved by : Authorized by : Party Approval					Order Qty.			
Production Inchange										Q.A. M.D.					Party Name			
										Card Board used for carton : <input type="checkbox"/> G/B <input type="checkbox"/> W/B <input checked="" type="checkbox"/> I.T.C. <input type="checkbox"/> Pearl					Packing			
										Blister strip of 10 capsules and 10 strips are packed in a Printed carton								
* NOTE: SINCE YOU HAVE APPROVED THE ARTWORK AND DID NOT IMPLEMENT OUR SUGGESTION. ANY CLAIM ARISING OUT OF SUCH CONTENTS OF ARTWORK SHALL NOT BE ENTERTAINED.																		