Profiling of Microorganism Isolated from Environment of Pharmaceutical Company Core Area

Dissertation submitted in partial fulfilment for the degree of

Master of Science in Applied Microbiology

Submitted by

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This is to certify that thesis entitled "**Profiling of Microorganism Isolated from Environment of Pharmaceutical company Core Area**" submitted to M.Sc. Biotechnology Department, KIIT University, Bhubaneswar, in partial fulfilment of Master degree in Applied Microbiology is a record of original research work, carried out by Ms. Ananya Kar, Roll no:- 1662004,Registration number:- 16530250267 under my direct supervision for a period of five months (January 2018 - May 2018) at the Ind-Swift Gbu, Jawaharpur, Derabassi, Punjab.

Date- **Signature**

Place-

CERTIFICATE

This is to certify that thesis entiled, "**Profiling of Microorganism Isolated from Environment of Pharmaceutical Company Core Area"** Submitted by Ananya kar bearing Roll No. 1662004 in Department of Biotechnology, KIIT University, in partial fulfilment of the requirements for the degree of Master of Science in Applied Microbiology. She has taken great accountability and utmost care for the success of this project. The project is entirely satisfactory to the best of my knowledge.

This is also to certify that the above said work has not been previously submitted for the award of any degree or diploma, fellowship in any Indian or foreign university.

Date:

Place: **Signature:**

DECLARATION

I hereby declare that the dissertation entitled "**Profiling of Microorganism Isolated from Environment of Pharmaceutical Company Core Area"** submitted by me, for the degree of Master of Science to KIIT University is a record of *bona fide* work carried by me under the supervision and guidance of 'Mr. Arvind Kumar, Manager, Quality control and Mr. Yogesh Sharma, Asst. Manager, Quality control, Microbiology Laboratory at Ind-Swift Gbu, Jawaharpur, Derabassi, Punjab.

Date: **Name:**

Place:

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List of Abbreviations:

GBU-Global business unit

TGA-Therapeutic Goods Administration AUSTRALIA

ANVISA-National Health Surveillance Agency BRAZIL

TFDA-TANZANIA food and drug authority

WHO-World health organisaton

MCC-Medicine control council SOUTH AEROBIC

FDA-Food and drug administration USA

QA-Quality assurance

QC-Quality control

TOC-Total organic carbon

TC-Total carbon

NPOC-Non-purgeable organic carbon

SOP-Standard operating procedure

CFU-Colony forming unit

MCB-Maconkey broth

RVSEB-Rappaport vassiliadis salmonella enrichment broth

XLDA-Xylose lysine deoxycholate agar

MCA-Maconkey agar

VRBGA-Violet red bile glucose agar

EBM-Enterobacteria enrichment broth

CA-Cetrimide agar

MSA-Mannitol salt agar

RCM-Renforced medium for clostridia

SDB-Sabouraud dextrose broth

SDA-Sabouraud dextrose agar

SCDA-Soybean casein digest agar

SCDM-Soybean casein digest medium

HEPA-High Efficiency Particulate Air

ULPA-Ultra Low Particulate Air

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Abstract

Introduction: The microbiological quality of air, surface and working personnel in a pharmacutical industry was investigated. Bacterial isolates recovered from the

processing environment were also identified.

Objectives: Isolates the microorganism which are collected from environmental production area and profiling the organism and identify it.

Methodology:Samples are collected from the environmental core area then isolate it in scda plates for 24hrs.we use the preincubate plates of media.we use scda plate which are universal media used for the grow of microorganism.the profiling the microorganism for the identification by gram staining and spore staining method.the for the further identification we can use profiling kit for it.this identification are done in the microbioogy department of IND-SWIFT gbu pvt ltd.

Achivement: By the above project we achive that bacillus and streptococcus are found on the production area.this study are helpfull for the control of microorganism in production area.

Result: After sampling of core area, the plates were incubated in the incubators 22.5±2.5°C and 32.5±2.5°C for 72 hrs and 48 hrs respectively. The colonies developed on these plates were eventually observed after 120 days. The shape, size, color and morphology of these colonies were noted.then Bacilus and Streptococcus are detected.

