DR. RAM MANOHAR LOHIA INSTITUTE OF MEDICAL SCIENCES
VIBHUTI KHAND, GOMTI NAGAR, LUCKNOW-10 (U.P.)
Phone no: - 0522–4918502, 4918510 **E-mail id:hrftendercell@gmail.com**

1002

Ref No. /HRF/PAC/2024

Date:-17.01.2025

Notice

Sub:- Procurement of following item on Proprietary/single quotation basis for different departments.

The Dr.RMLIMS, Lucknow intends to procure following item(s) manufactured as per mentioned against item names for Sodium copper chlorophyllin 500mg and 100mg tablet on Proprietary/single quotation basis from their authorized dealer/seller as per enclosed Technical Specifications.

Sl. No	Product Details	Principal Company (Manufacturer)	Subsidiary Company (Marketing)	Authorized Seller/Company/Dealer
1	Sodium copper chlorophyllin 500mg and 100mg tablet	Essenzaa Nutrition Pvt. Ltd, Plot No-713, New GIDC, Gundlav Valsad-396035, Gujrat, INDIA	IDRS Lab Pvt. Ltd, 235-H, Phase 3, Bommasandra Industrial Area, Bangalore-560099, INDIA	Shakun Sales Pvt. Ltd, 30A, 55A, Goal Market, Mahanagar, Lucknow

The PROPRIETARY CERTIFICATE for above items(s) submitted by principal company or their authorized seller/ Company/Dealer is attached. The above documents are being uploaded for open information to all manufacturer/ suppliers to submit comments/objections/representation on the above proposal/ Proprietary nature of the medicine/ surgical items within 10 working days to the Chairman (HRF), Dr.RMLIMS, Lucknow on e-mail ID dr.rmlims.hrf2020@gmail.com, from the date mentioned above, failing which it will be presumed that no other supplier is having any comment to offer and the case will be decided on merits. The comments/objections/representation to be submitted on the following:-

V) Whether the above medicine/surgical item is manufactured by any other manufacturer other than as per mentioned principal company or their Authorized seller/company/Dealer.

VI) Fulfill all the parameter(s) as per technical specifications.

Encl: - Related documents enclosed.

(7) HRF Requisition form.
(8) PAC Certificate of Company letter.
(9) Authorization from Company letter

Chairman (HRF)
Dr. RMLIMS, Lucknow

DR. RAM MANOHAR LOHIA INSTITUTE OF MEDICAL SCIENCES
VIBHUTI KHAND, GOMTI NAGAR, LUCKNOW-10 (U.P.)
Phone no: - 0522–4918502, 4918510 E-mail id:hrftendercell@gmail.com

Ref No. 1002. /HRF/PAC/2024 Date:-17.01.2025

To,
Computer Programmer,
Dr. RMLIMS, Lucknow

Subject: - To upload the Proprietary Product i.e. Sodium copper chlorophyllin 500mg and 100mg tablet for Department of Radiation and Oncology on Proprietary/ single quotation basis on Dr. RMLIMS website.

Please find the product details to be purchased on Proprietary/ single quotation basis from) Sodium copper chlorophyllin 500mg and 100mg tablet for Department of Radiation and Oncology, Authorized Seller/ Company/Dealer: Shakun Sales Pvt. Ltd, 30A, 55A, Goal Market, Mahanagar, Lucknow.

The PROPRIETARY CERTIFICATE for above items(s) submitted by principal company or their authorized seller/ Company/Dealer is attached. The above documents are being uploaded for open information to all manufacturer/ suppliers to submit comments/objections/representation on the above proposal/ Proprietary nature of the medicine/ surgical items within 10 working days to the Chairman (HRF), Dr.RMLIMS, Lucknow on e-mail ID dr.rmlims.hrf2020@gmail.com, from the date mentioned above. Kindly instruct the concerned to do the needful.

Chairman (HRF)
Dr. RMLIMS, Lucknow

HRF Requisition Form

Request for new items/upgraded version

(Drugs, Consumables & Disinfectants)

('X' if is not applicable)

1. Name of item (generic name only, no brand name)..Sodium....Copper.....chlorophyllin....500mg & 100mg.....
   Please note that if another brand of the same item is already available in HRF, the request will not be entertained for another brand.
2. Quantity needed (Per month) .....40 bottle each.....
3. Probable Source (I) .....I.D.R.S.....LAB.....
   (II) .....
   (III) .....
   (If only one source please sign. The P-3 Form on back page)
4. Similar item available In HRF inventory? -Yes/No
5. If yes then, why this item? .....
   .....
6. Do you want this item to be made available on regular basis -Yes/No
7. If yes, then what will be the monthly consumption of this item? .100..bottle..each
8. Is same item in single unit be used on many patients? If yes then specify the Number of times/Number of patients, the unit will be used.....
9. Will it be a part of any procedure (Dossier, please specify the name of procedure.....NO.....
10. If it is an upgraded version of an existing item in HRF inventory, do you want old version to continue? - -Yes/No
11. Justification for new requisition.....
    → To reduce the radiotherapy & its effects
    → It increase the therapeutic outcome.

