


Draft Indian Standard: Current Status and Ramifications on PiE/AMR

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AGENDA

1. Brief Introduction to the Proposed Environmental Standards for Bulk Drug and Formulation Industry
 2. Key Challenges and Ramifications for the Indian Industry
 3. Voice of Indian Pharma Companies – Outcome of ERM's Online Survey, August 2020
 4. Summary of Amendments and Modifications in the Draft Standard Proposed by the Expert Committee of MoEF&CC
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- A decorative graphic consisting of numerous small white dots arranged in a pattern that tapers from left to right, set against a light pink background.

Speaker Bio

Shivananda Shetty, Partner, ERM India Private Limited

- Shiva is Partner with ERM India, he is a graduate in Chemistry from Mumbai University, Post Graduate in Policy and Regulatory Studies from TERI and PhD from Delhi University. He has more than 25 years of experience in Environmental Health, Safety and Sustainability sector across various sectors including Pharmaceuticals. He started his career as a chemist at SGS India and has worked for more than 5 years in the Pharmaceutical services wherein he was involved in QA/QC studies of the pharmaceutical products as per the Indian, British, Europe and Japanese Pharmacopeia using chemical, instrumental (GC-MS, HPLC, FTIR) and microbiology techniques. He was the Director of the Laboratory Business at SGS India which included the pharma testing facility that had approvals from NABL, Indian GLP and USFDA for QA/QC of the Indian pharmaceutical products. He has been led the studies for various clients to assess the trace level of the pharma products in environment at various water bodies across India. His team was also involved in studying the impact of oregano grass on the MRSA (a well-known antibiotic-resistant bacterium) along for University of West England. SGS was awarded the prestigious 2008 SEED award for the work He was involved in developing the capability and getting ISO 17025 accreditation for testing antibiotics in seafood and other food products like Milk, Honey using modern techniques like HPLC, LC MS MS, GC MS etc.
- He leads the Sustainability and Climate Change Services at ERM India and has worked closely with Pharma companies in India which includes consulting for Sustainability reporting, Dow Jones Sustainability Index (DJSI) disclosure, Carbon disclosure program (CDP). He is also the partner in charge for various PSCI audits for companies like Pfizer, Novartis, GSK covering their major suppliers in India. He and his team are involved in supporting the companies in India for implementing the AMR Alliance guidelines across their own operations and the supply chain in India. He has also been involved as expert in Environment Due Diligence for healthcare, clinical research and pathological labs in India.



Speaker Bio

Mugundan Ramachandran, Senior Consultant, ERM India Private Limited

- Mugundan is a Senior Consultant currently working with ERM based in Bangalore, India. He has a Master's Engineering Degree in Environmental Science & Technology and a Bachelor's Degree in Biotechnology from Anna University, Chennai. He has over ten (10) years of consulting experience in the field of Environmental Engineering and Water Resource Management. Mugundan has a rich experience in undertaking Water audits, Wastewater Management studies, EHS Compliance audits, Regulatory review and Environmental Due Diligence (EDD) audits across a variety of industrial sectors. He is an expert in water balancing, process water optimization, wastewater treatment, due diligence, site assessments and regulatory compliance. His experience also includes design, adequacy assessment and commissioning of wastewater and sewage treatment plants. He has undertaken more than 200 environmental consulting assignments till date in diverse manufacturing sectors such as textiles/apparel, pharmaceutical, oil & gas, chemicals and paper. He is a Quality Council of India (QCI) certified '**Functional Area Expert**' in the field of Water Pollution, Prevention and Control. Mugundan has been closely working with some of the pharmaceutical companies in evaluating their overall AMR risks from the manufacturing facilities in line with guidelines of AMR Industry Alliance.
- Since 2016, Mugundan has been working with a number of pharmaceutical companies and other agencies on evaluating PiE/AMR impacts from antibiotic manufacturing. He is well-versed with the requirements of Common Antibiotic Manufacturing Framework (CAMF) by AMR Industry Alliance and has undertaken a number of assessments in this regard. He also played a vital role in the development of an in-house online tool to assess the compliance of manufacturing facilities against the requirements of CAMF.



Proposed Environmental Standards

- MoEF&CC published a draft notification on the proposed environmental standards for Bulk Drug and Formulation (Pharmaceutical) Industry on 23rd January 2020.
- The notification sets up effluent discharge standards at the final outlet of ETP - for various physico-chemical parameters, solvents, *API's and standards for 121 antibiotic residues*.
- In addition, the notification also includes emission standards for process reactor vents/tank farm vents and total solvent losses (<3% of the solvent used).
- No distinct exemption provided for ZLD industries in the draft notification.