1-COMPANY PROFILE

Established in 1986, Ind-Swift is a research driven pharmaceutical group that produces world class finished dosage forms, active pharmaceutical ingredients, and intermediates. Over the years, it has moved forward aggressively, consistently winning new customers worldwide and making inroads into challenging new markets and regions.

Combining cutting edge innovation with dynamic marketing, Ind-Swift has already become a US$ 450 million entity. In fact, it is confidently eyeing the one billion dollar revenue mark by 2020.

The Group's multiple state-of-the-art production facilities, at home and abroad, meet stringent international norms -- including those of the USFDA, UK MHRA, and the WHO.

Ind-Swift Ltd, is listed on the Bombay Stock Exchange and the National Stock Exchange.

Its business successes apart, the group sees itself as a stakeholder in the service to humanity, offering quality pharmaceuticals that mitigate illness and suffering, and contribute to a healthier and better world.

GBU: The global way

The Ace unit of Ind Swift Limited was created in the year 2005 with an aim to globalize the Ind Swift brand for finished dosage forms. The manufacturing site catering to the demand of the developed international markets was commissioned in 2006. A record was created when two major regulatory approvals, one from MHRA, UK and the other from TGA, Australia were received for this site within a record time of the site being commissioned. The approvals opened the gates for GBU to become a key supplier of products to the countries of EU, Australia, Canada, Singapore etc.

The initial set up had the manufacturing lines set up for oral solids to be given in the form of tablets and hard gelatin capsules with a limited capacity. GBU has to leap into an expansion mode within a short time frame to be able to cater to the demands of the customers across the target markets and started expanding its capacities in line with the customer demands. The following years saw addition of new customers with GBUs increasing reputation as a company that was able to meet all the desired quality and supply standards across the world. On further consumer demand, GBU

moved on the value chain to include a sachet packing facility in its premises which was again approved by all the regulatory authorities. ISL, GBU is one of the facilities that can provide specific environmental conditions for highly sensitive products.

The products from GBU are now available in more than 30 countries across the world spanning the countries of EU, Australia, Central & Latin America, Asia, CIS and Africa. The product selection for the various markets is based on the patent expiries in the developed countries and the high growth therapeutic segments like Cardiology, Diabetology and Osteoarthritis etc. in the emerging markets.

Branch offices in Singapore, Dubai and China underline GBU's direct market presence in key regions.

With the increasing regulatory demands from across the globe, GBU is geared up to handle all kinds of queries from the Ministry of Health of different countries and has about 300 products registered globally with another about 500 in the pipeline. Each product registration in a country gives a thrust to our business. GBU has regular audits from the country and company representatives and is always honored for the GMP standards that are maintained.

GBU today partners with the leading generic players in all the countries. The commitment to Supply chain excellence, cost competitiveness and a Total Quality Management program which is driven by systems has allowed GBU to be recalled as a 'Supplier of Choice' on all occasions.

A cohesive team has allowed GBU to move ahead in its path at an unimaginable pace. The turnover of the GBU is slated to touch USD 40mn with only 5 years of commercial operations. A glance at the following figures clearly showing a targeted and achievable growth of more than 100% in this Year (having completed 50% of the sales in the 1st five months of the year which is generally a rare instance in any industry around the world) establishes it all.

The focus of GBU for the prospective years is clear and the ground has already been laid. The markets where the attention will be centered for future growth are GCC, MENA, Brazil, Mexico, Africa, Russia and the CIS countries. GBU has already received the regulatory approvals from the MOH- UAE, GCC, and Anvisa-Brazil is now building the product portfolio for specific markets. The business models to be followed would include licensing and supply arrangements and marketing of our own brands in these countries by setting up representative offices.

Tough and Rough market and regulatory environment are not a deterrent for GBU but a challenge to overcome and create a sustainable niche.

Achivement-Regulatory approvals received & planned for

- MHRA – UK
- TGA - Australia
- Anvisa - Brazil
- GCC - Saudi Arabia
- TFDA - Tanzania
- WHO - GMP

- NDA - Uganda
- FMHACA - Ethiopia
- GMP - Yemen
- DPM Ivory - Coast
- PPB – Kenya
- MCAZ – Zimbabwe
- GMP – Ukraine
- MCC - South Africa
- FDB - Ghana

Business Opportunities

Ind-Swift aims, in all its endeavors, to realize their ultimate goal of **"Winning Global Customers Through Innovative Quality Pharmaceutical Products "** .

