health
Department:
Health
REPUBLIC OF SOUTH AFRICA

2030 NDP

Private Bag X828, PRETORIA, 0001 Dr AB Xuma Building1112 Voortrekker Road, Pretoria Townlands 351-JR, PRETORIA, 0187 Tel (012) 395 8000, Fax (012) 395 8918

Mr C Mukaratirwa
Cospharm Investments (Pty) Ltd
2 Concourse Crescent
Lonehill
Johannesburg

Dear Mr Mukaratirwa

Section 21 Authorization for CYCLOSPORIN 50MG/ML INJ

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

- **Cyclosporin 50mg/mL 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.
8. The full quantities imported in terms of this Section 21authorisation 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 **07 May 2027**.

Table 1: Provincial estimates

Province	Six Months Estimate
Correctional Services	0
EC-MT	0
EC-PE	60
FS	1 800
GP	1 200
KZN	0
LP	0
MP	60
NC	0
NW	144
SAMHS	0
WC	500
Total	**3 764**

Yours sincerely

KHADIJA JAMALOODIEN
CHIEF DIRECTOR: HEALTH PRODUCTS PROCUREMENT
DATE: 9/11/2026

S2100040527

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

Section 21 Outcome Letter

2026-11-07

Ms Khadija Jamaloodien

1112 Voortrekker Road

Pretoria

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 **2026-10-28** refers

A. STATUS: Approved

B. APPLICANT: Ms Khadija Jamaloodien

C. IMPORTING COMPANY: COSPHARM INVESTMENTS (PTY) LTD

D. NUMBER OF PATIENT/(S) INTENDED TO BE TREATED: 370

E. UNREGISTERED MEDICINES: GENERIC NAME (INN / ACTIVE INGREDIENT): Ciclosporin

F. TRADE NAME: Cyclosporin 50 mg/mL

G. QUANTITY: 3700 Packs (10)

SAHPRA
South African
Health Products
Regulatory Authority

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

H. LETTER NUMBER: S2100040527

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

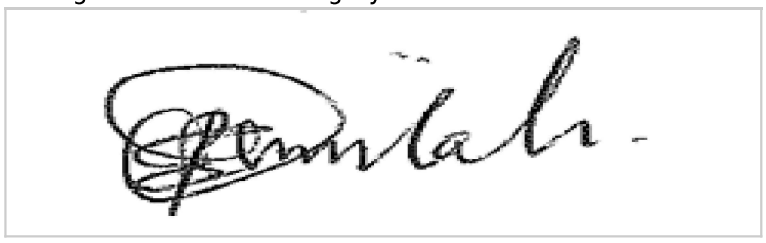
Comments:

No Data

Yours faithfully,

Ebenezer Minlah

Manager: Section 21 Category A Medicines



QUOTATION

Date 02/10/2026

VAT Reg No.:	4640290963
Reg no:	2018/468705/07
Quote No.	S21RFQ190/2026
Reference:	CYCLOSPORINE 50MG

FROM: COSPHARM INVESTMENTS (PTY)LTD	TO: DEPARTMENT OF HEALTH
2 Concourse Crescent Lonehill Johannesburg **010 110 9348**	Dr AB Xuma Building 1112, Voortrekker Road Preatoria Townlands 315 JR Pretoria, 0187 **012 395 8000**

BANKING DETAILS
COSPHARM INVESTMENTS (PTY) LTD **FNB** Account Number: 62850218241 Branch Code: 254605 Branch: Sandton City

Item Code	Item Description	Quantity	Disc %	Price excl	Price incl	Total (Excl)
CYC100	CYCLOSPORINE INJECTION USP 50MG	3760	0	R 40,55	R 46,63	R 152 468,00

Validity Period: 90 Days
Lead Times: 35 days after receipt of a formal Purchase Order
Country of origin: India
Manufacturer: Kwality Pharmaciticals

SubTotal (Excl)	**R**	**152 468,00**
VAT Total at 15%	R	22 860,80
Invoice Total ZAR	**R**	**175 328,80**

Name: Vibha Desai

Signature: Desai

Cospharm
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2 Concourse Crescent, Lonehill,
Johannesburg 2191 Gauteng
+27 10 110 9348
info@cospharm.org

