

Republic of the Philippines

PHILIPPINE CHILDREN'S MEDICAL CENTER

Quezon Ave. Quezon City

Tel. No.: 8588-9900 loc. 224, 226, 361, 355

Fax no.: 85889997 • e-mail: pcmcproc@gmail.com

PURCHASE ORDER	Nº 76232
FOR SUPPLIES OR EQU	IPMENT
P. R. NO. PHAR-2024-002-G	Dated: October 09, 2023
MODE OF PROCUREME NP-Emerge	NT A.C NO. 2024-026
CS No.	AC No.
DATE OF P. Qanuary 25, 2	024

TO: Sup Address	oplier/Dealer ::	Contractor	MARCBURG PHILIPPINES, IN Unit 2AB Symphony Tower 1, 0		t., Cor. Time	og Ave., South	Friangle, Quezon Cit	у
Is to be Location	made:	Materials Mana Ground Floor,	on/Unit where delivery agement Division PCMC Bldg.	Delivery per Performance Cash / Ca PCMC O.R.	Security I shier's / M	Posted:	Other Terms: Surety Bond eck No. Amount P	No
Item No.	QTY.	UNIT	A	RTICLES	7,12,14		UNIT COST	TOTAL COST
32 .1	3,000	/ amp /	Midazolam amp 15mg/3mL (box of 10's HBM Pharma S.R.O ******No	(M.IV) Midamar			7. 7. 7. 7. 7. 7. 7. 7. 7. 7. 7. 7. 7. 7	314,670.00 wwwwwwww fred Fourteen dred Seventy Pesos Only
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Funding	g Code _ <	-02-03-0	70 mg/g/ 1/24/24			TOTAL	AMOUNT P	314,670.00
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Distrib		hite (Origina llow (Duplic	l) - Attachment to pay ate) - Procurement	ment		Pin	k - Supply a	nd Property

PHILIPPINE CHILDREN'S MEDICAL CENTER

Quezon Avenue, Quezon City

TERMS OF REFERENCE CY 2024

Pharmaceutical Products, Containers, and Devices

The following are the requirements to winning suppliers in compliance with Administrative Order No. 2019-0041, dated October 4, 2019, re: *Implementing Guidelines in Assuring the Efficacy, Quality, and Safety of Pharmaceutical Products in the Public Health Facilities*.

1. All pharmaceutical products and devices shall be of fresh commercial stock as reflected in the Certificate of Product Registration (CPR) issued by the FDA upon delivery. The acceptable shelf life upon delivery is as follows:

Claimed Shelf Life in CPR	Minimum Remaining Shelf Life Upon Delivery
60 months	42 – 60 months
48 months	34 – 48 months
36 months	30 – 36 months
24 months	18 – 24 months
18 months	12 – 18 months
12 months	12 months

- 2. CPR must be valid for the entire period of the award. If the CPR is about to expire, the supplier must have submitted a copy of an application of renewal to the FDA at least 3 months before the expiry date (a copy of the expiring CPR which is stamped with an "extension of validity" shall be submitted as proof).
- 3. The Pharmacist-in-charge of inspection and acceptance of pharmaceutical products and devices shall conduct random sampling of the products delivered for batch testing.
 - 3.1 The samples collected shall be submitted to the FDA for test analysis. The Pharmacist shall determine the kind of test(s) to be done based on the physical inspection done. (Annex A)
 - 3.2 The supplier shall replace (same batch) or pay the cost of the samples collected for testing.
 - 3.3 The supplier shall pay the cost of testing the products collected.
- 4. The supplier shall be provided with a copy of the result of tests analysis done on their products.
- 5. The supplier shall submit the Batch Notification for antibiotic products and Lot or Batch Release Certificate for vaccines, toxoids and immunoglobulins issued by the FDA upon delivery as per COA Circular No. 2023-004 dated June 14, 2023

- 6. The performance of the suppliers shall be monitored based on the following Key Performance Indicators:
 - 6.1 Suppliers meet quality and service standards specified in the Terms of Reference (TOR)/Purchase Order (PO)/Contract
 - 6.2 Timeliness of delivery
 - 6.3 Completeness of quantity delivered.
 - 6.4 Zero defects of products
 - 6.5 Relevant additional services provided (e.g., disposal, recall)

CONFORMICALASIGAN

Trexie N. Marasigan

0997-977-1485

Authorized Signatory
Signature over printed name

Contact No:

Marcburg Philippines Inc.