MINISTRY OF ENVIRONMENT, FOREST AND CLIMATE CHANGE

NOTIFICATION

New Delhi, the 23rd January, 2020

G.S.R. 44(E).— The following draft of the notification, which the Central Government proposes to issue in exercise of the powers conferred by sections 6 and 25 of the Environment (Protection) Act, 1986 (29 of 1986) is hereby published, as required under sub-rule (3) of rule 5 of the Environment (Protection) Rules, 1986, for the information of the public likely to be affected thereby; and notice is hereby given that the said draft notification shall be taken into consideration on or after the expiry of a period of sixty days from the date on which copies of the Gazette containing this notification are made available to the public.

Any person interested in making any objections or suggestions on the proposals contained in the draft notification may forward the same in writing, for consideration of the Central Government within the period specified above to the Secretary, Ministry of Environment, Forest and Climate Change, Indira Paryavaran Bhawan, Jor Bagh Road, New Delhi-110003, or send it to Member Secretary, CPCB and Scientist 'E' Ministry at the e-mail address i.e. mscb.cpcb@nic.in and h.kharkwal@nic.in.

Draft Notification

The Central Government hereby makes the following rules further to amend the Environment (Protection) Rules, 1986, namely:-

1. **Short title and commencement-** (1) These rules may be called the Environment (Protection) Amendment Rules, 2019.
(2) They shall come into force on the date of their final publication in the Official Gazette.
2. In the Environment (Protection) Rules, 1986, in Schedule-1, for serial number 73 and the entries relating thereto, the following serial number and entries shall be substituted, namely:-

Sl. No.	Industry	Parameters	Standard
1	2	3	4
73	Bulk Drug and Formulation (Pharmaceutical)	A. EFFLUENT STANDARDS	
		For final outlet of ETP Limiting value for concentration (in mg/l except for pH and Bio assay)	
		i) Compulsory Parameters	
		pH	6.0 -8.5

Salient Aspects of the Standard

- Proposed concentration of API's at the final outlet of ETP shall be 0.05mg/L.
- Proposed concentration for 121 antibiotic residues is lesser than the PNEC values established by AMR Industry Alliance.
- Reuse of treated effluent for gardening/horticulture shall not be considered as ZLD in Bulk drug and Formulation industries.
- The notification also mandates incineration of sludge containing antibiotics.
- Since its release, various industries and industrial bodies have raised numerous concerns and objections on the draft notification*.

* <http://www.pharmabiz.com/NewsDetails.aspx?aid=121659&sid=1>

D. Antibiotic Residues in the treated effluent of Bulk Drug and Formulation Industry and CETP with membership of Bulk Drug and formulation Units
Individual antibiotic residues will be equal to or less than the values given in the below table.

Parameter	Limiting value for concentration (µg/l)
i. Amikacin	6.40
ii. Amoxicillin	0.10
iii. Amphotericin B	0.01
iv. Ampicillin	0.10
v. Anidulafungin	0.01
vi. Avilamycin	3.20
vii. Azithromycin	0.01
viii. Aztreonam	0.20
ix. Bacitracin	3.20
x. Bedaquiline	0.03
xi. Benzylpenicillin	0.10
xii. Capreomycin	0.80
xiii. Cefaclor	0.20
xiv. Cefadroxil	0.80
xv. Cefalonium	8.40
xvi. Cefaloridine	1.60
xvii. Cefalothin	0.80
xviii. Cefazolin	0.40
xix. Cefdinir	0.10
xx. Cefepime	0.20
xxi. Cefixime	0.02
xxii. Cefoperazone	0.20
xxiii. Cefotaxime	0.04
xxiv. Cefoxitin	3.20
xxv. Cefpirome	0.02
xxvi. Cefpodoxime	0.10
xxvii. Cefquinome	0.64
xxviii. Cefstaroline	0.02
xxix. Ceftazidime	0.20
xxx. Ceftibuten	0.10
xxxi. Ceftiofur	0.02
xxxii. Ceftobiprole	0.09
xxxiii. Cefzolozane	0.76
xxxiv. Ceftriaxone	0.01

Key Challenges and Ramification for the Indian Pharma Industry

5. PERSECUTIONS, REPUTATIONAL & BUSINESS RISKS

- Litigations, regulatory risks and penalties associated with the non-compliance to the proposed discharge standards.
 - Apprehension of Industry becoming economically constraint and non-competitive in the International market.

