KARNATAKA ANTIBIOTICS AND PHARMACEUTICALS LTD.
(A GOVT. OF INDIA ENTERPRISE)
International Marketing Dept.: ARKA The Business Centre, Plot No 37, NTTF
Main Road, Peenya Industrial Area,2nd Phase Bengaluru-560058.
CIN No: U24231KA1981GOI004145 **PHONE 080 23571590**
Website: www.kaplindia.com

Invitation of "Tender Enquiry" for Rate Contract Agreement for ANALYSIS OF ELEMENTAL IMPURITIES TESTING OF API, EXCIPIENTS & FINISHED PRODUCTS AT OUTSIDE TESTING LABORATORY DUE TO NON AVAILABILITY OF INHOUSE FACILITIES INITIALLY FOR 2 YEARS AND IT MAY BE EXTENDED FOR ONE MORE YEAR SUBJECT TO SATISFACTORY PERFORMANCE OF THE SERVICES ON THE SAME RATES, TERMS & CONDITION.

E-Tender under Two bid stage Part-1: Technical Bid and Part-2: Financial Bid is invited from OPEN TENDERS to KAPL PURCHASE DEPARTMENT as per terms & conditions for the period of three years.

Bidders will have to participate in bidding process through website www.tenderwizard.com/KAPL

Tender Enquiry No.	**KAPL/OTE/QC/SR/1051/2026-27**
Mode of Tender	E-Procurement System (Online Part I – Technical Bid & Part II– Financial Bid) through www.tenderwizard.com/KAPL. The intending bidders are required to submit their offer Electronically through e-tendering portal. No physical tender is Acceptable.
Tender issuing date	**09.09.2026**
Due date & time for bid submission	**28.09.2026 till 23.59 Hrs.**
Mode of bid submission	**Online**
Type of Tender	**OPEN TENDER ENQUIRY (OTE)**
Place of BID Submission & Opening of Bids	**KAPL E-Procurement portal**
Offer(EoI) validity	90 days or such extension sought for by KAPL by modification issued in this regard.
Contract Duration	Successful bidder(s) will be empanelled with KAPL for the period of three **years** renewable every year based on the performance.
Email ID for communication	purenp@kaplindia.com
Web Address	www.kaplindia.com

Annexure-A

Important Instructions for E-Tender

Bidders are requested to read the terms and conditions of this tender before submitting your online tender.

Process of E-Tender:

A) Registration: The process involves vendor's registration with KAPL e-procurement portal which is **free of cost**. Only after registration, the vendor(s) can submit his/their bids electronically. Electronic Bidding for submission of Technical Bid as well as Commercial Bid will be done over the internet. The Vendor should possess Class III signing type digital certificate. Vendors are to make their own arrangement for bidding from a P.C. connected with Internet.
KAPL is not responsible for making such arrangement. (Bids will not be recorded without Digital Signature).

SPECIAL NOTE: THE BID HAS TO BE SUBMITTED ON-LINE AT

www.tenderwizard.com/KAPL

1).Vendors are required to register themselves online with www.tenderwizard.com/KAPL - e-Procurement of KAPL. Register as Vendor -- Filling up details and creating own user ID and Password - Submit.

2). After successful registration send request mail with acknowledgement slip to purenp@kaplindia.com, for account activation.

3). Vendors will receive a system generated mail confirming their registration in their email which has been provided during filling the registration form. In case of any clarification, please contact KAPL, (before the scheduled time of the E-tender). Contact person (KAPL): Dealing Officer: Manager – Purchase
Phone no. 080-23571590 E-mail: - purenp@kaplindia.com,

Vendors should upload the below mentioned supporting documents (based on their type of Organization) during registration process:

1. PAN Card.
2. Certificate of Incorporation (for Indian organizations)
3. GST Certificate.
4. An Address proof is also to be submitted in case of Individuals.
5. If the firm is registering in joint venture, they also need to upload deed agreement.

NOTE 1:

1) Uploaded copy of all these supporting documents must be self-attested by authorized signatory. Attested signature shall also be verified by Tender Wizard Helpdesk for further authentication process.

2) Tenderer digital signature on the E- Tender form will be considered as their confirmation that they have read and accepted all the conditions laid down in the tender documents, unless specific deviation is quoted in the techno- commercial offer form.

E- Tender form is not transferrable and the same is to be submitted with digital signature/ signed & scanned copy by the pre-authorized personnel of the bidder. Tender is to be submitted through e-tender-mode only at website www.tenderwizard.com/KAPL along with scanned copies of credential papers.

3) For what so ever reasons, if any part of KAPL tender document is not uploaded/ submitted by the bidder, other than financial and technical offers and requisite Pre-Qualifying credentials, in that case the missing part of the tender document shall be treated as read and acceptable to bidder.

4) Tenders completed as per instructions will be submitted through e-tendering mode only in the website www.tenderwizard.com/KAPL as per the prescribed date and time mentioned in the tender notice.

NOTE 2: Bidding in e-tender:

a) The process involves Electronic Bidding for submission of Bids.

b) The vendor(s) should submit their Technical Bid and Financial Bid through internet in KAPL website www.tenderwizard.com/KAPL**.**

c) The vendor should allow running JAVA application. This exercise has to be done immediately after opening of Bid floor. Then they have to fill up Common terms/Commercial specification and save the same.

d) In all cases, vendor should use their own ID and Password along with Digital Signature at the time of submission of their bid.

e) During the entire e-tender process, the vendors will remain completely anonymous to one another and also to everybody else.

f) The e-tender floor shall remain open from the pre-announced date & time and for as much duration as mentioned above.

g) All electronic bids submitted during the e-tender process shall be legally binding on the vendor. Any bid will be considered as the valid bid offered by that vendor and acceptance of the same by the Buyer will form a binding contract between Buyer and the Vendor for execution of supply.

h) It is mandatory that all the bids are submitted with digital signature certificate otherwise the same will not be accepted by the system.

i) Buyer reserves the right to cancel or reject or accept or withdraw or extend the tender in full or part as the case may be without assigning any reason thereof.

j) No deviation of the terms and conditions of the tender document is acceptable. Submission of bid in the e-tender floor by any vendor confirms his acceptance of terms & conditions for the tender.
Any order resulting from this tender shall be governed by the terms and conditions mentioned therein.