1. Contract Manufacturing

Harnessing our Manufacturing Facilities, approvable by renowned International Regulatory Authorities of the likes of

- MCC South Africa,
- FDA USA,
- ANVISA Brazil.

For the benefit of our business partners to help them realize their potential in today's highly competitive international market. These compliances give us the capability to develop and formulate products through Contract Manufacturing & related services.

- Capability to manufacture a variety of Solid Dosage forms (Except Beta Lactams)

2. Technology Transfer

Enabling rapid entry into the high value markets by transferring Technology to our partners.

- Partnership for numerous products developed / registered / ready to be registered across the world.
- Range of products, under different phases of development.

3. Out licensing

Marketing arrangements with partners for technology driven products that can be initiated at various stages of development.

4. Contract Research and Development

We command comprehensive Research and Development facilities to assist global pharmaceutical

companies from conceptualization of product till the dossier development thereby offering the possibilities of:

- Collaborative R & D.
- Developing patentable non infringing processes.
- Competence in Chiral Technology, Sustained Release Technology and Flash Tab Development
- Developing NDDS using Patentable & Innovative Technologies

5. Distribution / Marketing Alliances

- Collaborating with organizations with local expertise in marketing & logistics, to complement them with our Manufacturing & Technical capabilities resulting into synergistic relationship.
- Providing our business partners with the option of Co-Marketing.

6. Supply Agreements

- Entering into Supply Agreements with the distinguished Marketing & Distribution companies.
- Providing our Partners with the options of finished product in the retail pack as per their requirement.
- Or in the bulk pack to be repackaged in their respective facilities based on their local requirements.

Manufacturing prowess

Ind-Swift operates six manufacturing plants dedicated to finished dosage forms and another three to the production of active pharmaceutical ingredients.

The group's first company, Ind-Swift Ltd, is dedicated to the former. It runs plants at Jawaharpur in Punjab(operated by GBU, it's exports arm), at Jammu (in Jammu & Kashmir), as well as two facilities each at two distinct locations in Himachal Pradesh -- at Parwanoo (Units 1 & II) and at Baddi (Units III & IV). Between them, they manufacture the complete array of finished dosage forms; producing everything from tablets, capsules, soft gels and injectables, to ointments, dry syrups, dry powder and granule filled sachets.

A company subsidiary, Ind-Swift Labs Ltd, is focused on producing active pharmaceutical ingredients. Plants at Derabassi in Punjab, at Jammu in J&K, as well as a joint venture project in Iran are operational.

Vision

To make a positive contribution in global healthcare, by pursuing research based excellence

Mission

Winning global customers through innovative quality pharmaceutical products

Products

Anti-Infectives (Macrolides)

Brand	Active Substance	Formulation Dosage Form	Presentation
Clarie OD/ Swift OD	Clarithromycin	500 mg XR Tablets	10x1x7 Blisters
Claris 250	Clarithromycin	250 mg Tablets	10x2x7 Blisters
Claris DS 125 Claris DS 250	Clarithromycin Granules for reconstitution	125 mg/5ml	HDPE bottle of 50ml
Claris DS 125 Claris DS 251	Clarithromycin Granules for reconstitution	250 mg/5ml	HDPE bottle of 50ml
Clone DT	Clarithrornycin	125mg Dispersible Tablets	5x1x10 Strips
Swazi 250	Azithromycin	250 mg Tablets	10x1x6 Blisters
Swazi 500	Azithromycin	500 mg Tablets	10x1x3 Blisters
Swoxy 150	Roxithromycin	150 mg Tablets	10x1x10 Blisters

Anti-Infectives (Fluoroquinolones)

Brand	Active Substance	Formulation Dosage Form	Presentation
Indpro 250	Ciprofloxacin	250 mg Tablets	10x1x10 Blisters
Indpro 500	Ciprofloxacin	500 mg Tablets	10x1x10 Blisters
Swoflox 100	Ofloxacin	100 mg Tablets	10x1x10 Blisters
Swoflox 200	Ofloxacin	200 mg Tablets	10x1x10 Blisters