4. IMPLICATION ON OPERATING CAPITAL

- Higher operating cost associated with technological upgradation of wastewater treatment plants in order to comply with the discharge standard.
- Additional cost expenditure with respect to laboratory analysis of effluents and handling & disposal of sludge containing antibiotics.



3. ANALYSIS OF API'S & ANTIBIOTIC RESIDUES

- Uncertainty on the test methods and standards for all API's and antibiotics in complex wastewater streams.
- Laboratory infrastructure in India.

1. STRINGENT DISCHARGE LIMITS FOR API'S & ANTIBIOTIC RESIDUES

- Proposed Antibiotic discharge concentrations are much lesser than the PNEC values.
- India is the first country to prescribe antibiotic discharge standards.*

2. NON-DISTINCTION BETWEEN ZLD AND NON-ZLD UNITS

- No clear distinction between ZLD and non-ZLD units in the draft notification.
- Reuse of treated effluent for gardening/horticulture shall not be considered as ZLD.

Outcome of ERM's Online Survey

- Online Survey to gather views and perception of Indian Pharmaceutical Companies on the draft notification.
- 11 questions focussing on the interpretation and challenges for the industry.
- More than forty (40) companies invited for the survey.
- Survey duration of four weeks – 1st to 31st August 2020.
- 75% of the respondents are into antibiotic manufacturing.
- 66% of the respondents mentioned to have an on-site wastewater treatment plant followed by Zero Liquid Discharge (ZLD).

Online survey on the proposed draft notification on API and Residual Antibiotic Limits

* Required

1. Is your company involved in the manufacturing of antibiotics in any form such as API's or Formulation? *

Yes

No

No immediate plan to commence antibiotic manufacturing.

Plan to commence manufacturing of antibiotics in the next 2-5 Years.

2. How do you manage wastewater at your manufacturing facilities? *


On-site wastewater treatment plant with ZLD.

On-site wastewater treatment plant followed by discharge to a CETP.

On-site wastewater treatment plant followed by discharge on land (or) to a surface water receptor.

No on-site wastewater treatment plant.

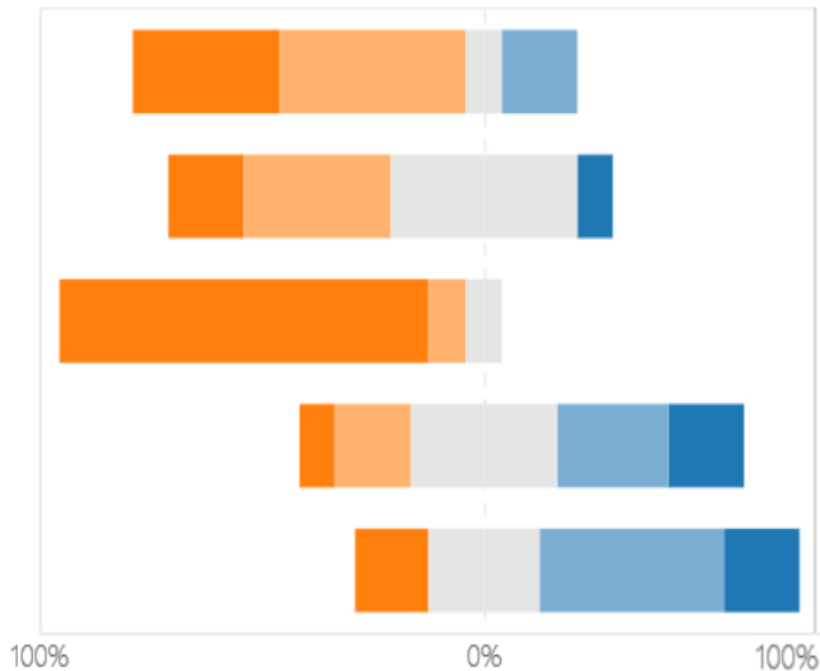
Other



Outcome of ERM's Online Survey

Q.1) Based on your view, can you please identify and rate the key challenges (on a scale of 1 to 5, with 1 being the highest priority) associated with the implementation of this draft standard?

