



ENQUIRY REF. No.	KAPL/CG/011/1567
DATE	17/10/2024
DUE DATE	25/10/2024 (13.00HRS)

Dear Sir,

Please submit your lowest and competitive offer in a SEALED ENVELOPE, DULY SUPERSCRIBING OUR ABOVE ENQUIRY REF. NO., DATE and DUE DATE on it/ OR MAIL, with other details of F.O.R terms, Taxes, Credit period, Delivery offered, Name of the Make, Detailed Specification etc., for below mentioned material/s

SL. NO.	ITEM CODE	ITEM DESCRIPTION	UOM	QTY.
01	QADAMPKIT1	AMPOULE VISUAL INSPECTION KIT –AMBER COLOUR	NOS	01

Please ensure that your reaches us on or before Due date by courier OR Speed post or by hand in sealed cover only to below office address:

M/s. Karnataka Antibiotics and pharmaceuticals limited
Plot No.37,Arka The Business Centre ,NTTF Main Road ,Peenya Industrial Area
2nd phase, Bengaluru -560058 Ph.No.080-23571590

OTHER TERMS:

- | | |
|---------------------------------|------------------|
| 1. F.O.R TERMS | : DOOR DELIVERY |
| 2. GST % | : PLEASE SPECIFY |
| 3. PACKING & FORWARDING CHARGES | : NOT APPLICABLE |
| 4. CREDIT PERIOD | : 30 DAYS |
| 5. DELIVERY OFFERED | : |


NOTE:

01. IF YOU ARE NOT PARTICIPATING IN THE TENDER PLEASE SEND A REGRET LETTER.
02. VENDOR HAS TO QUOTE AS PER OUR TENDER IN YOUR COMPANY LETTER HEAD.
03. QUOTATION MUST BE SUBMITTED IN TWO SEALED COVERS (TECHNICAL & COMMERCIAL /PRICE BID)SEPARATELY AND IN ONE ENVELOPE OR ELSE YOUR PROPOSAL WILL NOT BE CONSIDERED.

IF YOU NEED ANY CLARIFICATION ,PLEASE CONTACT US .

Thanking you,

Yours faithfully,
For KARNATAKA ANTIBIOTICS
& PHARMACEUTICALS LIMITED


YUVARAJA M
DEPUTY MANAGER PURCHASE DEPT
MOB:9945317873

KARNATAKA ANTIBIOTICS & PHARMACEUTICALS LIMITED**QUALITY ASSURANCE DEPARTMENT****TITLE****REQUIREMENTS FOR VISUAL INSPECTOR'S QUALIFICATION KIT****A. Container Details of Defect Kit:**

2ml Amber Colour Ampoules

B. Particle Defect Type, Size & Quantity:

- As per requirement each particle defect shall be created by using real source of Primary packaging material (PPM), Material used for machine parts/product contact part, Filter and garments using in Aseptic area.
- Each particle shall be washed and dried before using.
- Each particle shall be measured through (2dimensional & 3 dimensional) high resolution & high density digital microscope.
- Insertion of single particle in each container shall be done in clean room environment under the LAF
- Numbering of each defect container with a unique ID written by permanent high quality UV marker in cap position. UV marking shall be done for good ampoule in the kit also.
- During process it is taken care not to have other or multiple defects other than said defect.

S.No.	Kit Description	Particle Size (In Micron)						Total
		100	200	300	500	1000	2000	
1	Glass Particle	2	2	NA	2	2	NA	8
2	Black particle	2	2	NA	2	2	NA	8
3	White particle	2	2	NA	2	2	NA	8
4	Stainless Steel Particle	2	2	NA	2	2	NA	8
5	White Fibre	NA	NA	NA	2	2	2	6
6	Black Fibre	NA	NA	NA	2	2	2	6
7	Hair	NA	NA	NA	2	2	2	6
Total Number of particle defect container per KIT:								50



QUALITY ASSURANCE DEPARTMENT

TITLE

REQUIREMENTS FOR VISUAL INSPECTOR'S QUALIFICATION KIT

C. Cosmetic defects:

- Cosmetic defects are falling under Minor category based on the impact on patient and product.
- As per the requirement, each cosmetic defect shall be prepared with high precaution by trained technical staff.
- Upon preparation of cosmetic defects each unit shall be verified with high resolution magnification followed by high density digital microscope.
- During process it is taken care not to have other or multiple defects other than said defect.
- Numbering of each defect container with a unique ID written by permanent high quality UV marker in cap position. Good ampoules also to be numbered with UV marker.

S.No.	Kit description	Quantity
1.	Improper sealing	2
2.	Cracked unit	2
3.	Missing O ring	2
4.	Damaged O ring	2
5.	High level (overfilled)	2
6.	Low level (under filled)	2
Total Cosmetic Defects for each kit		12

KARNATAKA ANTIBIOTICS & PHARMACEUTICALS LIMITED**QUALITY ASSURANCE DEPARTMENT****TITLE****REQUIREMENTS FOR VISUAL INSPECTOR'S QUALIFICATION KIT****D. Defect Kit Bifurcation:**

Kit Description	Defect Type & Quantities		Total Kit Quantity
	Particle defect	Cosmetic defect	
2ml Amber Colour Ampoules	50	12	62

E. Shelf life:

3Years

F. General Information:

- Defective kit (particulate matters & cosmetic defect) shall be prepared in KAPL factory premises.
- Probability of detection (POD) evaluation shall be done using KAPL employees
- Each unit of defective kit ampoules & good ampoules shall be identified with UV numbering or any other suitable technique.
- Training & assistance to be provided to KAPL officers at KAPL factory site.
- Defective kit shall be USP 1790 compliant



QUALITY ASSURANCE DEPARTMENT

TITLE

REQUIREMENTS FOR VISUAL INSPECTOR'S QUALIFICATION KIT

G. Training & Documentation:

- Master Certificate of each defect kit
- Probability of detection (POD) evaluation sheet (Each container 10 time inspection)
- Master list of the kit along with UV numbering
- Training & assistance during qualification process of visual inspectors
- KIT expiry certification (3 years)
- Replacement of ampoule in case of any breakage
- NIST traceable microscope Calibration Certificate
- Microscopic Image of particulate matter & cosmetic defects
- Size Certificate sheet of particulate matters in Packaging Components
- Providing defects library for training & qualification purpose
- Individual particle analysis record (Measurement & digital photograph of each particle defect)
- Any type of regulatory queries on defect kit (Online support to be provided by experts 24 X 7)