Cardiovasculars

Brand	Active Substance	Formulation Dosage Form	Presentation
Acerip 10	Ramipril	10 mg Tablets	3x10 Alu-Alu
Acerip 2.5	Ramipril	2.5 mg Tablets	3x10 Alu-Alu
Acerip 5	Ramipril	5 mg Tablets	3x10 Alu-Alu
Atstat 10/ Atswift 10/ Qest 10	Atorvastatin	10 mg Tablets	3x10 Alu-Alu
Atstat 20/ Atswift 20/ Qest 20	Atorvastatin	20 mg Tablets	3x10 Alu-Alu
Atstat 40/ Atswift 40/ Qest 40	Atorvastatin	40 mg Tablets	3x10 Alu-Alu
Atstat 80/ Atswift 80/ Qest	Atorvastatin	80 mg Tablets	3x10 Alu-Alu

80			
Atstat-AM	Atorvastatin +Amlodipine	10 mg + 5 mg Tablets	3x10 Alu-Alu
Atstat-EB	Atorvastatin + Ezetimibe	10 mg + 10 mg Tablets	3x10 Alu-Alu
Atstat-EB	Atorvastatin + Ezetimibe	20 mg + 10 mg Tablets	3x10 Alu-Alu
Candez 16	Candesartan	16 mg Tablets	3010 Blisters
Candez 4	Candesartan	4mg Tablets	3x10 Blisters
Candez 8	Candesartan	8 mg Tablets	3x10 Blisters
Caplor	Clopidogrel	75 mg Tablets	3x10 Alu-Alu
Caplor-AS	Clopidogrel + Aspirin	75 mg + 75 mg Tablets	3x10 Alu-Alu
Indol 100	Alenolol	100 mg Tablets	10x10 Blisters
Indol 50	Alenolol	50 mg Tablets	10x10 Blisters
Ivadin 5	Ivabradine	5 mg Tablets	3 x10 Blisters
Ivadinn 7.5	Ivabradine	7.5 mg Tablets	3 x10 Blisters
Staro 10	Rosuvastatin	10 mg Tablets	3x10 Alu-Alu
Staro 20	Rosuvastatin	20 mg Tablets	3x10 Alu-Alu
Staro 40	Rosuvastatin	40 rig Tablets	3x10 Alu-Alu
Staro 5	Rosuvastatin	5 mg Tablets	3x10 Alu-Alu
SwamJo-AT	Amlodipine +Atenolol	5 mg + 50 mg	3x10 Strips
Swarnlo 10	Amlodipine	10 mg Tablets	3x10 Strips
Swarnlo 5	Amlodipine	5 mg Tablets	3x10 Strips
Swilix 2.5	lndapamide	25 mg Tablets	3x10 Alu-Alu

Swilix SR 1.5	lndapamide	1.5 mg SR Tablets	3x10 Alu-Alu
Telmiswift 80	Telmisartan	80 mg Tablets	3x10 Alu-Alu
Telmiswift H-40	Telmisartan + Hydrochlorthi-azide	40 mg + 12.5 mg Tablets	3x10 Alu-Alu
Telmiswift H-80	Telmisartan + Hydrochlorthi-azide	80 mg + 12.5 mg Tablets	3x10 Alu-Alu
Telrniswift 40	Telmisartan	40 mg Tablets	3x10 Alu-Alu

Anti-Histamines

Brand	Active Substance	Formulation Dosage Form	Presentation
Fexidine	Fexofenadine Hcl	30 mg/5ml Suspension	HOPE bottle of 60 ml
Fexidine 120	Fexofenadine Hcl	120 mg Tablets	3x10 Blisters
Fexidine 180	Fexofenadine Hcl	180 mg Tablets	3x10 Blisters
Fexidine KID	Fexofenadine Hcl	60 mg Dispersible Tablets	10x1x10 Strips
Indizine/ C-Swift	Cetirizine	10 mg Tablets	10x1x10 Blisters
Levocet/ Levoswift	Levocetirizine	5 mg Tablets	10x1x10 Blisters
Lora D	Desloratadine	5mg	1x10 Blisters

Anti-Diabteics and Diabetes Related Neuropathy

Brand	Active Substance	Formulation Dosage Form	Presentation
Glitter 15/	Pioglitazone	15 mg Tablets	10x1x10 Blisters