(Sign. of Consultant)

(Signature of Head of Department)

→ New P3

19/11/19

Please note that new item will be processed for short-term rate contract- this may take about 1-2 months tim

FORM P-3

Dr. Ram Manohar Lohia Institute of Medical Sciences, Lucknow

PROPRIETARY ARTICLE CERTIFICATE

It is certified that the items required should be purchased from M/s. IDRS LAB .....Who are the sole manufacture/agents of the sole manufacturers M/s .....IDRS LAB.....

Similar items manufactured by other firm(s) shall not be suitable for our purpose for the following reasons: - Product Developed through a collaboration between IDRS and Tata Hospital Mumbai & Bhabha Atomic research centre (BARC) and co-own all property Rights including Patents & copyrights.

Signature of Indenter

Dr. [illegible] MD
Professor & Head
Department of Radiation Oncology
Dr. RMLIMS, Gomti Nagar, Lucknow

Requisition No:

Department : Radiation

Dated : 11/11/24

Designation &
Sign of Head of
Department/ Section

Dr. [illegible]
Professor & Head
Department of Radiation Oncology
Dr. RMLIMS, Gomti Nagar, Lucknow

N.B. The Indenter before recording the above certificate should satisfy himself that the article is genuinely of proprietary nature manufactured under patent laws.

Reference No.: IDRS/L/24/0150

Date: 13-Dec-24

idrs

PROPRIETARY CERTIFICATE

To Whom It May Concern

This is to certify that **IDRS Labs Private Limited (IDRS)**, a company registered under the laws of Karnataka and located at 235H, Phase 3, Bommasandra Industrial Area, Hosur road, Bangalore 560068, Karnataka, India, is the exclusive owner of the Formulation and Manufacturing technology and holder of proprietary rights to the Nutraceutical product named **AKTOCYTE 500™ (Sodium Copper Chlorophyllin Tablets 500 mg).**

Details of the Product:

Generic Name	Sodium Copper Chlorophyllin Tablets 500 mg
Brand Name	**AKTOCYTE 500™**
Dosage Form	Tablet
Strength	500 mg
Indication	Antioxidant and Immune booster
Approval Status	Approved by FSSAI
Patent Status	**US Patent**: Granted (Patent No.:US20170290843A1) **EP Patent**: Pending (Appl. No. 4059493 A1) **India Patent**: Pending (Appl. No. 202124060493)
Manufacturing License No.	Mfg. License no.: 10721999000886 Re-labellar license no.: 11223302000099

Proprietary Rights & Ownership:

- **AKTOCYTE 500™** was developed through a collaboration between IDRS Labs Private Limited (IDRS), Advanced Centre for Treatment Research and Education in Cancer (ACTREC), and Bhabha Atomic Research Centre (BARC). IDRS, ACTREC, and BARC jointly and equally co-own all intellectual property rights related to **AKTOCYTE 500™**, including any patents and copyrights.
- IDRS is the **sole owner** of Formulation and Manufacturing technology, trademarks, and trade secrets, related to **AKTOCYTE 500™**.
- IDRS holds exclusive marketing rights for **AKTOCYTE 500™** and is authorized to promote, distribute, and sell the product in India.
- No other entity, individual, or company is authorized to manufacture, distribute, or sell the said drug product under the same brand name or formulation, unless explicitly authorized by IDRS.

By issuing this certificate, IDRS affirms its ownership of the proprietary rights to **AKTOCYTE 500™** and the exclusive authority to market and distribute the product.

Thank you.

Sincerely,

IDRS LABS PVT. LTD. BANGALORE

Shivkumar Madki
Managing Director

IDRS Labs Private Limited

ESSENZAA NUTRITION PVT. LTD.
Plot no.713, New GIDC, Gundlav
Valsad - 396035, Gujarat, INDIA.
CIN: U51101MH2010PTC208168

01.01.2025

To Whomsoever it may concern

Essenzaa Nutrition Pvt Ltd is a manufacturer of AKTOCYTE, AKTOCYTE 500 and

AKTOCYTE LD at 713, New GIDC, Gundlav, Valsad, Gujarat. 396035. India.

FSSAI Licence No.10721999000886 (Essenzaa Nutrition Pvt Ltd)

IDRS Labs Pvt Ltd solely holds the Marketing Authorization of the said products for India and overseas markets.

FSSAI Licence No.11223302000099 (IDRS Labs Pvt Ltd)

Authorized Signatory

Name: Ms.Madhuri Gaikar

Designation: Sr. Regulatory affairs Executive

Company Seal:

U.S. FOOD & DRUG ADMINISTRATION

U.S. Food and Drug Administration

Over-the-Counter (OTC) Monograph M026:
Deodorant Drug Products for Internal Use for Over-the-Counter Human Use
(Posted November 23, 2021)[1]

Part A—General Provisions

Sec.
M026.1 Scope
M026.3 Definitions

Part B—Active Ingredients

M026.10 Active ingredients for deodorant drug products for internal use

Part C—Labeling

M026.50 Labeling of deodorant drug products for internal use

SOURCE: 55 FR 19865, May 11, 1990, unless otherwise noted.