No deviation to the technical and commercial terms & conditions are allowed.

The tender inviting authority has the right to cancel this e-tender or extend the due date of receipt of bid(s) without assigning any reason thereof.

Annexure-B

General Terms & Conditions

1. Mere participation in e-tender will not mean that a particular bidder will be automatically considered qualified and their bids will be entertained. Such qualification will be reviewed at the time of evaluation of bids also.

2. Micro & Small Enterprises (MSEs) registered with NSIC under Single Point Registration Scheme (SPRS) are eligible to get the benefits under new Public Procurement policies for MSEs as notified by Govt. of India, Ministry of Micro, Small & Medium Enterprises (MSME) vide Gazette Notification, dated 26.03.2012.

3. If eligible for the supply, the benefits as per prevailing norms will be extended to MSEs registered with NSIC as per New Public procurement Policy as notified by the Government of India, Ministry of Micro, small & medium enterprises (MSME) in The Gazette of India vide No. 503, dated 26.03.2012. It is not obligatory on the part of the Trustees to accept of Lowest Tender. They reserve the right to accept a Tender in full or in part and/or reject a Tender without assigning any reason thereof.

4. Copy of valid NSIC Certificate for MSEs along with DIC's (DISTRICT INDUSTRIES CENTRE) Certificate has to be submitted along with the bid.

5. Due date of submission of tender may be extended as per KAPL's discretion by releasing corrigendum in website of KAPL.

6. SCOPE OF WORK: As per E-Tender Document

7. The Terms and Conditions of E-Tender shall be read in conjunction with the General Conditions of Contract, Specifications, Bill of Quantities and other Documents forming part of this Contract wherever the Contract so requires.

8. Validity: Rate will be valid for three years from the date of Letter/Agreement.

9. EVALUATION CRITERIA: As per relevant clause of Tender Document and Only Technically qualified bidders Financial bid will be opened.

10. PAYMENTS: Monthly 30 Days Credit after receipt and acceptance.

11. In case of a dispute between the Bidder & KAPL, all possible attempts should be made to settle such dispute activities by & between the parties. Arbitration any disputes arising out of and in relation to this agreement will be settled to arbitrator appointed DF/MD of KAPL. The arbitration would be conducted and governed by and under the provisions of Arbitration Act 1996. Any legal dispute will be subject to jurisdiction of Bengaluru Courts and no other Court shall have the Jurisdiction.

12. JURISDICTION OF COURT: The contract shall be governed by all relevant Indian Acts applicable within the jurisdiction of Bengaluru.

13. The relatives of KAPL Employees shall in no way be connected with carrying out business activity as per the terms and conditions of the tender documents without prior permission of KAPL management.

14. KAPL may at any time terminate the contract for any reason by giving the bidders a 3 months prior notice of termination.
15. The method of evaluation of bidder for awarding the contract shall be on basis of overall lowest bidder (L1) for delivery up to KAPL,Bengaluru.

***COMPANY BACKGROUND*:**

Karnataka Antibiotics & Pharmaceuticals Limited (KAPL) (A Govt. of India Enterprise), Bengaluru, Karnataka-560058 is engaged in manufacturing and marketing of various Pharmaceutical /Ayurvedic / Veterinary and Agro-chemical products since 1984.

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Karnataka Antibiotics & Pharmaceuticals Limited (KAPL) is a PSU and pioneer in Pharmaceuticals under the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Govt. of India. KAPL is involved in the production and marketing of Pharmaceutical products at affordable prices to the consumers in India and outside India.

The following annexures are attached to this document and bidders are required to submit the same in the technical Bid.

- **List of Annexure attached-Technical Bid**

  Annexure-II: Scope of work (Page No: 10)

List of Annexure attached-Financial Bid

Financial Bid (Page No: Attached Online)

The Tender enquiry will be opened as per scheduled due dates. In the event of the date being declared as a holiday for KAPL, the due date for submission of bid and opening will be the following working day at the appointed time.

Deputy General Manager (Purchase)
Arka The Business Centre
Plot No 37,NTTF Main Road Peenya Industrial Area,2nd Phase Bengaluru-560058.

Terms & Conditions:

1. **Selection Criteria:** Only bidders qualified in all parameters identified and mentioned as **Eligibility criteria** (Page No: 7) will be considered for **"Financial Bid opening"**.
2. **Price:** Bidders should quote their C/F prices to KAPL.
3. Payment Terms: Monthly 30days credit from the date of receipt of Bills.
4. Agreement: Rate contract agreement for man power services for two years and it may be extendable for one more year subject to satisfactory performance of the contractor on the same rates, terms & conditions.
5. Risk Purchase: In case of not provided service against the Work Order Risk Purchase will be applicable.
6. **If a Bidder is debarred/delisted by any Central/ State Government Department/ Institution/ Subordinate office or Public Sector Enterprise, the said Manufacturer/Bidder will be disqualified for participation in the empanelment EoI.**

   All bidders must enclose an Ink Signed declaration on their letter head that they were not debarred/delisted by any Central/State Government Department/Institution/Subordinate office or Public Sector Enterprise. (Page No: 21) will be considered for **"DECLARATION"**
7. **RIGHTS OF KAPL:**
   - **(i) KAPL reserves the right to accept / reject the offers received without assigning any reasons whatsoever, or may call for any additional information / clarification if so required.**
   - **(ii) KAPL reserves the right to limit or delete any item mentioned in this document and extend the last date of submission of the bid.**
   - **(iii) KAPL reserves the right to modify the Bid, Terms & Conditions, etc. before the last date of submission of applications and thereafter extend the due date and the same shall be published in the Company's website. KAPL also reserves the right to cancel either in part or whole Bid without assigning any reason whatsoever.**
   - **(iv) Decision of KAPL will be final.**
8. **COURT JURISDICTION:** This shall be subject to the exclusive jurisdiction of courts at Bengaluru, India.
9. **Dispute Resolution:**- In case of a dispute between the Bidder & KAPL ,all possible attempts should be made to settle such dispute activities by & between the parties. **In case the dispute could not be settled mutually by & between the parties the same would be settled by an Arbitration Proceeding strictly in compliance with the Arbitration & Conciliation Act, 1996.**
   The Managing Director of KAPL reserves exclusive right to appoint the Arbitrator & the decision of the Arbitrator will be final & binding on all the parties.