Glit 15			
Glitter 30/ Glit 30	Pioglitazone	30 mg Tablets	10x1x10 Blisters
Glitter 45/ Glit 45	Pioglitazone	45 mg Tablets	10x1x10 Blisters
Glypar 1	Glimepride	1 mg Tablets	3x10 Alu Ala
Glypar 2	Glimepride	2 mg Tablets	3x10 Alu Alu
Glypar 3	Glimepride	3 mg Tablets	3x10 Alu Alu
Glypar 4	Glimepride	4 mg Tablets	3x10 Alu Alu
Losorb 25	Acarbose	25 mg Tablets	10 x10 Strips
Losorb 50	Acarbose	50 mg Tablets	10 x10 Strips
Metswift 500	Metformin	500 mg Tablets	2x14 Blisters
Metswift 850	Metformin	850 mg Tablets	4x14 Blisters
Prezel 100	Pregabalin	100 mg Capsules	3x10 Alu Alu
Prezel 150	Pregabalin	150 mg Capsules	3x10 Alu Alu
Prezel 200	Pregabalin	200 mg Capsules	3x10 Alu Ala
Prezel 225	Pregabalin	225 mg Capsules	3x10Alu Alu
Prezel 25	Pregabalin	25 mg Capsules	3x10 Alu Ala
Prezel 300	Pregabalin	300 mg Capsules	3x10 Alu Alu
Prezel 50	Pregabalin	50 mg Capsules	3x10 Alu Alu
Prezel 75	Pregabalin	75 mg Capsules	3x10 Alu Alu
Reserve 250	Methylcobalamin	250 mcg Tablets	10x1x10A1u-Alu
Reserve 500	Methylcobalamin	500 mcg Tablets	10x1x10A1u-Alu
Switrim Sachet	Sucralose	1 gm Powder	Box of 50/100 Sachet
Switrim	Sucralose	6.5 mg Sucralose	100's and 300's Dis-pensing Bottles

Tabs		tabs	
Zswift IR	Gliclazide	80 mg	3x10 Alu Alu
Zswift SR 30	Gliclazide	30 mg Tablets	2x14 Blister
Zswift SR 60	Gliclazide	60 mg Tablets	2x14 Blister

Central Nervous System

Brand	Active Substance	Formulation Dosage Form	Presentation
Lopram 10	Citalopram	10 mg Tablets	10x1x10 Blisters
Lopram 20	Citalopram	20 mg Tablets	10x1x10 Blisters
Lopram 40	Citalopram	40 mg Tablets	10x1x10 Blisters
Quip 100	Quetiapine Hemifumarate	100 mg Tablets	3x10 Nu Alu
Quip 150	Quetiapine Hemifumarate	150 mg Tablets	3x10Alu Alb
Quip 200	Quetiapine Hemifumarate	200 mg Tablets	3x10Alu Alu
Quip 25	Quetiapine Hemifumarate	25 mg Tablets	3x10Alu Ala
Quip 300	Quetiapine Hemifumarate	300 mg tablets	3x10Alu Alu
Zorax 0.25	Alprazolam	0.25 mg Tablets	10x1x10 Blisters
Zorax 0.50	Alprazolam	0.50 rng Tablets	10x1x10 Blisters

Gastrointestinal Drugs

Brand	Active Substance	Formulation Dosage Form	Presentation
Ezo 20	Esomeprazole	20 mg Tablets	10x1x10 Alu-Alu
Ezo 40	Esomeprazole	40 mg Tablets	10x1x10A1u-Alu

Gasgon	Fennel Oil + Ajowan Oil + Caraway Oil + Coriander Oil + Cardamom oil + Menthol	10 mg + 10 mg + 10 mg + 10 mg + 10 mg + 5 mg Soft Gelatin Capsules	10x1x10 Blisters
Netazox	Nitazoxanide	100 mg/ 5ml Susp	HOPE bottle of 30 ml
Netazox -DT	Nitazoxanide	200 mg Dispersible Tablets	10x/x6 Blisters
Netazox 500	Nitazoxanide	500 mg Tablets	10x1x6 Blisters
Netazox-OF	NItazoxanide + Ofloxacin	500mg + 200mg Tablets	10x1x10 Blisters
Panswift 20	Pantoprazole	20 mg Tablets	10x1x10 Alu-Alu
Panswift 40	Pantoprazole	40 mg Tablets	10x1x10 Alu-Alu
Rabiswift 10	Rabeprazole	10 mg Tablets	10x1x10 Alu-Alu
Rabiswift 20	Rabeprazole	20 mg Tablets	10x1x10Alu-Alu