Name of Company/Firm

trexiebidding8.marcburg@gmail.com mmmillo.marcburg@gmail.com Company's Official Email Address (where notices will be sent)

09171271017/8743-6958/Fax: 8245-6477

Company's Official Contact No.

ANNEX A

Minimum Number of Sample Units Required for Each Test Analysis (FDA Circular No. 2014-014 dated 16 March 2014)

PHARMACEUTICAL PRODUCTS

a. Microbiological Tests

Sample Type	Test Parameter	Number of
		Sample Units
Nonaqueous/aqueous	•Total Aerobic Microbial Count	Minimum of 2
preparation for oral	•Total Combined Yeast & Mold Count	commercial
use	•Absence of Escherichia coli in 1g or mL	presentations with a
Rectal Use	Total Aerobic Microbial count	total net weight or
	•Total Combined Yeast & Mold Count	volume of not less
Oromucosal/Gingival/	•Total Aerobic Microbial Count	than 50g or mL
Cutaneous/Nasal/Auri	Total Combined Yeast & Mold Count	
cular use	•Absence of Staphylococcus aureus in 1g or mL	
	•Absence of Pseudomonas Aeroginosa in 1 g or mL	
Inhalation use (special	•Total Aerobic Microbial Count	
requirements apply to	•Total Combined Yeast & Mold Count	
liquid preparations for	•Absence of Staphylococcus aureus in 1g or mL	
nebulization)	•Absence of bile-tolerant Gram-negative bacteria in 1 g or	
	mL	

b. Biological Tests

Sample Type	Test Parameter	Number of Sample Units
Liquid Preparations ImL to 100mL More than 100mL	Bacterial endotoxin test	20 bottles 6 bottels
1mL to 100mL 500 to 1000mL	Sterility Test	20 bottles 6 bottles
Solid Preparations	Sterility Test	20 units

c. Physico-chemical Tests

Sample Type	Test Parameter	Number of
		Sample Units
Tablet/Capsule	Assay/Potency	60 tablets/capsules
	Dissolution	50 tablets/capsules
	Uniformity of Dosage Units	40 tablets/capsules
	Identification Test	20 tablets/capsules
	Disintegration	20 tablets/capsules
	Tablet hardness	10 tablets/capsules
Granules/Powder for	Assay and Minimum Fill	10 bottles
Suspension/Syrup	• pH	2 bottles
	Identification Test	3 bottles
Injectables	Assay/Potency	20 vials/ampules
(1mL to 2mL)	• pH	10 vials/ampules
Injectables		20 vials/ampules
(5mL to 10mL)		5 vials/ampules
Injectables		10 vials/ampules
(20mL to 100mL)		2 vials/ampules
Ointment/Cream/Gel	Assay/Potency	10 tubes
Aerosol		10 pressurized cans
Suppositories		30 pieces

PHARMACEUTICAL CONTAINERS

Sample Type	Test Parameter	Number of
		Sample Units
Plastic container fo	Nonvolatile residue	
suspension/syrup,	Residue on Ignition	
oral preparations	• Lead	
a. 10 mL	Buffering Capacity	120 pcs
b. 30 to 60 mL		60 pcs
c. 60 to 100mI		40 pcs
d. 250 mL		20 pcs
e. 500 to		10 pcs
1000mL		
Plastic bottles/IV	Sterility Test	
infusion		
a. 100mL		15 pcs
b. 250mL		10 pcs
c. 500 to		6 pcs
1000mL		
Polyampules		
a. 1 to 2 mL		300 pcs
b. 3 to 5 mL		250 pcs
c. 6 to 10 mL		200 pcs
Vials		
a. 10 mL		120 pcs
b. 20 to 25 mL		60 pcs
c. 30 to 50 mL		30 pcs
Caps (Diameter)		000
a. ≤ 0.5 cm		800 pcs
b. Between 1 &		48 pcs
2.5 cm		
c. > 2.5 cm		30 pcs