10. Eligibility Criteria for Selection of Contract for rate contract agreement for Analysis Of Elemental Impurities Testing Of Api, Excipients & Finished Products At Outside Testing Laboratory Due To Non Availability Of Inhouse Facilities For 3 Years for: (Fill up the chart & upload, with all relevant documents with technical Bid as per indicated below).

Parameters	Min Eligibility Criteria
1. Other statutory Documents	Copies of GST Certificate,. Pan, Aadhar etc.(All Should be As on date valid) to be enclosed.
2. Accepted Bid Document	This tender document to be accepted with duly signed stamped in all the pages and to be uploaded. For any Clause found not acceptable, bidders to submit deviation statement separately.
3. Security Deposit	EMD Demand Draft for Rs.60,500/-(Rupees Sixty thousand five hundred only) as EMD Interest free Deposit payable to M/s. Karnataka Antibiotics & Pharmaceuticals Limited, Bangalore to be submitted along with separate envelope
	Offers without the EMD will be ignored Without any further correspondence
	The EMD of successful tenderer (s) will be retained as security deposit till the completion of the contract
	The EMD of such of the unsuccessful tenders will be returned without interest within 30 days of finalization of the contract
4. Annual Turn Over	Annual turnover more than 30 lakhs in the last three financial years (2023-24, 2024-25 and 2025-26.

Bid Form

(Custom House Agent)

Name & Address of the Party	
Telephone No with STD code	
Email Address	
Name of the Contact Person	
Whether Proprietary/Partnership/Limited Company	
Years of Experience (Please attach documentary proof)	
Details of Tax Registration	
a) GST No with Certificate	
b) PAN Card	
c) TIN No with certificates	
Name & Address of your Bankers	
Bank A/C NO : with IFSC Code	
Number of Technical Person	
Technical Skill	Y/N
Creativity & Innovation	Y/N
Time Management(Timely completion of Job)	Y/N
Sound knowledge in English Language	Y/N

Annexure - I

CHECKLIST OFFER TECHNICAL BID

S/N	Particular of Document	Attached/ Not	Page No	Remarks
1.	Forwarding letter indicating the submission of Bid documents along with check list of document			
2.	Tender Document duly Signed and Stamped in all Pages along with Corrigendum (if Any)			
3.	Duly filled in Bid Form			
4.	PAN No			
5.	ISO Certificate if any			
6.	GST No			
7.	Specifications duly signed and stamped in all papers as Annexure-II			
8.	Non Debarment /black list certificate as per point no 08 of terms and conditions of tender document.			
9.	Attachment List if any			

ANNEXURE-II : TECHNICAL COMPLIANCE STATEMENT OF THE TENDER

Technical Compliance Statement:-

S.L.NO	Technical Specifications Description	Whether agreed by the bidder YES/NO	Deviation if any
5.10.Elemental Impurities:-			
	The Procedures section of this General Chapter has been harmonized with corresponding texts of the European Pharmacopoeia, the Japanese Pharmacopoeia and the United States Pharmacopeia	**YES AGREED**	
	Portions of the IP text that are not part of the PDG harmonized text, are marked with symbols (♦♦)	**YES AGREED**	
	This chapter specifies limits for the amounts of elemental impurities in drug products. The strategy for controlling elemental impurities is aligned with the principles outlined in the ICH Q3D guideline. Regardless of the approach used, compliance with the limits specified is required for all drug products unless otherwise specified in an individual monograph or specifically excluded in this chapter	**YES AGREED**	
	Elemental impurities include catalysts and environmental contaminants that may be present in drug substances, excipients, or drug products. These impurities may occur naturally, be added intentionally, or be introduced inadvertently (e.g., by interactions with processing equipment and the container–closure system). When elemental impurities are known to be present, have been added, or have the potential for introduction, assurance of compliance to the specified levels is required. A risk-based control strategy may be appropriate when analysts determine how to assure compliance with this standard. Due to the ubiquitous nature of arsenic, cadmium, lead, and mercury, they (at the minimum) must be considered in the risk assessment	**YES AGREED**	
	This chapter does not apply to herbal products, radiopharmaceuticals; vaccines; cell metabolites; DNA products; allergenic extracts; cells, whole blood, cellular blood components or blood derivatives including plasma and plasma derivatives; products based on genes (gene therapy); cells (cell therapy); tissue (tissue engineering); dialysate solutions not intended for systemic circulation; total parenteral nutrition (TPN) and elements that are intentionally included in the drug product for therapeutic benefit	**YES AGREED**	
	The limits presented in this chapter do not apply to excipients and drug substances, except where specified in an individual monograph. However, manufacturers of pharmaceutical products need certain information about the content of elemental impurities in drug substances or excipients in order to meet the criteria of this chapter. Drug product manufacturers can use elemental impurity test data on components from tests performed by drug substance or excipient manufacturers, who may provide test data, or if applicable, risk assessments. Elemental impurity data generated by a qualified supplier of drug product components are acceptable for use by a drug product manufacturer to demonstrate compliance with this chapter in the final drug product. Drug substance or excipient manufacturers who choose to perform a risk assessment must conduct that risk assessment using Table 2 in this chapter. Elements that are inherent in the nature of the material, as in the case of some naturally-	**YES AGREED**	

