



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 NITROGLYCERIN 1MG/ML INJECTION 10ML

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

- **Nitroglycerin 1mg/mL Injection 10mL**

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.

Section 21 Authorisation re Nitroglycerin 1mg INJ 10mL 14122023

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 over stocking 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 **13 June 2024**.

Table 1: Provincial estimates

Provinces	Six Months Estimated Quantity
EC -MT	120
EC-PE	0
FS	1260
GP	6000
KZN	5000
LP	0
MP	110
NC	600
NW	332
SAMHS	0
WC	7000
Total	20422

Yours sincerely


KHADIJA JAMALOODIEN
CHIEF DIRECTOR: SECTOR WIDE PROCUREMENT
DATE: 14/12/2023



Section 21 Response Letter

12/13/2023 10:39 AM

Khadija Jamaloodien

National Department of Health
Dr AB Xuma Building
1112 Voortrekker Rd
Pretoria Townlands 351-JR
Pretoria
0187

Buhle.Mbongo@health.gov.za

Dear Khadija Jamaloodien,

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

Your application dated 12/12/2023 2:16 PM refers

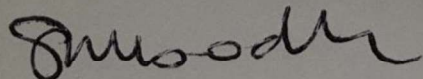
- A. STATUS: Approved**
- B. APPLICANT: Khadija Jamaloodien**
- C. IMPORTING COMPANY: Equity Pharmaceuticals (Pty) Ltd**
- D. PATIENT/(S):**
- E. UNREGISTERED MEDICINES:**
 - GENERIC NAME: Nitroswiss Injection**
 - USP 1mg/mL**
 - TRADE NAME: Nitroglycerine**
 - 1mg/mL**
- F. QUANTITY: Nitroglycerine**
 - 1mg/mL Injection 10mL x 20 500**
 - vials**
- G. LETTER NUMBER: B-23232**

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

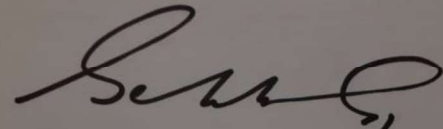
Comments:

Yours faithfully,

Dr S Munbodh
Manager: Section 21 Category A Medicines

A handwritten signature in black ink on a grey background, appearing to read 'S. Munbodh'.

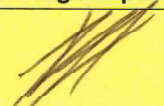
T Sehloho
Senior Manager: Clinical Evaluations Management

A handwritten signature in black ink on a grey background, appearing to read 'T. Sehloho'.



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				
<ul style="list-style-type: none"> 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	S21RFQ132
QUOTE ENQUIRY DATE	07/11/2023	QUOTE CLOSING DATE	16/11/2023	
FOR CRITICAL DELIVERY, DELIVERY REQUESTED ON/BEFORE <i>(SCM Practitioner to Specify if applicable)</i>				
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	GLYCERYL TRINITRATE 1MG/ML INJECTION 10ML			
TRADE DESCRIPTION	Nitroswiss (Nitroglycerine) Injection USP 1mg/ml (1 x 10ml)			
UNIT OF MEASURE	1's	PACK or BOX <i>(SIZE/ QUANTITY)</i>	1's	
QUANTITY REQUIRED	20500 Vials			
TO BE COMPLETED BY THE SUPPLIER/ SERVICE PROVIDER				
SUPPLIER CONTACT DETAILS (as per CSD)				
COMPANY NAME	Equity Pharmaceuticals (Pty) Ltd			
SUPPLIER NUMBER	MAAA0007480			
SECURITY CODE				
SUPPLIER CODE (NDoH)				
CONTACT PERSON 1	NAME	Ehrard van Zyl		
	PHONE	0123451747	FAX	0123451412
	MOBILE	0720408511		
	E-MAIL	ehrd@equitypharma.co.za		
CONTACT PERSON 2	NAME	Jaco Schoeman		
	PHONE	0123451747		

	MOBILE	0767340080	
	E-MAIL	jacos@equitypharma.co.za	
<u>QUOTE DETAILS</u>			
PRICE PER UNIT (INCL. VAT)	R 35.47	TOTAL PRICE (INCL. DELIVERY & VAT)	R 727 135.00
VOLUMES AVAILABLE – 14DAYS			
VOLUMES AVAILABLE – 28DAYS			
VOLUMES AVAILABLE – 56DAYS			
VOLUMES AVAILABLE – 112DAYS	20 500		
QUOTE VALIDITY PERIOD	180 days		
NORMAL LEAD/DELIVERY TIME	3 days		
<u>DEVIATION TO SPECIFICATION</u>			
<i>COMMENTS:</i>			
<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 <i>(OF A DULY AUTHORISED REPRESENTATIVE OF THE SUPPLIER)</i>			
DATE	16/11/2023		
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)
- 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 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 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.
- 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 be submitted in two decimals. Failure to do so will result in NDoH determining their own final price.
- 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.
- Email subject line for responses with quotes must be kept unchanged from the originally sent RFQ email.
- **Only** quotations should be sent to Section21Quotes@health.gov.za. All other queries to be directed to Buhle.Mbongo@health.gov.za
- Any quotation sent to Buhle.Mbongo@health.gov.za will not be considered.