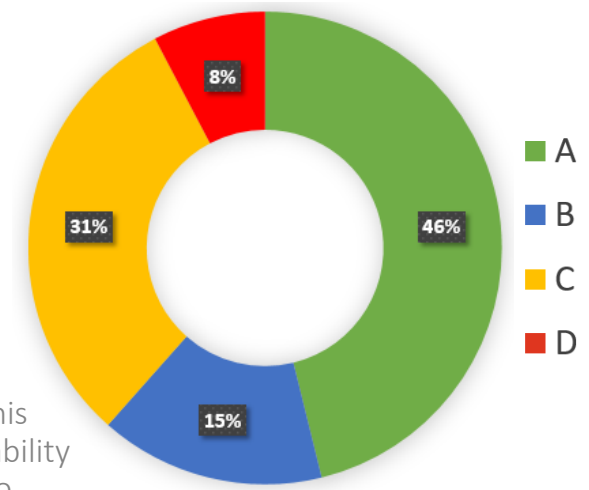
1. Stringent discharge limits for Antibiotics and API's
2. Need for technological upgradation in wastewater treatment plants
3. Measurement and Monitoring of Antibiotics and API in wastewater
4. Mandatory incineration of sludge containing antibiotics
5. Persecutions and Reputational risks posed by NGOs/regulators post implementation of the standard



1 2 3 4 5

Q.2) The proposed standard does not provide a clear distinction between ZLD and Non-ZLD units. What is your perspective on this aspect?

- A. ZLD units should be completely excluded from the scope of this standard as there is no discharge of treated/untreated effluents from the site premises.
- B. While the standard should exclude ZLD units, there is a need for additional infrastructure/controls to be implemented while managing the antibiotic/API containing wastewater in ZLD Units;
- C. ZLD units should also come in ambit of this standard as there is an uncertainty on the ability of existing wastewater treatment systems to completely remove (or) inactivate the antibiotics/APIs present in pharmaceutical effluents;
- D. None of the above



Outcome of ERM's Online Survey

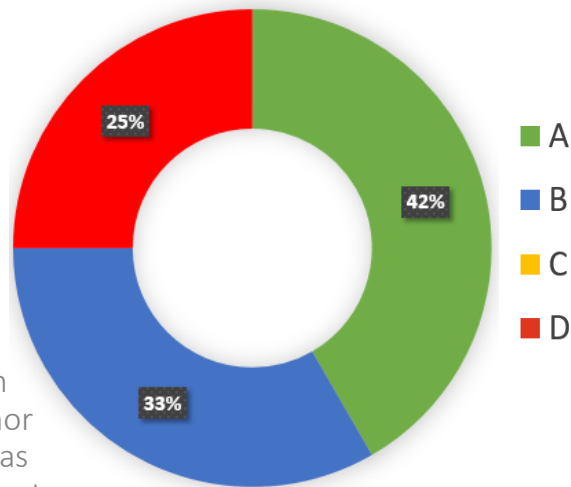
Q.3) What is your opinion on the need for technological upgradation in the wastewater treatment plants in order to meet the proposed discharge standards for API's and Antibiotic Residues?

A. Uncertain. Currently, there is no strong scientific evidence to substantiate the antibiotic removal efficiencies of various conventional and advanced wastewater treatment technologies.

B. The existing wastewater treatment plants need major upgradation and revamp in order to comply with the proposed discharge standards for API's and Antibiotics; Significant CAPEX needs to be earmarked for this purpose;

C. No major upgradation would be required in the wastewater treatment plants. Certain minor operational intervention in the process (such as source control and segregation) will be sufficient to comply with the proposed discharge standards for API's and Antibiotics;

D. None of the above



- A
- B
- C
- D

Q.4) Draft standard mandates incineration of sludge containing antibiotic residues. What is your perspective on this?

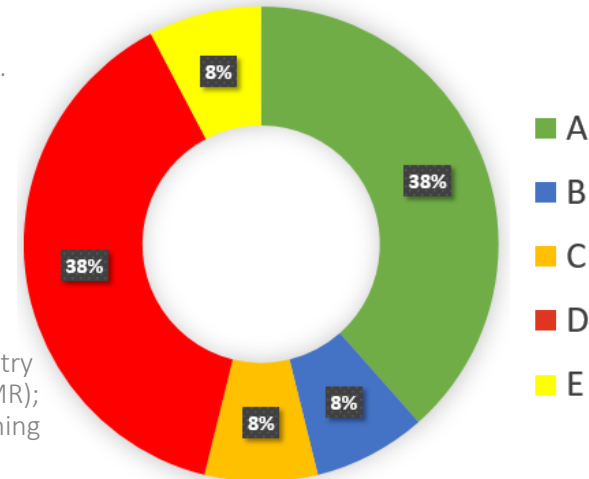
A. Mandatory incineration would mean significant increase in operational cost. This will lead to the Indian pharmaceutical industry becoming economically constraint and non-competitive with international markets; Companies should be allowed to dispose such sludge in approved TSDF facilities or for co-incineration.