	sourced materials, must be considered in the risk assessment		
	Speciation:-		
	The determination of the oxidation state, organic complex, or combination is termed "speciation". Each of the elemental impurities has the potential to be present in differing oxidation or complexation states. However, arsenic and mercury are of particular concern because of the differing toxicities of their inorganic and complexed organic forms	**YES AGREED**	
	The arsenic limits are based on the inorganic (most toxic) form. Arsenic can be measured using a total-arsenic procedure under the assumption that all arsenic contained in the material under test is in the inorganic form. Where the limit is exceeded using a total-arsenic procedure, it may be possible to show, via a procedure that quantifies the different forms, that the inorganic form meets the specification	**YES AGREED**	
	The mercury limits are based upon the inorganic (2^+) oxidation state. The methyl mercury form (most toxic) is rarely an issue for pharmaceuticals. Thus, the limit was established assuming the most common (mercuric) inorganic form. Limits for articles that have the potential to contain methyl mercury (e.g., materials derived from fish) are to be provided in the monograph	**YES AGREED**	
	Routes of administration		
	The elements included in the tables below have been placed into three classes, based on their toxicity and likelihood of occurrence in the drug product. The classification scheme is intended to focus the risk assessment on those elements that are the most toxic but also have a reasonable probability of inclusion in the drug product, shown in Table 2	**YES AGREED**	
	The toxicity of an elemental impurity is related to its extent of exposure (bioavailability). The extent of exposure has been determined for each of the elemental impurities of interest for the following routes of administration: oral, parenteral, inhalational and cutaneous and transcutaneous. These limits are based on chronic exposure. For other routes of administration, consider the oral permitted daily exposures (PDEs) in Table 1 as a starting point in developing specific PDEs for other routes of administration, except where otherwise stated in the individual monograph. Some elemental impurities for which PDEs have not been established due to their low inherent toxicity, if these elemental impurities are present or included in the drug product, they are addressed by ICH Q3D guideline	**YES AGREED**	
	Drug Products:-		
	The limits described in the third through sixth columns of Table 1 are the base daily dose PDEs of the elemental impurities of interest for a drug product taken by a patient according to indicated routes of administration	**YES AGREED**	
	Parenteral products. Parenteral drug products with maximum daily volumes up to 2 litre may use the maximum daily volume to calculate permissible concentrations from PDEs. For products whose daily volumes, as specified by labeling and/or established by clinical practice, may exceed 2 litre (e.g., saline, dextrose, and solutions for irrigation), a 2- litre volume may be used to calculate permissible concentrations from PDEs	**YES AGREED**	
	Permitted daily exposures. The information in Table 1 applies to oral, parenteral, inhalation, and cutaneous and transcutaneous drug products (referred to as cutaneous product) whether intended for local or systemic effects. This table does not apply to products intended for mucosal administration. Products not covered by Table 1 should be assessed following the principles described for other routes of administration. For cutaneous products, an additional limit is provided for elements that have been demonstrated to be sensitizers (i.e., cobalt and nickel). The cutaneous and transcutaneous concentration limit (CTCL) was added because sensitization interactions have a concentration effect (not simply related to the total amount of the sensitizing element). The current limits for the stated routes of exposure for each element are provided in Table 1	**YES AGREED**	

Table 1 – Permitted Daily Exposures for Elemental Impurities								
Element	Class	Oral PDE (µg/day)	Parenteral PDE (µg/day)	Inhalation PDE (µg/day)	Cutaneous Products			
					PDE (µg/day)	CTCL for Sensitizers (µg/day)		
Cadmium	1	5	2	3	20	--	YES AGREED	
Lead	1	5	5	5	50	--	YES AGREED	
Arsenic	1	15	15	2	30	--	YES AGREED	
Mercury	1	30	3	1	30	--	YES AGREED	
Cobalt	2A	50	5	3	50	35*	YES AGREED	
Vanadium	2A	100	10	1	100	--	YES AGREED	
Nickel	2A	200	20	6	200	35*	YES AGREED	
Thallium	2B	8	8	8	8	--	YES AGREED	
Gold	2B	300	300	3	3000	--	YES AGREED	
Palladium	2B	100	10	1	100	--	YES AGREED	
Iridium	2B	100	10	1	100	--	YES AGREED	
Osmium	2B	100	10	1	100	--	YES AGREED	
Rhodium	2B	100	10	1	100	--	YES AGREED	
Ruthenium	2B	100	10	1	100	--	YES AGREED	
Selenium	2B	150	80	130	800	--	YES AGREED	
Silver	2B	150	15	7	150	--	YES AGREED	
Platinum	2B	100	10	1	100	--	YES AGREED	
Lithium	3	550	250	25	2500	--	YES AGREED	
Antimony	3	1200	90	20	900	--	YES AGREED	
Barium	3	1400	700	300	7000	--	YES AGREED	
Molybdenum	3	3000	1500	10	15000	--	YES AGREED	
Copper	3	3000	300	30	3000	--	YES AGREED	
Tin	3	6000	600	60	6000	--	YES AGREED	
Chromium	3	11000	1100	3	11000	--	YES AGREED	
For elements with a cutaneous PDE and a CTCL, both limits need to be met. In case the results are conflicting, the lowest limit is applied. Using cobalt as an example, based on the PDE and a 1 g maximum daily dose of drug product, the calculated cutaneous concentration is 50 µg per g, which exceeds the CTCL of 35 µg per g. In this situation, the CTCL should be used							YES AGREED	
Recommendations for Elements to be considered in the Risk Assessment							YES AGREED	
Table 2 identifies elemental impurities for inclusion in the risk assessment. This table can be applied to all sources of elemental impurities in the drug product							YES AGREED	

Table 2 – Elements to be Considered in the Risk Assessment								
Element	Class	If Intentionally Added (All Routes)	If Not Intentionally Added*					
			Oral	Parenteral	Inhalation	Cutaneous		
Cadmium	1	Yes	Yes	Yes	Yes	Yes	YES AGREED	
Lead	1	Yes	Yes	Yes	Yes	Yes	YES AGREED	
Arsenic	1	Yes	Yes	Yes	Yes	Yes	YES AGREED	
Mercury	1	Yes	Yes	Yes	Yes	Yes	YES AGREED	
Cobalt	2A	Yes	Yes	Yes	Yes	Yes	YES AGREED	