Part A—General Provisions

FDA GRAS Generally Recognised As Safe

§ M026.1 Scope

An over-the-counter (OTC) deodorant drug product for internal use in a form suitable for oral administration is generally recognized as safe and effective and is not misbranded if it meets each condition in this OTC monograph and each general condition established in 21 CFR 330.1.

§ M026.3 Definitions

As used in this OTC monograph:

(a) Colostomy. An external operative opening of the colon.

(b) Deodorant for internal use. An ingredient taken internally to reduce odors arising from conditions such as colostomies, ileostomies, or fecal incontinence.

[1] Final Administrative Order (OTC000016), effective upon enactment of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), Public Law 116-136, on March 27, 2020.

(c) Ileostomy. An external operative opening from the ileum.

(d) Incontinence. An inability to retain urine or feces.

Part B—Active Ingredients

§ M026.10 Active ingredients for deodorant drug products for internal use

The active ingredient of the product consists of either of the following when used within the dosage limits established for each ingredient in § M026.50(d):

(a) Bismuth subgallate.

(b) Chlorophyllin copper complex.

Part C—Labeling

§ M026.50 Labeling of deodorant drug products for internal use

(a) Statement of identity. The labeling of the product contains the established name of the drug, if any, and identifies the product as a "deodorant for internal use" or as a "colostomy or ileostomy deodorant."

(b) Indications. The labeling of the product states, under the heading "Uses," any of the phrases listed in § M026.50(b) as appropriate. Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in § M026.50(b) may also be used, as provided in 21 CFR 330.1(c)(2), subject to the provisions of section 502 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 352) relating to misbranding and the prohibition in section 301(d) of the FD&C Act (21 U.S.C. 331(d)) against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the FD&C Act (21 U.S.C. 355(a)).

(1) For products containing bismuth subgallate identified in § M026.10(a). "An aid to reduce odor from a colostomy or ileostomy."

(2) For products containing chlorophyllin copper complex identified in § M026.10(b).

(i) "An aid to reduce odor from a colostomy or ileostomy."

(ii) "An aid to reduce fecal odor due to incontinence."

(c) Warnings. For products containing chlorophyllin copper complex identified in § M026.10(b). the labeling of the product contains the following warnings under the heading "Warnings":

(1) "If cramps or diarrhea occurs, reduce the dosage. If symptoms persist, consult your doctor."

(2) The warning required by 21 CFR 330.1(g) concerning overdose is not required on products containing chlorophyllin copper complex identified in § M026.10(b).

(d) Directions. The labeling of the product contains the following information under the heading "Directions."

(1) For products containing bismuth subgallate identified in § M026.10(a). Adults and children 12 years of age and over: Oral dosage is 200 to 400 milligrams up to 4 times daily. Children under 12 years of age: consult a doctor.

(2) For products containing chlorophyllin copper complex identified in § M026.10(b). Adults and children 12 years of age and over: Oral dosage is 100 to 200 milligrams daily in divided doses as required. If odor is not controlled, take up to an additional 100 milligrams daily in divided doses as required. The smallest effective dose should be used. Do not exceed 300 milligrams daily. Children under 12 years of age: consult a doctor.

Dr. Santosh Kumar Sandur
Scientific Officer (H)
Head, Free Radical Biology Section

Mumbai 400 085, India.

Tele: 91-22-25595356
E-MAIL: sskumar@barc.gov.in

Government of India
Bhabha Atomic Research Centre
Radiation Biology and Health Sciences Division

02 January 2023

To Whomsoever Concerned

We would like to inform the concerned department that, **AKTOCYTE™** i.e., **Sodium Copper Chlorophyllin 750 mg Tablets** is developed by IDRS LABS PRIVATE LIMITED, Bangalore, in Collaboration with **Bhabha Atomic Research Centre, Mumbai** and **Tata Memorial Centre – Advanced Centre for Treatment, Research and Education in Cancer (ACTREC).** AKTOCYTE™ is intended to be used as an antioxidant and to improve immunity.

The following patents have been filed for the product.

1. ***US Patent No 10183026*** (***Application*** No 15094679) filed by Bhabha Atomic Research Centre (BARC) Mumbai and Advanced Centre for Treatment, Research and Education in Cancer (ACTREC), Navi Mumbai (2019).
2. ***US Patent Application no. 16/214,450, European patent application no. EP21162765.8 and Indian Patent application no 202124060493*** filed jointly by Department of Atomic Energy (DAE), Government of India and IDRS Labs Pvt Ltd Bengaluru, India (2021).

2/1/2023
Dr. Santosh Kumar Sandur

डॉ. एस. संतोष कुमार/Dr. S. Santosh Kumar
वैज्ञानिक, मुक्त मूलक जैविकी अनुभाग
Scientific Officer (H)
Head, Free Radical Biology Section
विकिरण जैविकी एवं स्वास्थ्य विज्ञान प्रभाग
Radiation Biology & Health Sciences Division
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ट्रॉम्बे, मुंबई/Trombay, Mumbai-400 085.