



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
Nelmapius Drive
Irene
Pretoria

Dear Mr van Zyl

Section 21 Authorization for STREPTOKINASE 1.5MU INJECTION

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

- **Streptokinase 1.5MU Injection**

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.

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

Batho Pele - putting people first

Section 21 Outcome Letter

2025-06-27

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 **2025-06-19** 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: 500**
- E. UNREGISTERED MEDICINES: GENERIC NAME: No Data**
- F. TRADE NAME: Streptokinase for Injection BP 1.5 MU**
- G. QUANTITY: 1000 Packs (1)**

H. LETTER NUMBER: S2100005862

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



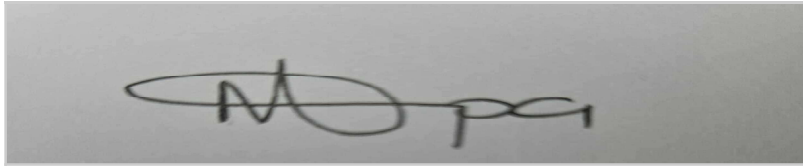
Mahlodi Maropa

Final Approver

S2100005862



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





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	S21RFQ154
QUOTE ENQUIRY DATE	29/05/2025	QUOTE CLOSING DATE			09/06/2025
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	STREPTOKINASE 1.5MI INJECTION		
TRADE DESCRIPTION	Streptokinase for Injection BP 1500 000IU		
UNIT OF MEASURE	1's	PACK or BOX (<i>SIZE/ QUANTITY</i>)	1's
QUANTITY REQUIRED	1000 vials		

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@equitypharma.co.za	
<u>QUOTE DETAILS</u>			
PRICE PER UNIT (INCL. VAT)	R 289.80	TOTAL PRICE (INCL. DELIVERY & VAT)	R 289 800.00
VOLUMES AVAILABLE – 14DAYS			
VOLUMES AVAILABLE – 28DAYS			
VOLUMES AVAILABLE – 56DAYS	1 000		
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	09/06/2025		
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.
- 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)

09/06/2025



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 # 20250609

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
	Streptokinase for Injection BP 1 500000IU	1 vial	1	R 252.00	R 289.80
			1 000	R 252 000.00	R 289 800.00
			1 000	R 252 000.00	R 289 800.00

Valid for 180 days

Employee Signature: _____

Date: 09/06/2025

Approved by: Ehrard van Zyl / Carel Bouwer

09/06/2025

National Department of Health

Directorate: Affordable Medicines

E-mail: Section21Quotes@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 – Streptokinase 1 500 000IU – Section 21 Supply

Trust you are well. Please find below our quotation for *Streptokinase 1 500 000IU* supplied under section 21 terms.

- | | |
|--------------------------|---|
| • Quantity: | 1 000 vials |
| • Delivery Time (Weeks): | 6 Weeks |
| • Price (Vat Inclusive): | R 289.80 |
| • Generic Name: | Streptokinase |
| • Trade Name: | Streptokinase for Injection BP 1 500 000IU |
| • Packaging: | 1 vial |
| • Specifications: | 1 500 000IU/vial |
| • Shelf Life: | 18 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


Ehrard van Zyl

1500000 IU

STREPTOKINASE
FOR INJECTION BP

Label size : 50 x 29 x 70 mm

1 vial + 1 Ampoule of sterile water
for injection 10 ml

STREPTOKINASE
FOR INJECTION BP

1500000 IU

Lyophilized for intravenous use

STERILE & PYROGEN FREE

Composition:
Each vial contains :
Streptokinase Concentrated
Solution BP 1500000 IU

Dosage:
As directed by the Physician.

Storage:
Store below 25°C.
Do not freeze.

Direction for use:
Dissolve the content of the
vial in 4-5 ml of Physiological
Saline or Sterile Water for
Injection.

The constituted solution
should be used immediately
after preparation.

**THE PREPARATION IS
ANTIGENIC**

1 vial + 1 Ampoule of sterile water
for injection 10 ml

STREPTOKINASE
FOR INJECTION BP

1500000 IU

Lyophilized for intravenous use

STERILE & PYROGEN FREE

Keep out of the reach of children.

Mfg. Lic. No.: 1804-B
Batch No. :
Mfg. Date :
Exp. Date :

Sterile water for injection 10ml

Batch No. }
Mfg. Date } As per
Exp. Date } inside
 } ampoule




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

Expiry Date is 36 months from the Mfg. Date. For eg. Feb 2022 to Jan 2025

Check List for Labeling													Formulation No.:	
Work Order No. :	Version	Pharmacop.	Spell.	Compo.	Batch, Mfg. Exp.	Expiry as per Schedule 'P'	M.R.P.	Mfg. Lic.No./ Nutral Code	Packing	Category	Mfg. Name	Reg. No.	Check Order for strength Volume & Packing	STORAGE
Matching all parameters between Box and Label														
Matching the parameter with label of leader brand														
Previous specimen artwork : REPEAT				Designed by : Lakhwinder Singh				Order Quantity		Party Name		Packing		
Checked by :		Approved by :		Authorized by:		Party Approval								
Production Incharge		QC Incharge		Q.A.		M.D.		Card Board used for carton :						
								□ G/B □ W/B □ I.T.C. □ Pearl						