Vanadium	2A	Yes	Yes	Yes	Yes	Yes	**YES AGREED**	
Nickel	2A	Yes	Yes	Yes	Yes	Yes	**YES AGREED**	
Thallium	2B	Yes	No	No	No	No	**YES AGREED**	
Gold	2B	Yes	No	No	No	No	**YES AGREED**	
Palladium	2B	Yes	No	No	No	No	**YES AGREED**	
Iridium	2B	Yes	No	No	No	No	**YES AGREED**	
Osmium	2B	Yes	No	No	No	No	**YES AGREED**	
Rhodium	2B	Yes	No	No	No	No	**YES AGREED**	
Ruthenium	2B	Yes	No	No	No	No	**YES AGREED**	
Selenium	2B	Yes	No	No	No	No	**YES AGREED**	
Silver	2B	Yes	No	No	No	No	**YES AGREED**	
Platinum	2B	Yes	No	No	No	No	**YES AGREED**	
Lithium	3	Yes	No	Yes	Yes	No	**YES AGREED**	
Antimony	3	Yes	No	Yes	Yes	No	**YES AGREED**	
Barium	3	Yes	No	No	Yes	No	**YES AGREED**	
Molybdenum	3	Yes	No	No	Yes	No	**YES AGREED**	
Copper	3	Yes	No	Yes	Yes	No	**YES AGREED**	
Tin	3	Yes	No	No	Yes	No	**YES AGREED**	
Chromium	3	Yes	No	No	Yes	No	**YES AGREED**	
This also applies to materials for which the element is intrinsically associated with (e.g., as can be found in naturally occurring materials).							**YES AGREED**	
Options for Demonstrating Compliance							**YES AGREED**	
A. **Drug Product Analysis Option**							**YES AGREED**	
The results obtained from the analysis of a typical dosage unit, scaled to a maximum daily dose, are compared to the Daily Dose PDE							**YES AGREED**	
Daily Dose PDE ≥ measured value (µg per g) × maximum daily dose (g per day)							**YES AGREED**	
The measured amount of each impurity is not more than the Daily Dose PDE, unless otherwise stated in the individual monograph. Based on this calculation formula mentioned for limit is as follows							**YES AGREED**	
Measured value ug per g (ppm)= PDE (ug per day) / Maximum daily dose (g per day) (Specification Limit)							**YES AGREED**	
Example For Limit							**YES AGREED**	
Elements	Class	PDE (µg per day)	Daily dose (g per day)	Specification Limit			**YES AGREED**	
Cadmium	1	5	10	0.5			**YES AGREED**	
Summation Option							**YES AGREED**	
Separately, add the amounts of each elemental impurity (µg per g) present in each of the components of the drug product							**YES AGREED**	
Where							**YES AGREED**	
M = each ingredient used to manufacture a dosage unit;							**YES AGREED**	
C_M=element concentration in component (drug substance or excipient) (µg per g); W_M							**YES AGREED**	
W_M =weight of component in a dosage unit (g per dosage unit);							**YES AGREED**	

D_M = number of units in the maximum daily dose (unit per day)		
The result of the summation of each impurity is not more than the Daily Dose PDE, unless otherwise stated in the individual monograph. Before products can be evaluated using this option, the manufacturer must ensure that additional elemental impurities cannot be inadvertently added through the manufacturing process or via the container–closure system over the shelf life of the product	**YES AGREED**	
Individual Component Option	**YES AGREED**	
For drug products with a daily dose of not more than 10 g, if all drug substances and excipients in a formulation meet the concentration limits shown in Table 3, then these components may be used in any proportion. No further calculation is necessary. While elemental impurities derived from the manufacturing process or the container–closure system are not specifically provided for in the Individual Component Option, it is expected that the drug product manufacturer will ensure that these sources do not contribute significantly to the total content of elemental impurities	**YES AGREED**	
Drug Substance and Excipients	**YES AGREED**	
The acceptable levels of elemental impurities depend on the material's ultimate use. Therefore, manufacturers of pharmaceutical products need certain information about the content of elemental impurities in drug substances or excipients in order to meet the criteria of this chapter. Drug product manufacturers can use elemental impurity test data on components from tests performed by drug substance manufacturers or excipient manufacturers, who may provide test data, or, if applicable, risk assessments. Elemental impurity data generated by a qualified supplier of drug product components are acceptable for use by a drug product manufacturer to demonstrate compliance with this chapter in the final drug product. Drug substance or excipient manufacturers who choose to perform a risk assessment must conduct that risk assessment using Table 2 in this chapter. Elements that are inherent in the nature of the material, as in the case of some naturally-sourced materials, must be considered in the risk assessment	**YES AGREED**	
The values provided in Table 3 are example concentration limits for components (drug substances and excipients) of drug products dosed at a maximum daily dose of 10 g per day. These values serve as default concentration limits to aid discussions between drug product manufacturers and the suppliers of the components of their drug products	**YES AGREED**	
NOTE — Individual components may need to be limited at levels different from those in the table depending on monograph-specific mitigating factors	**YES AGREED**	

Table 3 – Permitted Concentrations of Elemental Impurities for Individual Component Option (based on a maximum 10 g dose)

Element	Class	Oral Concentration on (µg/g)	Parenteral Concentration on (µg/g)	Inhalation Concentration on (µg/g)	Cutaneous Concentration On (µg/g)	CTCL Concentration on (µg/g)		
Cadmium	1	0.5	0.2	0.3	2	--	**YES AGREED**	
Lead	1	0.5	0.5	0.5	5	--	**YES AGREED**	
Arsenic	1	1.5	1.5	0.2	3	--	**YES AGREED**	
Mercury	1	3	0.3	0.1	3	--	**YES AGREED**	
Cobalt	2A	5	0.5	0.3	5*	35	**YES AGREED**	
Vanadium	2A	10	1	0.1	10	--	**YES AGREED**	
Nickel	2A	20	2	0.6	20*	35	**YES AGREED**	
Thallium	2B	0.8	0.8	0.8	0.8	--	**YES AGREED**	
Gold	2B	30	30	0.3	300	--	**YES AGREED**	
Palladium	2B	10	1	0.1	10	--	**YES AGREED**	
Iridium	2B	10	1	0.1	10	--	**YES AGREED**	

Osmium	2B	10	1	0.1	10	--	**YES AGREED**	
Rhodium	2B	10	1	0.1	10	--	**YES AGREED**	
Ruthenium	2B	10	1	0.1	10	--	**YES AGREED**	
Selenium	2B	15	8	13	80	--	**YES AGREED**	
Silver	2B	15	1.5	0.7	15	--	**YES AGREED**	
Platinum	2B	10	1	0.1	10	--	**YES AGREED**	
Lithium	3	55	25	2.5	250	--	**YES AGREED**	
Antimony	3	120	9	2	90	--	**YES AGREED**	
Barium	3	140	70	30	700	--	**YES AGREED**	
Molybdenum	3	300	150	1	1500	--	**YES AGREED**	
Copper	3	300	30	3	300	--	**YES AGREED**	
Tin	3	600	60	6	600	--	**YES AGREED**	
Chromium	3	1100	110	0.3	1100	--	**YES AGREED**	

