



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 MAGNESIUM SULPHATE 50% INJ 2ML

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

- **Magnesium Sulphate 50% Injection 2mL**

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 • Muthasho 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 Authorisation re Magnesium Sulphate 50% INJ 2mL 23062025-1

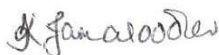
8. The full quantities imported in terms of this Section 21 authorisation must be accounted for.
9. Note that this authorization DOES NOT cover supplies to the private sector.
10. Where this authorization is obtained to provide security of supply due to supply challenges from the contracted supplier, 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 **23 December 2025**.

Table 1: Provincial estimates

Province	Six Months Estimate
Correctional Services	9
EC-MT	0
EC-PE	0
FS	24 000
GP	108 000
KZN	79 500
LP	22 000
MP	24 900
NC	15 000
NW	25 800
SAMHS	1 500
WC	23 800
Total	324 509

Yours sincerely



KHADIJA JAMALOODIEN
CHIEF DIRECTOR: SECTOR WIDE PROCUREMENT
DATE: 27/6/2025

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Section 21 Outcome Letter

2025-06-21

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 **2025-06-17** 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: 40625**
- E. UNREGISTERED MEDICINES: GENERIC NAME: Mama**
- F. TRADE NAME: Magnesium Sulfate Injection USP**
- G. QUANTITY: 325000 Packs**

H. LETTER NUMBER: S2100005583

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

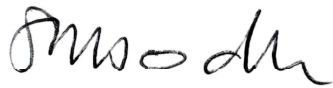
A progress report must be submitted once treatment is completed or on a reauthorization request

Comments:

Yours faithfully,

Dr S Munbodh

Manager: Section 21 Category A Medicines



Mahlodi Moropa

Final Approver

S2100005583



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

A handwritten signature in black ink, appearing to be 'M. P. P.', is positioned above a horizontal teal line.

Chairperson: Prof Helen Rees | Vice-Chairperson: Dr Obakeng Khaole | Prof Joyce Tsoka-Gwegweni
Board Members: Prof Patrick Demana | Dr Xolani Khayaletu Ngobese | Adv Hasina Cassim | Ms Ditaba Lucy Maraka
Mr Itani Elias Mashau | Ms Loretta Molefe | Dr Alfred Kgasi | Prof Johanna Meyer | Ms Mandisa Skhosana
Mr Faizal Docrat | Prof Yahya Choonara | CEO: Dr Boitumelo Semetle-Makobolela



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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	S21RFQ155
QUOTE ENQUIRY DATE	30/05/2025	QUOTE CLOSING DATE	10/06/2025	
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	MAGNESIUM SULPHATE 50% INJECTION 2ML		
TRADE DESCRIPTION	Magnesium Sulfate Injection USP 1g/2ml		
UNIT OF MEASURE	1's	PACK or BOX (SIZE/ QUANTITY)	1's
QUANTITY REQUIRED	325000 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 3.03	TOTAL PRICE (INCL. DELIVERY & VAT)	R 984 750.00
VOLUMES AVAILABLE – 14DAYS			
VOLUMES AVAILABLE – 28DAYS			
VOLUMES AVAILABLE – 56DAYS	325 000		
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	10/06/2025		
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)

10/06/2025



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 # 20250610

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
	Magnesium Sulfate Injection USP 1g/2ml	1 amp	1	R 2.64	R 3.03
			325 000	R 858 000.00	R 984 750.00
			325 000	R 858 000.00	R 984 750.00

Valid for 180 days

Employee Signature: _____

Date: 10/06/2025

Approved by: Ehrard van Zyl / Carel Bouwer

10/06/2025

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 – Magnesium Sulfate – Section 21 Supply

Trust you are well. Please find below our quotation for *Magnesium Sulfate* supplied under section 21 terms.

- Quantity: **325 000 amps**
- Delivery Time (Weeks): **6 Weeks**
- Price (Vat Inclusive): **R 3.03**
- Generic Name: **Magnesium Sulfate**
- Trade Name: **Magnesium Sulfate Injection USP**
- Packaging: **1 amp**
- Specifications: **1g/2ml**
- 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

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

Ehrard van Zyl



Component : CARTON
Dimension : 150 x 17 x 75 mm
Colour : CMYK
Specification: Cyber XL 350 GSM
U.V (Double Coating) + 3D Hologram

10 ampoules of 2ml

NOT FOR DIRECT INJECTION
MUST BE DILUTED BEFORE IV USE

1 g/2 ml
FOR IM OR IV USE

Magnesium Sulfate
Injection USP

Composition: Each ml contains:
Magnesium Sulfate
Heptahydrate USP 500 mg. eq. to
4.05 mOsmol /ml.
Water for Injection USP q.s.