Label size : 55 x 20 mm

Composition: Each vial contains : Streptokinase Concentrated Solution BP 1500000 IU Dosage: As directed by the Physician. Storage: Store below 25°C. Do not freeze. Direction for use: Dissolve the content of the vial in 4-5 ml of Physiological Saline or Sterile Water for Injection. The constituted solution should be used immediately after preparation. THE PREPARATION IS ANTIGENIC	<p style="text-align: center;">STREPTOKINASE FOR INJECTION BP</p> <p style="text-align: center;">1500000 UI</p> <p style="text-align: center;">Lyophilized for intravenous use</p> <p style="text-align: center;">STERILE & PYROGEN FREE</p> 	Keep out of the reach of children. Mfg. Lic. No.: 1804-B Batch No. : Mfg. Date : Exp. Date : Manufactured by: KWALITY PHARMACEUTICALS LTD. Nag Kalan, Majitha Road, Amritsar - INDIA
---	--	--

Expiry Date is 36 months from the Mfg. Date. For eg. Feb 2022 to Jan 2025

Check List for Labeling													Formulation No.:	
Work Order No. :	Version	Pharmacop.	Spell.	Compo.	Batch, Mfg. Exp.	Expiry as per Schedule 'P'	M.R.P.	Mfg. Lic.No./ Nutral Code	Packing	Category	Mfg. Name	Reg. No.	Check Order for strength Volume & Packing	STORAGE
Matching all parameters between Box and Label														
Matching the parameter with label of leader brand														
Previous specimen artwork : REPEAT				Designed by : Lakhwinder Singh				Order Quantity		Party Name		Packing		
Checked by :		Approved by :		Authorized by :		Party Approval								
Production Incharge		QC Incharge		Q.A.		M.D.		Card Board used for carton : <input type="checkbox"/> G/B <input type="checkbox"/> W/B <input type="checkbox"/> I.T.C. <input type="checkbox"/> Pearl						

100 x 172 mm

STREPTOKINASE FOR INJECTION BP

1500000 IU

COMPOSITION:

Each vial contains:

Streptokinase concentrated solution BP 1500000 IU

CATEGORY

Plasminogen activator; Fibrinolytic.

MOA

Streptokinase forms a complex with plasminogen which then converts plasminogen to plasmin. Plasmin breaks down clots as well as fibrinogen and other plasma proteins.

Absorption: Rapidly cleared from the circulation after IV use.

Excretion: Elimination half-life of streptokinase-activator complex: 23 minutes.

INDICATIONS & DOSAGE

Intravenous

Acute myocardial infarction

Adult: 1.5 million units as a single dose infused over 1 hr immediately after onset of symptoms.

Intravenous

Pulmonary thromboembolism ; Arteriovenous occlusions

Adult: Loading dose: 250,000 units infused over 30 min. Maintenance: 100,000 units/hr for 24-72 hr depending on the condition to be treated. For cerebral retinal thrombosis, 12 hr may be sufficient. Monitor treatment by maintaining thrombin clotting time at 2-4 times normal values.

Child: Loading dose: 2500-4000 units/kg over 30 min, followed by infusion of 500-1000 units/kg/hr, continued until reperfusion occurs, up to 3 days. Initial dose may be estimated by streptokinase resistance test. Monitor treatment by maintaining thrombin clotting time at 2-4 times normal values.

CONTRAINDICATIONS

Severe hypertension, recent stroke, cerebral neoplasm, recent history of peptic ulcer disease, ulcerative colitis, pancreatitis, subacute bacterial endocarditis, coagulation defects also due to liver or kidney disease, recent surgery, childbirth. Hypersensitivity, increased risk of cerebral bleeding, trauma. Pregnancy. Active internal bleeding, bleeding GI lesions.

ADVERSE EFFECTS

Fever, chills, back pain, abdominal pain, nausea, vomiting, arrhythmia, bruising, rash, pruritus, acute renal failure due to embolism and haemorrhage. Cerebral, peripheral and pulmonary embolism. Allergic reactions, liver enzyme abnormalities, hypotension.

Potentially Fatal: Haemorrhage; anaphylactic shock.

SPECIAL PRECAUTIONS&WARNINGS

Mitral stenosis associated with AF. Streptokinase treatment within last 12 mth, use after prolonged or traumatic CPR; diabetic retinopathy. Elderly.

DRUG INTERACTIONS

Antagonistic effects with antifibrinolytic agents e.g. aminocaproic acid.

Potentially Fatal: Anticoagulants, heparin, antiplatelet agents e.g. aspirin and dipyridamole affect platelet function increasing the risk of haemorrhage.

STORAGE

Store below 25°C. Do not freeze

Keep out of the reach of children.

PRESENTATION

one vial of 1 g powder + one 10 ml ampoule of sterile water for injection packed in a printed carton.

Manufactured by:

KWALITY PHARMACEUTICALS LTD.

Nag Kalan, Majitha Road,

Amritsar - INDIA