For elements with a cutaneous PDE and a CTCL, both limits need to be met. If the results are conflicting, the lowest limit is applied. Using cobalt as an example, based on a 10 g maximum daily dose of the drug product, the calculated cutaneous concentration is 5 µg per g; based on a 1 g maximum daily dose of drug product, the calculated cutaneous concentration is 50 µg per g, which exceeds the CTCL of 35 µg per g. In this situation, the CTCL should be used.	**YES AGREED**	
Analytical Testing	**YES AGREED**	
If, by process monitoring and supply chain control, manufacturers can demonstrate compliance, then further testing may not be needed. When testing is done to demonstrate compliance, following procedures may be used	**YES AGREED**	
Procedures	**YES AGREED**	
This chapter describes two analytical procedures (Procedures 1 and 2) and validation criteria for the evaluation of the levels of elemental impurities. The chapter permits the use of any procedure that meets the validation criteria specified in this chapter. As the chemical composition of the considered substances and the specification limits for the element(s) of interest vary considerably, it is difficult to describe all suitable test solution preparation and measurement methods. By means of validation studies, analysts will confirm that the analytical procedure is suitable for use on specified material. It is not necessary to verify whether or not the same result can be obtained from the corresponding analyses for the same sample against either procedure 1 or 2	**YES AGREED**	
As elemental impurities may be ubiquitous, they have the potential to be present in trace amounts therefore special precautions may be necessary to avoid sample contamination	**YES AGREED**	
(NOTE — Methods such as atomic absorption spectrometry other than methods described in this chapter, if validated, can also be used without cross validation against analytical procedure 1 or 2.)♦	**YES AGREED**	
Test solution preparation:-	**YES AGREED**	
Forms of test solution preparation include Neat, Direct aqueous solution, Direct organic solution, and Indirect solution. The selection of the appropriate test preparation depends on the substance under examination and is the responsibility of the analyst. When a test preparation is not indicated in the monograph, an analyst may use any appropriately validated test preparation procedures, including but not limited to procedures described below. In cases where spiking of a substance under examination is necessary to provide an acceptable signal intensity, the blank should be spiked with the same Target elements, and where possible, using the same spiking solution. The material or mixture under test must be spiked before any test solution preparation steps are performed. Reference solutions may contain multiple Target elements. *(NOTE — if intended for a quantitative test, appropriate material handling procedures should be followed e.g. volatile liquids should be pipetted,* viscous liquids should be weighed	**YES AGREED**	

Neat. Used for liquids or alternative procedures that allows the examination of unsolved samples	**YES AGREED**	
Direct aqueous solution. Used when the sample is soluble in an aqueous solvent	**YES AGREED**	
Direct organic solution. Used where the sample is soluble in an organic solvent	**YES AGREED**	
Indirect solution. Generally, an indirect solution is obtained when a material is not directly soluble in aqueous or organic solvents. Total digestion is the preferred test solution preparation approach to obtain an indirect solution. Digest the sample using the closed vessel digestion procedure provided below or one similar to it. ♦ (NOTE — The test solution preparation scheme should yield sufficient sample to allow quantification of each element at the limit specified in the corresponding monograph or chapter)	**YES AGREED**	
Closed vessel digestion. This test solution preparation procedure is designed for samples that must be digested in concentrated acid using a closed vessel digestion apparatus. closed vessel digestion minimizes the loss of volatile impurities. The choice of a concentrated acid depends on the sample matrix. The use of any of the concentrated acids may be appropriate, but each introduces inherent safety risks. Therefore, appropriate safety precautions should be used at all times. (NOTE — Weights and volumes provided may be adjusted to meet the requirements of the digestion apparatus used).	**YES AGREED**	
An example procedure that has been shown to have broad applicability is the following. Dehydrate and predigest 0.5 g of substance under examination in 5 ml of freshly prepared concentrated acid. Allow to sit loosely covered for 30 minutes in a fume hood. Add an additional 10 ml of concentrated acid, and digest, using a closed vessel technique, until digestion or extraction results in a clear solution. Repeat, if necessary, by adding an additional 5 ml of concentrated acid	**YES AGREED**	
NOTE — Where closed vessel digestion is necessary, follow the manufacturer's recommended procedures to ensure safe use	**YES AGREED**	
Clear solutions are expected in the validation. In those cases where a clear solution cannot be obtained, appropriate studies should ensure that the recovery is suitable for the intended use	**YES AGREED**	
Reagents. All reagents used for the preparation of test and reference solutions should be sufficiently pure for the intended purpose	**YES AGREED**	
Analytical Procedures 1 and 2	**YES AGREED**	
System standardization and suitability evaluation using applicable reference materials should be performed for each analytical sequence	**YES AGREED**	
Procedure and Detection Technique	**YES AGREED**	
Procedure 1 can be used for elemental impurities generally amenable to detection by inductively coupled plasma–atomic (optical) emission spectroscopy (ICP–AES or ICP–OES). Procedure 2 can be used for elemental impurities generally amenable to detection by inductively coupled plasma-mass spectrometry (ICP–MS). Before initial use, the analyst should verify that the procedure is appropriate for the instrument and test used (procedural verification) by meeting the procedure validation requirements below	**YES AGREED**	
Procedure 1. Inductively Coupled Plasma-Optical Emission Spectrometry (ICP-OES) (2.4.42)	**YES AGREED**	
Test solution (a). Proceed as directed in test solution preparation above. Allow the sample to cool, if necessary. For mercury determination, add an appropriate stabilizer	**YES AGREED**	
Test solution (b). Dilute test solution (a) with an appropriate solvent to obtain a final concentration of the Target element(s) within the calibrated range	**YES AGREED**	
Reference solution (a). 1.5 J of the Target element(s) in a matrix matched solution	**YES AGREED**	
Reference solution (b). 0.5 J of the Target element(s) in a matrix matched solution.	**YES AGREED**	
Blank Matrix matched solution	**YES AGREED**	
Elemental spectrometric system	**YES AGREED**	
-- Mode. ICP	**YES AGREED**	