B. While the requirement of mandatory incineration should be reconsidered by MoEF&CC, there is a need for additional controls to be implemented by pharmaceutical companies for ensuring deactivation and destabilization of active antibiotics in such sludge before disposal;

C. This is a welcome decision by MoEF&CC as sludge containing active antibiotics from Pharmaceutical industry poses a high risk towards Anti-Microbial Resistance (AMR); this standard should be mandated for all sludge containing residual antibiotics;

D. MoEF&CC should also take into account the availability of common hazardous waste incinerators across different pharmaceutical clusters and states in India before implementing this standard.

E. None of the above



- A
- B
- C
- D
- E

Outcome of ERM's Online Survey

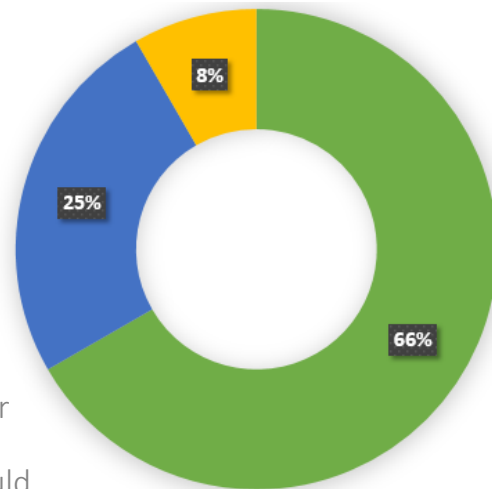
Q.5) As per the draft standard, the API's and Antibiotic residues are required to be analysed regularly in the treated effluent? What is your perspective on the analytical tools such as test methods and standards for such analysis?

A. Validated test methods, standards and laboratory infrastructure may not be available for all API's and Antibiotics manufactured in India;

B. While the standard methods are either already available (or) can be developed with the help of scientific community, conducting such tests on a regular basis is not-viable considering the financial implications and the management time involved;

C. Validated test methods, standards and laboratory infrastructure are readily available for all API's and Antibiotics manufactured in India; the regular analysis of API's and Antibiotics should be mandated for all pharmaceutical units irrespective of the status of implementation of ZLD.

D. None of the above



- A
- B
- C
- D

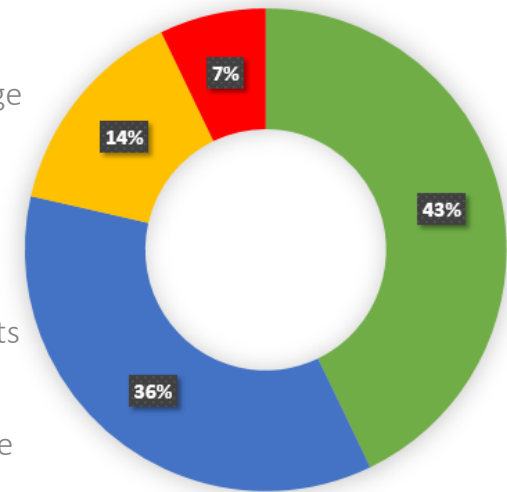
Q.6) In your view, what are the key changes / modifications that needs to be considered by MoEF&CC in the draft standard?

A. MoEF&CC should revisit certain aspects of the standard (such as PNEC values, sludge incineration etc.) and revise the same in accordance with inputs and consultation with a larger group of stakeholders from the industry and scientific community before prescribing the final discharge standard;

B. The standard should be made applicable for non-ZLD units only as ZLD units don't discharge any wastewater outside the site premises.