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**	**S21RFQ190/2026**
QUOTE ENQUIRY DATE	**28/09/2026**	QUOTE CLOSING DATE			**05/10/2026**
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	**Cyclosporin 50mg INJ**		
TRADE DESCRIPTION	CYCLOSPORINE INJECTION USP 50MG		
UNIT OF MEASURE	1's	PACK or BOX (*SIZE/ QUANTITY*)	1
QUANTITY REQUIRED	**3 760**		

TO BE COMPLETED BY THE SUPPLIER/ SERVICE PROVIDER

SUPPLIER CONTACT DETAILS (as per CSD)

DID YOU BID ITEM FOR TENDER	YES		NO	✓	IF NO, WHY	SECTION 21
COMPANY NAME	COSPHARM INVESTMENTS (PTY) LTD					
SUPPLIER NUMBER	MAAA0922336					
SECURITY CODE	1DED17CF-07F8-4709-9F5F-6E477D4359AE					

2 Concourse Crescent, Lonehill,
Johannesburg 2191 Gauteng
+27 10 110 9348
info@cospharm.org

SUPPLIER CODE (NDoH)	VK0P8			
CONTACT PERSON 1	NAME	VIBHA DESAI		
	PHONE	010 110 9348	FAX	N/A
	MOBILE	*083 236 7123*		
	E-MAIL	rp@cospharm.org		
CONTACT PERSON 2	NAME	GLENDA MOROBANE		
	PHONE	010 110 9348		
	MOBILE	*060 908 8468*		
	E-MAIL	marketingza1@cospharm.org		

QUOTE DETAILS

PRICE PER UNIT (INCL. VAT)	R 46.63	TOTAL PRICE (INCL. DELIVERY & VAT)	R 175 328.80
VOLUMES AVAILABLE – 14DAYS			
VOLUMES AVAILABLE – 21DAYS			
VOLUMES AVAILABLE – 28DAYS			
VOLUMES AVAILABLE – 35DAYS	3760		
VOLUMES AVAILABLE – 42DAYS			
VOLUMES AVAILABLE – 49DAYS			
VOLUMES AVAILABLE – 56DAYS			
VOLUMES AVAILABLE – 112DAYS			
QUOTE VALIDITY PERIOD	90 DAYS		
NORMAL LEAD/DELIVERY TIME	7 DAYS		

DEVIATION TO SPECIFICATION

COMMENTS: NONE

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DECLARATION BY SUPPLIER	
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	VIBHA DESAI
CAPACITY	RESPONSIBLE PHARMACIST
SIGNATURE *(OF A DULY AUTHORISED REPRESENTATIVE OF THE SUPPLIER)*	
DATE	02/10/2026

PROVINCIAL ESTIMATES	
Province	**Six Months Estimate**
DCS	**0**
EC-MT	**0**
EC-PE	**60**
FS	**1 800**
GP	**1 200**
KZN	**0**
LP	**0**
MP	**60**
NC	**0**
NW	**144**
SAMHS	**0**
WC	**500**

Dimension : 100 x 180 mm

CYCLOSPORINE

INJECTION USP

50 mg/ml

COMPOSITION

Each ml contains:

Cyclosporine USP 50 mg.

INDICATIONS

Organ rejection prophylaxis in kidney, liver, and heart allogeneic transplants, in combination with corticosteroids. Treatment of chronic rejection in patients previously treated with other immunosuppressants. IV: reserved for patients who are unable to take caps or oral solution.

DOSAGE AND ADMINISTRATION

Adult:

Observe continuously for the first 30mins after start of infusion and frequently thereafter. Give by slow IV infusion over 2–6hrs. Administer IV at ⅓ oral dose. Initially 5–6mg/kg/day as a single dose given 4–12hrs prior to transplantation. Adjunct corticosteroid therapy is recommended. Conversion from Neoral, blood concentration monitoring.

CONTRAINDICATIONS

IV: hypersensitivity to Cremophor EL.

WARNINGS/PRECAUTIONS

Not bioequivalent to all other forms of cyclosporine; do not interchange without physician supervision. Increased risk of infections, lymphomas and other malignancies (eg, skin). Monitor BP, renal and hepatic function. Control hypertension if develops. Malabsorption. Elderly. Pregnancy (Cat.C).

Do not use the Injection if it is not clear.