Detector. Optical detection system	YES AGREED	
Rinse. Diluent used	YES AGREED	
Standardization. Reference solution (a), Reference solution (b), and blank	YES AGREED	
System suitability	YES AGREED	
Sample. Reference solution of the Target element(s) in a matrix matched solution at a concentration within the calibrated range	YES AGREED	
Suitabilityrequirements	YES AGREED	
Short term Instrumental Stability. Compare results obtained from System suitability sample before and after the analysis of the Test solution (b)	YES AGREED	
Suitability criteria. Not more than 20 per cent deviation from the theoretical concentration of the system suitability sample	YES AGREED	
NOTE — If samples are high in mineral content, rinse the system well in order to minimize carryover and check it by measuring a blank solution before introducing the System suitability sample	YES AGREED	
Analysis. Analyze according to the manufacturer's suggestions for program and wavelength. Calculate and report results on the basis of the original sample size	YES AGREED	
NOTE — Appropriate measures must be taken to correct for matrix induced interferences (e.g., wavelength overlaps	YES AGREED	
Procedure 2. Inductively Coupled Plasma-Mass Spectrometry (ICP-MS) (2.4.42).	YES AGREED	
Test solution (a). Proceed as directed for test solution preparation above. Allow the sample to cool, if necessary. For mercury determination, add an appropriate stabilizer	YES AGREED	
Test solution (b). Dilute test solution (a) with an appropriate solvent to obtain a final concentration of the Target elements within the calibrated range	YES AGREED	
Reference solution (a). 1.5 J of the Target element(s) in a matrix matched solution	YES AGREED	
Reference solution (b). 0.5 J of the Target element(s) in a matrix matched solution	YES AGREED	
Blank. matrix matched solution	YES AGREED	
Elemental spectrometric system	YES AGREED	
Mode. ICP, [NOTE — An instrument with a cooled spray chamber is recommended. (A collision cell or reaction cell may also be beneficial.)]	YES AGREED	
Detector. Mass spectrometer	YES AGREED	
Rinse. Diluent used	YES AGREED	
Standardization. Reference solution (a), Reference solution (b), and blank	YES AGREED	
System suitability	YES AGREED	
Sample. Reference solution of the Target element(s) in a Matrix matched solution at a concentration within the calibrated range	YES AGREED	
Suitability requirements	YES AGREED	
Short term Instrumental Stability. Compare results obtained from System suitability sample before and after the analysis of test solution (b)	YES AGREED	
Suitability criteria. Not more than 20 per cent deviation from the theoretical concentration of the system suitability sample	YES AGREED	
NOTE — If samples are high in mineral content, rinse the system well in order to minimize carryover and check it by measuring a blank solution before introducing the System suitability sample	YES AGREED	
Analysis. Analyze according to the manufacturer's suggestions for program and m/z. Calculate and report results based on the original sample size.	YES AGREED	
NOTE — Appropriate measures must be taken to correct for matrix-induced interferences (e.g. argon chloride interference with arsenic determinations). Requirements for Procedure Validation	YES AGREED	
Requirements for Procedure Validation	YES AGREED	

NOTE — Some validation requirements provided below may differ from those provided in chapter 2.4.2 and 2.4.42	**YES AGREED**	
All procedures must be validated in accordance with the validation requirements described below. The level of validation necessary to ensure that an alternative procedure is acceptable depends on whether a limit test or a quantitative determination is used. Any alternative procedure that has been validated and meets the acceptance criteria that follow is considered to be suitable for use	**YES AGREED**	
During procedure validation, the system suitability requirements as established for the procedure must be met	**YES AGREED**	
Procedures for Limit Tests	**YES AGREED**	
The following section defines the validation parameters for the acceptability of limit tests. Meeting these requirements must be demonstrated experimentally using an appropriate tests and reference material	**YES AGREED**	
The suitability of the method must be determined by conducting studies with the material or mixture under test spiked with known concentrations of each *Target element* of interest at the appropriate target concentration	**YES AGREED**	
Detection Limit	**YES AGREED**	
The detection limit is shown to be sufficiently low by the analysis of samples with known concentrations of analyte at and below the target concentration	**YES AGREED**	
For the purposes of this chapter, detection limit does not mean that the procedure must demonstrate lowest possible analytical result	**YES AGREED**	
Reference solution. A preparation of reference materials for the Target element(s) at 1.0 J in a matrix matched solution	**YES AGREED**	
Spiked test solution (a). Prepare a solution of sample under test, spiked with appropriate reference materials for the Target elements at the target concentration, solubilized or digested as described in test solution preparation	**YES AGREED**	
Spiked test solution (b). Prepare a solution of the sample under test, spiked with appropriate reference materials for the Target element(s) at 80 per cent of the target concentration, solubilized or digested as described in test solution preparation	**YES AGREED**	
Unspiked test solution. A sample of material under examination, solubilized or digested in the same manner as the spiked sample solutions	**YES AGREED**	
Acceptance criteria	**YES AGREED**	
Non-instrumental procedures. Spiked test solution (a) provides a signal/ response, e.g., colour, or intensity equivalent to or greater than that of the Reference solution. Spiked test solution (b) must provide a signal/response, e.g., colour, or intensity less than that of spiked test solution (a) (NOTE — The signal/response, e.g., colour, or intensity from each spiked test solution is not less than the unspiked test solution determination)	**YES AGREED**	
Instrumental procedures. The average value of the three replicate measurements of spiked test solution (a) is within ± 15 per cent of the average value obtained for the replicate measurements of the reference solution. The average value of the replicate measurements of spiked test solution (b) must provide a signal intensity or value less than that of the reference solution *(NOTE — Correct the values obtained for each of the spiked solutions using the unspiked test solution)*	**YES AGREED**	
Specificity	**YES AGREED**	
The procedure must be able to unequivocally assess (2.5.10 Validation of Analytical Procedures) each *Target element* in the presence of components that may be expected to be present, including other *Target elements*, and matrix components	**YES AGREED**	
Precision, only for Instrumental Methods (Repeatability)	**YES AGREED**	
Test solutions. Six independent samples of the substance under examination, spiked with appropriate reference materials for the *Target elements* at the target concentration	**YES AGREED**	
Acceptance criteria	**YES AGREED**	