Erectile Dysfunction

Brand	Active Substance	Formulation Dosage Form	Presentation
Erick 100	Sildenafil	100 mg Tablets	20x1x4 Blisters
Erick 50	Sildenafil	50 mg Tablets	20.1.4 Blisters

Osteoarthritis

Brand	Active Substance	Formulation Dosage Form	Presentation

Osican Forte 500	Glucosamine Hydrochloride + Chondriotin Sulphate Sodium	500 mg + 400 mg	60's HDPE Bot
Osican Forte 750	Glucosamine Sulphate Potas-sium Chloride + Chondriotin Sulphate Sodium	750 mg + 400 mg Tablets	60's HDPE Bot
Osicart 1000	Glucosamine HCI	1000 mg Tablets	60's HDPE Bot
Osicart 1250	Glucosamine HCI	1250 mg Tablets	60's HDPE Bot
Osicart 1500	Glucosamine HCI	1500 mg Tablets	60's HDPE Bot
Osicart 1500 Sachet	Glucosamine Sulphate	1500mg Sachets	1x15 /1x30 Sachets
Osicart 500	Glucosamine HCI	500 mg Tablets	60's HDPE Bot
Osicart 750	Glucosamine HCI	750 mg Tablets	60's HDPE Bot
Osicart Plus Sachet	Glucosamine HCI + Chondroi-tin Sulfate	1500 mg + 1200 mg Sachets	1x15 / 1x30 Sachets

Anti Malarial

Brand	Active Substance	Formulation Dosage Form	Presentation
Lamitar AM	Artemether + Lumefantrin	20 mg + 120 mg Tablets	3x8Alu-Alu

NSAID's

Brand	Active Substance	Formulation Dosage Form	Presentation
Ibuprofen 400	Ibuprofen	400 mg Sachet	1x40 Sachets
Ibuprofen	Ibuprofen	600 mg Sachet	1x40 Sachets

600			

Cold Relief

Brand	Active Substance	Formulation Dosage Form	Presentation
Cozy Plus	Paracetamol + Phenylephrine Hydrochloride + Chlorphe- niramine Maleate + Caffeine) Anhydrous)	500 mg + 5 mg + 2 mg + 30 mg Tablets	20x10 Strips
Cozy-Kid	Phenylephrine Hydrochloride + Chlorpheniramine Maleate + Paracetamol	2.5 mg + 1 mg + 125 mg/ 5 ml Syrup	60 ml Bottle
Indol Plus	Camphor + Chlorothymol +Ter- pineol + Eucalyptol + Menthol	25 mg + 5 mg +110 mg + 130 mg + 55 mg Soft Gelan Inhalant Capsules	10x1x10 Blisters
Swicolif Sachet	Paracetamol+Phenyle phrine+P heniramine maleate+Vit C	500mg+10mg+20 mg+50mg	1x30 Sachets

Alkalinizer

Brand	Active Substance	Formulation Dosage Form	Presentation
Urisol	Sod Bibarbonate+Tartaric Acid + Citric Acid + Sodium Citrate Anhydrous	1.76 gms+ 890 mg+ 720 mg+ 630 mg	1x14 Sachets

Gynaecology

Brand	Active Substance	Formulation Dosage Form	Presentation
Anich-3	Clindamycin + Clotrmazole	100 mg + 200 mg Vaginal Suppositories	1x3 Blisters
Calswift	Elemental calcium (as Car- bonate) + Cholecalciferol (Vit D3) + Magnesium (as Oxide) + Zinc (as oxide) + Copper (as Oxide) + Manganese (as Sulfate)	600mg + 5mcg (200IU) + 50 mg+ 7.5 mg + 1mg +1.8 mg	60's HOPE Bottle
Calswift SG	Calcium Carbonate (eq. to Elemental Calcium 200 mg) + Calcitriol + Zinc (as Zinc Sul- fate monohydreate)	500 mg+ 0.25 mcg + 7.5 mg Soft Gelatin Capsules	10x1x10 Blisters
Ferritop	Ferrous Sulphate	200 mg Tablets	100's HOPE Bottle
Fewo XT	Ferrous Ascorbate (eq. to Elemental Iron) + FolicAcid + Methylcobalamin+ DHA	50 mg +750 mcg+ 500 mcg +50 mg Soft Gelatin capsules	10x1x10Blisters