INTERACTIONS

Avoid other nephrotoxic drugs (eg, ciprofloxacin, gentamicin, tobramycin, vancomycin, SMX/TMP, melphalan, amphotericin B, ketoconazole, cimetidine, ranitidine, tacrolimus, NSAIDs, colchicine), fibric acid derivatives, methotrexate. Cyclosporine levels increased by CYP3A inhibitors (eg, calcium channel blockers, amiodarone, azithromycin, azole antifungals, erythromycin, clarithromycin, quinupristin/dalfopristin, boceprevir, telaprevir, methylprednisolone, allopurinol, colchicine, bromocriptine, danazol, metoclopramide, probably indinavir, saquinavir, nelfinavir, ritonavir, imatinib, nefazodone, oral contraceptives). Avoid alcohol, grapefruit juice.

ADVERSE REACTIONS

Renal dysfunction, tremor, hirsutism, hypertension, gum hyperplasia, cramps, convulsions, headache, diarrhea, nausea, vomiting; increased risk of infections or malignancies, progressive multifocal leukoencephalopathy, polyoma virus-associated nephropathy, hypomagnesemia, hyperkalemia, hyperuricemia, thrombotic microangiopathy, hepatotoxicity, neurotoxicity; IV: anaphylactic reactions.

STORAGE

Store below 25°C. Do not freeze. Protect from Sunlight.

KEEP OUT OF THE REACH OF CHILDREN.

PRESENTATION

10 ampoules of 1ml in a plastic tray and each try packed in a printed carton.

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

KWALITY PHARMACEUTICALS LTD.

ARTWORK DETAILS

Component : Carton
Dimension : 149 x 15 x 67mm
Colour : CMYK
GSM : 320 gsm FBB
Varnish / coating: U.V. coating

Carton Size : 149 x 15 x 67mm



If this product's is registered. Provide us the Registration and submitted Documents.
Please approve the label.

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 strength, Volume & Packing	Storage	
16453/1	English													
Matching all parameters between Box and Label			Country of Export : Taiwan						Registered / Not Registration Artwork Status: ☐ Registered ☐ Not Registered					
Previous Specimen Artwork		Designed by : DESIGNER 7							Order Qty.	Party Name		Packing		
Checked By.		Approved by :		Authorized by :		Party Approval			60000 Tabs	VP Rogantak				
Production Incharge	Q.C. Incharge	Q.A.		M.D.					Card Board used for carton : ☐ G/B ☐ W/B ■ I.T.C. ☐ Pearl					

*** 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.**

Component : Label
Dimension : 30 x 19mm
Colour : CMYK
GSM : 60 gsm Chromo art sticker paper
Varnish / coating: U.V. coating

Label Size : 30 x 19mm

CYCLOSPORINE 1 ml

INJECTION USP

Sterile solution ***for intravenous infusion only***

FOR INTRAVENOUS INFUSION ONLY

DILUTE BEFORE USE

50 mg/ml

Dosage: As directed by the physician.

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

COMPOSITION:

Each ml contains:

Cyclosporine USP 50 mg.

Store below 25°C. Do not freeze.

Protect from Sunlight.

Keep out of the reach of children.

Mfg. Lic. No: 1804-B

Manufactured by:

KWALITY PHARMACEUTICALS LTD.

Nag Kalan, Majitha Road, Amritsar - INDIA

NVZ

If this product's is registered. Provide us the Registration and submitted Documents. Please approve the label.

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 strength, Volume & Packing	Storage
16453/1	English												

Matching all parameters between Box and Label	Country of Export : Taiwan	Registered / Not Registration Artwork Status: ☐ Registered ☐ Not Registered
Previous Specimen Artwork	Designed by : DESIGNER 7	Order Qty. 60000 Tabs / Party Name VP Rogantak / Packing

Checked By.		Approved by :	Authorized by :	Party Approval
Production Incharge	Q.C. Incharge	Q.A.	M.D.	

Card Board used for carton : ☐ G/B ☐ W/B ■ I.T.C. ☐ Pearl

*** 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.**


CYCLOSPORINE
INJECTION USP
Sterile solution for intravenous infusion only
FOR INTRAVENOUS INFUSION ONLY
DILUTE BEFORE USE
50 mg/ml
10 Ampoules of 1 ml
CYCLOSPORINE
INJECTION USP
50 mg/ml
COMPOSITION