The relative standard deviation is not more than 20 per cent for each *Target element*	**YES AGREED**	
Procedure for Quantitative Tests	**YES AGREED**	
The following section defines the validation parameters for the acceptability of procedures for quantitative tests. Meeting these requirements must be demonstrated experimentally, using appropriate tests and reference materials	**YES AGREED**	
Accuracy	**YES AGREED**	
Reference solutions. Prepare solutions containing the *Target elements* at three concentrations ranging from 0.5 J to 1.5 J, using appropriate reference materials, in a Matrix matched solution	**YES AGREED**	
Test solutions. Prepare 3 independent test solution preparations of the substance under examination spiked with appropriate reference materials for the Target element(s) at the target concentration, J, before any sample preparation steps (digestion or solubilization). Spike concentrations should range from 0.5 J to 1.5 J and should include not less than 3 individual concentrations	**YES AGREED**	
Acceptance criteria	**YES AGREED**	
Spike recovery. 70 per cent to 150 per cent for the mean of three independent sample preparations at each concentration	**YES AGREED**	
Precision	**YES AGREED**	
Repeatability	**YES AGREED**	
Test solutions. Six independent samples of substance under examination (taken from the same lot) spiked with appropriate reference materials for the *Target element(s)* at the target concentration or at least 9 determinations (e.g. 3 replicates of 3 concentrations) covering the specified range	**YES AGREED**	
Acceptance criteria	**YES AGREED**	
Relative standard deviation in both cases, not more than 20 per cent for each *Target element*	**YES AGREED**	
Intermediate precision (ruggedness)	**YES AGREED**	
Perform the repeatability analysis again either on a different day, with a different instrumentation, with a different analyst, or a combination thereof. Combine the results of this analysis with the repeatability analysis	**YES AGREED**	
Acceptance criteria	**YES AGREED**	
Relative standard deviation is not more than 25 per cent for each *Target element*	**YES AGREED**	
Specificity	**YES AGREED**	
The procedure must be able to unequivocally assess each *Target element* in the presence of components that may be expected to be present, including other *target elements*, and matrix components	**YES AGREED**	
Range and Linearity	**YES AGREED**	
Demonstrated by meeting the Accuracy requirement	**YES AGREED**	
Quantitation Limit	**YES AGREED**	
Use the results from the accuracy study	**YES AGREED**	
QL of 0.5 J is confirmed when the accuracy acceptance criteria for 0.5 J spiked solution is met.	**YES AGREED**	
Acceptance criterion: the QL is less than or equal to 0.5 J	**YES AGREED**	
Definition of Terms	**YES AGREED**	
Concentrated acid. Concentrated ultra-pure nitric, sulphuric, hydrochloric, or hydrofluoric acids or any other acid or mixture of acids that are demonstrated to be suitable	**YES AGREED**	
Matrix matched solution. Solutions having the same solvent composition as the test solution. In the case of an aqueous solution, Matrix matched solution would indicate that the same acids, acid concentrations, and mercury stabilizer are used in both preparations	**YES AGREED**	

Target elements. Elements must be evaluated according to the requirements defined in other chapters		**YES AGREED**	
Target limit or Target concentration. The acceptance value for the elemental impurity being evaluated. Exceeding the target limit indicates that a material under test exceeds the acceptable value. *(NOTE —Target limits can be approximated by dividing the permitted daily exposures (PDEs) by the maximum daily dose of the drug product)*		**YES AGREED**	
Final concentration of the Target element(s) in the reference and the test solutions. It corresponds to the concentration (w/v) of the Target element(s) at the Target limit, appropriately diluted to the working range of the instrument. If a dilution is not necessary J is equal to the target concentration. For example, if the target elements are lead and arsenic for an analysis of an oral solid drug product with a daily dose of 10 g per day using inductively coupled plasma–mass spectrometry (ICP–MS), the target limit for these elements would be 0.5 µg per g and 1.5 µg per g. However, in both cases, the linear dynamic range of the ICP–MS is known to extend from 0.01 ng per ml to 0.1 µg per ml for these elements. Therefore, a dilution factor of at least 1:100 is required to ensure that the analysis occurs in the linear dynamic range of the instrument. J would thus equal 5 ng per ml and 15 ng per ml for lead and arsenic, respectively *(NOTE — The density of the test solution may have to be considered)*		**YES AGREED**	
Appropriate reference materials. Where Appropriate reference materials are specified in the chapter, certified reference materials (CRM) from a national metrology institute (NMI), or reference materials that are traceable to the CRM of an NMI should be used		**YES AGREED**	
Cross validation. Verification whether or not the same result can be obtained from the corresponding analyses for the same sample		**YES AGREED**	
The following elemental impurities shall be considered for routine testing applicable		**YES AGREED**	
a) Parenteral Products		**YES AGREED**	
Each batch of parenteral product shall be tested for the specified elemental impurities, including		**YES AGREED**	
• Cadmium • Lead • Arsenic • Mercury • Cobalt	• Vanadium • Nickel • Lithium • Antimony • Copper	**YES AGREED**	
The analysis shall be performed using a validated ICp-MS method, as applicable		**YES AGREED**	
b) Non-Parenteral Oral Products		**YES AGREED**	
Each batch of parenteral product shall be tested for the specified elemental impurities, including		**YES AGREED**	
• Cadmium • Lead • Arsenic • Mercury • Cobalt	• Vanadium • Nickel	**YES AGREED**	
The analysis shall be performed using a validated ICP-MS method, as applicable		**YES AGREED**	
The applicable elemental impurity limits shall be established and controlled in accordance with the approved product specification and current pharmacopoeial/regulatory requirements		**YES AGREED**	

Tender No: KAPL/OTE/QC/SR/1051/2026-27 dated 09.09.2026

(To be submitted on the letterhead)

DECLARATION

I) We do hereby declare that,

1. We do hereby declare that as on the date of submission of bid against this tender we are not in the list of ineligible/ blacklisted/ banned/ debarred entity by KAPL/any Government Agency, for participating in its tenders.

Further, we agree, in case we get blacklisted/ banned/ debarred by KAPL/any Government Agency, any time prior to finalization of tender/ contract, our bid shall not be considered for further evaluation/ award of order.

2. The director/proprietor of the bidding firm are not closely related to KAPL.

In case, at any time the information furnished is found to be false, you may disqualify/ debar me/ us as deemed fit.

II) We do hereby declare that we have read and understood all terms and conditions of tender document including GIT, SIT, GCC, SCC, Technical Specification, Quality Control Criteria and confirm to abide to those conditions without any counter conditions.

Signature _____

Name----------

Designation----------

Date----------

Stamp of the Organization----------