Storage:
Store between temperature 20° to 25°C.
Protect from light.
Keep out of the reach of children.
Dosage: As directed by the Physician.

Mfg. Lic. No.: 1804-B
Manufactured by :
Kwality Pharmaceuticals Ltd.
Nag Kalan, Majitha Road, Amritsar- India

Batch No. :
Mfg. Date :
Exp. Date :



Magnesium Sulfate Injection USP
1 g/2 ml

Magnesium Sulfate
Injection USP

1 g/2 ml
FOR IM OR IV USE

NOT FOR DIRECT INJECTION
MUST BE DILUTED BEFORE IV USE

10 ampoules of 2ml



Leaflet Size 120 x 180mm

Magnesium Sulfate Injection USP

1 g/2 ml

COMPOSITION

Each ml contains:

Magnesium Sulfate Heptahydrate USP 500 mg

eq. to 4.05 mOsmol /ml.

Water for Injection USP q.s.

CATEGORY

Osmotic laxative; used in treatment of electrolyte deficiency.

PHARMACOLOGY

Magnesium is the second most plentiful cation of the intracellular fluids. It is essential for the activity of many enzyme systems and plays an important role with regard to neurochemical transmission and muscular excitability. Deficiencies are accompanied by a variety of structural and functional disturbances. Some of the effects of magnesium on the nervous system are similar to those of calcium. An increased Concentration of magnesium in the extracellular fluid causes depression of the central nervous system (CNS). Magnesium has a direct depressant effect on skeletal muscle. Abnormally low concentrations of magnesium in the extracellular fluid result in increased acetylcholine release and increased muscle excitability that can produce tetany.

Magnesium slows the rate of SA nodal impulse formation. Higher concentrations of magnesium (greater than 15 mEq/L) produce cardiac arrest in diastole. Excess magnesium causes vasodilation by both a direct action on blood vessels and ganglionic blockade. Magnesium is excreted principally by the kidney by glomerular filtration.

PHARMACOKINETICS

Absorption : Immediately absorbed (IV) and last for approximately 30 minutes. Following IM administration, the onset of action occurs within 3 to 4 hours..

Distribution : Approximately 1% to 2% of total body magnesium is in the extracellular fluid space; 30% bound to albumin.

Metabolism : Magnesium is not metabolized.

Elimination : Excreted solely by the kidneys at a rate proportional to the serum concentration and glomerular filtration.

INDICATIONS AND USAGE

- As a CNS depressant, primarily in preeclampsia and eclampsia of pregnancy;
- As an electrolyte replenisher for hypomagnesemia and magnesium deficiency to maintain normal neuro muscular irritability.

DOSAGE AND ADMINISTRATION

Intravenous : 1 to 4 g Magnesium Sulfate Injection, USP 50% may be given intravenously in 10% to 20% solution, but only with great caution; the rate should not exceed 1.5 mL of 10% solution or equivalent per minute until relaxation is obtained.

Usual Dose Range : 1 to 40 g daily.

CONTRAINDICATIONS

Magnesium Sulfate Injection, USP 50% should not be administered parenterally in patients with heart block or myocardial damage.

SPECIAL PRECAUTIONS

Administer with caution if flushing and sweating occurs. When barbiturates, narcotics or other hypnotics (or systemic anesthetics) are to be given in conjunction with magnesium, their dosage should be adjusted with caution because of additive CNS depressant effects of magnesium. A preparation of calcium salt should be readily available for intravenous injection to counteract potential serious signs of magnesium intoxication. Since magnesium is excreted almost entirely by the kidneys, it should be given very cautiously in the presence of serious impairment of renal function.

DRUG INTERACTIONS

When barbiturates, narcotics, hypnotics (or systemic anesthetics), or other central nervous system depressants are to be given in conjunction with magnesium, their dosage should be adjusted with caution because of the additive central nervous system depressant effects of magnesium. Central nervous system depression and peripheral transmission defects produced by magnesium may be antagonized by calcium.

ADVERSE REACTIONS

Principal adverse reactions are related to the high plasma levels of magnesium and include flushing, sweating, hypotension, circulatory collapse, and cardiac and central nervous system depression. Respiratory depression is the most life-threatening effect.

STORAGE

Store between temperature 20° to 25°C. Protect from light.
Keep out of the reach of children.

PRESENTATION:

10 ampoule of 2 ml enclosed in a plastic tray and each tray packed in a printed carton.

Manufactured by :

Kwality Pharmaceuticals Ltd.

Nag Kalan, Majitha Road, Amritsar- India