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

16/11/2023



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 # 20231116

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
	Nitroswiss (Nitroglycerine) Injection USP 1mg/1ml	1 x 10ml	1	R 30.85	R 35.47
			20 500	R 632 425.00	R 727 135.00
			20 500	R 632 425.00	R 727 135.00

Valid for 180 days

Employee Signature: _____

Date: 16/11/2023

Approved by: Ehrard van Zyl / Carel Bouwe

16/11/2023

National Department of Health

Directorate: Affordable Medicines

E-mail: Section21Quotes@health.gov.za

Attention: Ms Buhle Mbongo

Dear Ms Mbongo

Re: Request for quotation – Glyceroltrinitrate 1mg/ml – Section 21 Supply

Trust you are well. Please find below our quotation for *Glycerol Trinitrate 1mg/ml* supplied under section 21 terms.

- Quantity: **20 500 vials**
- Delivery Time (Weeks): **12 weeks**
- Price (Vat Inclusive): **R 35.47 incl. vat per pack of 10 vials**
- Generic Name: **Nitroglycerin (Glycerol Trinitrate)**
- Trade Name: **Nitroswiss Injection USP 1mg/ml**
- Packaging: **1 x 10ml**
- Specifications: **1mg/ml**
- Shelf Life: **24 months**
- Package Insert: **Attached**
- Manufacturer: **Swiss Parenterals 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

EQUITY
PHARMACEUTICALS

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

NITROSWISS

Prescription Only Medicine

Nitroglycerin Injection USP

1 mg/ml, 10 ml

(Glyceryl Trinitrate)

NITROSWISS

For IV Infusion only



10 x 10 ml Ampoule

NITROSWISS

Composition :

Each ml contains :

Diluted Nitroglycerin USP (10%)

Equivalent to Nitroglycerin.....1 mg

Ethanol BP30 % v/v

Propylene Glycol BP30 % v/v

Water for Injections BP.....q.s.

Batch No. :

Mfg. Date :

Exp. Date :

Dosage : As directed by the physician.

Not for direct IV Injection, Must be diluted before use.

Discard unused portion.

Storage : Store below 30°C. Protect from light.

KEEP OUT OF REACH OF CHILDREN.

For more information, refer package insert.

Manufactured by:
SWISS PARENTERALS LTD.
808, 809 & 810,
Kerala Industrial Estate,
GIDC, Nr. Bavla,
Dist.: Ahmedabad-382 220,
Gujarat, INDIA.



(00)00000000000000
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NITROSWISS

218.20.110

NITROSWISS

-  PANTONE 1525 C
-  PANTONE 721 C
-  BLACK

Prescription Only Medicine

NITROSWISS
Nitroglycerin Injection USP 1 mg/ml, 10 ml
(Glyceryl Trinitrate)
For IV Infusion only

Composition :

Each ml contains :	Batch No. :
Diluted Nitroglycerin USP (10%)	Mfg. Date :
Equivalent to Nitroglycerin... 1 mg	Exp. Date :
Ethanol BP.....30 % v/v	
Propylene Glycol BP.....30 % v/v	
Water for Injections BP.....q.s.	

Dosage: As directed by the physician.
Not for direct IV Injection, Must be diluted before use.
Discard unused portion

Storage :
Store below 30°C, Protect from light,
KEEP OUT OF REACH OF CHILDREN.

Manufactured by :
SWISS PARENTERALS LTD.
808, 809 & 810, Kerala Industrial Estate,
GIDC, Nr. Bavla, Dist.: Ahmedabad-382220,
Gujarat, INDIA.

Actual size

Prescription Only Medicine

NITROSWISS
Nitroglycerin Injection USP 1 mg/ml, 10 ml
(Glyceryl Trinitrate)
For IV Infusion only

Composition :



Each ml contains :	Batch No. :
Diluted Nitroglycerin USP (10%)	Mfg. Date :
Equivalent to Nitroglycerin... 1 mg	Exp. Date :
Ethanol BP.....30 % v/v	
Propylene Glycol BP.....30 % v/v	
Water for Injections BP.....q.s.	

Dosage: As directed by the physician.
Not for direct IV Injection, Must be diluted before use.
Discard unused portion

Storage :
Store below 30°C, Protect from light,
KEEP OUT OF REACH OF CHILDREN.

Manufactured by :
SWISS PARENTERALS LTD.
808, 809 & 810, Kerala Industrial Estate,
GIDC, Nr. Bavla, Dist.: Ahmedabad-382220,
Gujarat, INDIA.

Enlarge size

	PANTONE 1525 C
	PANTONE 721 C
	BLACK