DEVICES

Sample Type	Test Parameter	Number of Sample Units
Medical Devices	Bacterial endotoxin test	20 units
	Sterility Test	20 units

CONFORME: Trexie N. Marasigan	0997-977-1485	
Authorized Signatory Signature over printed name	Contact No:	
Marcburg Philippines Inc.		
Name of Company/Firm		Mercandon de mantina marco de la companya del companya del companya de la company

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HAZARDOUS PHARMACEUTICALS

- The winning bidders for hazardous pharmaceuticals (see attached list) shall provide PCMC two copies (one for Property and Supply and one for the Pharmacy Division) of the corresponding Materials Safety Data Sheet (MSDS) of said medicine upon delivery.
- 2. The supplier shall make sure that these pharmaceuticals are properly packed for safety from breakage and spills upon delivery to PCMC. Likewise, these pharmaceuticals shall be properly labeled as a hazardous product (e.g., flammable, cytotoxic, radioactive, poison.etc.).
- 3. Suppliers shall provide the PCMC with the appropriate Spill Kit upon the request of the Pharmacy Division for use in the wards/clinical areas using these products.
- 4. The supplier shall be responsible for disposing of the expired and defective hazardous pharmaceuticals. The Pharmacy Division shall inform the corresponding supplier three months before the expiry date of their product. The supplier shall be informed about the defective products as soon as they have been detected.
- 5. Upon request of the corresponding end-user, the supplier shall provide training on safe handling of their product(s), including management of spills.

CONFORME: The grant gan Trexie N. Marasigan	0997-977-1485
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LIST OF HAZARDOUS PHARMACEUTICALS

ANTINEOPLASTICS

- 1. Bleomycin Sulfate 15 mg inj.
- 2. Calcium Folinate 50 mg inj.
- 3. Carboplatin 150 mg vl.
- 4. Cisplatin 50 mg vl
- 5. Cyclophosphamide 200 mg and 500 mg vl
- 6. Cytarabine 100 mg, 500 mg, and 1 g vl.
- 7. Dactinomycin 500 mcg inj
- 8. Doxorubicin 10 mg, and 50 mg vl
- 9. Etoposide 20 mg/ml, 5 mL inj
- 10. Fluorouracil vl 500mg IV
- 11. Hydroxyurea 500mg cap
- 12. Idarubicin HCl 5 mg inj.
- 13. Ifosfamide 1 g and 2 g vl
- 14. Imatinib 100mg tab
- 15. Irinotecan 100 mg/5mL and 40 mg/2mL (HCl) concentrate, vl (IV infusion)
- 16. L-asparaginase 10,000 IU vl
- 17. Melphalan 50mg vl
- 18. Mercaptopurine 50 mg tab
- 19. Methotrexate 500 mg, 1 g, and 50 mg vl; 2.5 mg tablet
- 20. Mitoxanthrone 20 mg Inj.
- 21. Paclitaxel 6mg/mL 17mL (IV) vl
- 22. Rituximab 500mg inj. 50mL vial and 100mg inj. 10mL vial
- 23. Vinblastine 10 mg Inj
- 24. Vincristine 1 mg and 2 mg inj.

NON-ANTINEOPLASTICS DRUGS

- 1. Azathioprine
- 2. Carbamazepine
- 3. Chloramphenicol
- 4. Ciclosporin
- 5. Deferiprone
- 6. Mycophenolate mofetil
- 7. Mycophenolic acid
- 8. Oxcarbazepine
- 9. Phenytoin
- 10. Risperidone
- 11. Sirolimus
- 12. Spironolactone
- 13. Clonazepam
- 14. Topiramate
- 15. Sodium valproate + valproic acid tab
- 16. Gadoteric acid (all dosage preparations)
- 17. Gadobutrol (all dosage preparations)
- 18. Iodixanol 652mg/mL (320mg iodine), 50mL

- 19. Iohexol (all dosage preparations)
- 20. Ioversol (all dosage preparations)
- 21. Iopamidol (all dosage preparations)
- 22. Iopromide (all dosage preparations)
- 23. Sevoflurane Inhalation 250 mL

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