C. With a long term vision of curbing AMR and its impacts in the country, the standard should be rolled out in its complete form without any modification; however MoEF&CC should provide sufficient time for the industries to implement operational and technological changes required in order to comply with various requirements of the standard;

D. None of the above



- A
- B
- C
- D

Amendments and Modifications Recommended by the Expert Appraisal Committee

- The draft notification was considered for finalization in the 19th Meeting of Expert Committee for Environmental Standards on 20th May 2020.
- More than 35 suggestions received from industry associations, individual experts and industries were deliberated for their relevance and feasibility.
- Joint Secretary, Ministry of Chemicals and Fertilisers, Department of Pharmaceuticals stressed on the following aspects:
 - Proposed norms shouldn't result in excess financial burden to the Industry
 - Standard on AMR may be a challenge for the industry to meet
 - The committee may consider appropriate concerns raised by the industry

No. Q-15017/42/2007-CPW
GOVERNMENT OF INDIA
MINISTRY OF ENVIRONMENT, FOREST & CLIMATE CHANGE
(CP Division)

Indira Paryavaran Bhawan
Level -II, Prithvi Wing, Jorbagh Road
New Delhi-110003

Dated: 3rd June, 2020

To

As per list enclosed

Subject: Minutes of the 19th Meeting (through Video Conference) of Expert Committee for Environmental Standards on 20th May, 2020 -regarding.

Sir,

I am directed to forward herewith a copy of minutes of the 19th Meeting (through Video Conference) of Expert Committee for Environmental Standards on 20th May, 2020 for perusal and necessary action.

Yours faithfully,

Vinod
3/06/2020
(V.K. Kushwaha)
Section Officer (CPW)

Encl: As above

Amendments and Modifications Recommended by the Expert Appraisal Committee

01

Applicability (ZLD/Non-ZLD)

The notification will be applicable for **any discharge of treated process water** to inland water bodies or for horticulture or irrigation or land disposal from any industry and or CETP.

02

API Discharge Norms

Total API discharge norms **shall be removed** owing to the complexity and non-availability of standardised test methods.

03

Antibiotic Discharge Standards

PNEC values shall be applicable at the outlet/discharge point for both CETP as well as industry (other than member industries of CETP).

04

Industries Discharging to CETP's

Member industries discharging to CETP's will be governed by the **provision of CETP norms** dated 01.01.2016* .

05

CETP's

CETP's receiving effluent from any bulk drug and formulation manufacturing shall be **subjected to AMR parameters** (antibiotic standards).

06

Sludge Management

Antibiotic containing sludge can be handled in **accordance with** the Hazardous and Other Wastes (Management and Transboundary Movement) Rules, 2016.

- *CPCB to issue guidelines and requisite protocol on sampling and analysis for AMR tests within 12 months.*
- *AMR parameters shall be applicable after expiry of one year from the date of this notification.*

Summary of Exemptions/Applicability of the Draft Notification*

Nature of Bulk Drug & Formulation Industry / CETP	Applicability of the Draft Notification* #
Zero Liquid Discharge along with complete reuse/recycle of treated process wastewater in utility/process applications (no discharge on land)	No
On-site wastewater treatment followed by discharge of treated process wastewater to inland water bodies or for horticulture or irrigation or land disposal	Yes
Member industries disposing wastewater to CETP's	No
Non-member industries disposing wastewater to CETP's	Yes
CETP's receiving effluents from bulk drugs and formulation units (for the applicability of AMR parameters)	Yes

**Subject to the recommendations of expert committee being accepted by MoEF&CC.*

Some aspects of the notification are applicable to all/certain types of industry irrespective of how the wastewater is handled. Please refer the minutes of expert committee meeting for detailed information.

Analysis of API's and Antibiotics

- Requires specialised high end equipment's like LC-MS/MS-MS, GC-MS/ MS-MS, with additional accessories like purge and trap options.
- Sample preservation and transportation.
- Not much officially published methodology for API/ Antibiotics; VOC and SVOC methodology already available as per USEPA.
- Validation of the extraction and detection process; first time validation requires system suitability, Specificity, Linearity, Precision, Accuracy, LOD, LOQ & Robustness. Normally it takes couple of months for validation.
- The Reference Standards are very expensive. 20,000- 100,000/- per standard.
- Several Indian commercial laboratories (> 15 numbers) are funded by the government and have the capability for testing API and antibiotic residue across India – Hyderabad, Chennai, Delhi-NCR, Kolkata, Cochin, Mumbai. These laboratories are regularly testing food products- Seafood, Milk products for export to Europe and US for antibiotic
- Multi-residue analytical methodology can be developed in collaboration with leading Indian commercial laboratories and regular proficiency testing methodology through a project.

D. None of the above

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About the Secretariat

Carnstone Partners Ltd is an independent management consultancy, specialising in corporate responsibility and sustainability, with a long track record in running industry groups.