CORPORATE SOCIAL RESPONSIBILITY

Corporate Social Commitment and Public Service is at the upmost priority list of the Company. Over the years serious efforts have been directed towards making a meaningful contribution to

uplifting and transforming the lives of the community and the underprivileged. The Company is also extremely conscious of its duty and responsibility towards the environment. We continue to make sincere efforts to promote good health, social development and better environment, through various Company programs that contribute to sustainable, all round growth.

At Ind-Swift we are fully conscious about our responsibility towards society. We are just not limited to business but strongly believe in giving back to the society what we have got from it. We at Ind-Swift make honest efforts to help section of the society who struggle for basic amenities.Our continuous efforts are towards making a healthier happier World through our various programmes and activities. Ind-Swift carries out all its activities through its society named as "Swift Fundamental Research & Education Society (SFRES)". **"Because life is precious"**—we believe every life on this planet is precious so we take utmost care in our business processes to ensure environmentalism by applying Safety Health & Environment (SHE)Policy

Quality Assurance & Quality Control

Quality is the mainstay of our competitiveness.
At Ind-Swift, we take considerable focus in adherence to the QA policies. Our policies direct our operation to constantly create an environment of quality and compliance in line with the best recognized global practices.

Quality Assurance, though an independent function, works as an interface between R&D and manufacturing strictly abiding with the standardized quality system, providing consistency, effectiveness and efficiency for all manufacturing activities of formulation across all our manufacturing locations.

Focused on:

- Establishing Quality Standards
- Training personnel
- Developing processes to achieve set standards
- Close Monitoring
- Consistency at every stage

It engages itself towards driving the quality philosophy of the organization and assuring that the global standards of cGMP are implemented in form and spirit at every level and during each process.

Our systems & policies bring effectiveness through periodic quality reviews, periodic audits, review of compliance to regulatory inspections and customer audits.

Focuses on review of failures, rejections, market complaints, deviations, non-compliances, product stability and various corrective & preventive actions planning.

Our endeavour is to constantly achieve QUALITY EXCELLENCE.

Quality Control Microbiology Laboratory

There is specific entry and exit standard operating procedure for the microbiology laboratory.

There are three area in the microbiology laboratory

- Non classified area
- Classified area
- Classified control area

For the routine activates documentation lab, Incubator section, Media storage section, Media preparation area & Wash area are part of non classified areas

2-Microbiology department instrument

2.1 Ph meter

A Ph meter is used to determine the acidity or alkalinity of the solution.PH is the concentration of hydrogen ions in the solution.A solution containing more H+ ions remains acidic while the solution containing more OH- ions remains alkaline.PH value of solutions ranges from 1 to 14.

The solution having ph value 1 will be the highly acidic and with ph value 14 will be highly besic.the acidity and alkalinity of any solution depend upon the concentration of hydrogen ions and hydroxyl ions respectively.a natural solution as pure water has PH 7.

PH meter used to determine the ph of different solutions in pharmaceuticals.it is more accurate method then the ph strip.a ph meter contains a ph probe that passes the electrical signals to the ph meter and ph meter displays the ph value of the solution.

In the microbiology department of quality control here they do the daily calibration for check the proper working of the ph meter.The buffer used for the daily calibration are 1.68,4.01,6.86,9.18,12.45.That time they use two probe for the daily calibration.One probe use for the pre calibration and other one used for the conformation.

The glass ph probe contains 2 electrodes.a sensor electrode and a reference electrode.these electrodes are in the form of glass tubes one contains ph 7 buffer and other contains saturated potsssium chloride solution.the sensor electrode bulb is made up of porous glass or permeable glass membrane coated with silica and metal salts.

When the probe is placed in a solution to measure the ph,hydrogen ions accumulate around the bulb and replace the metal ions from the bulb.the exchange of ions generates some electric flow that is catured by the silver wire.

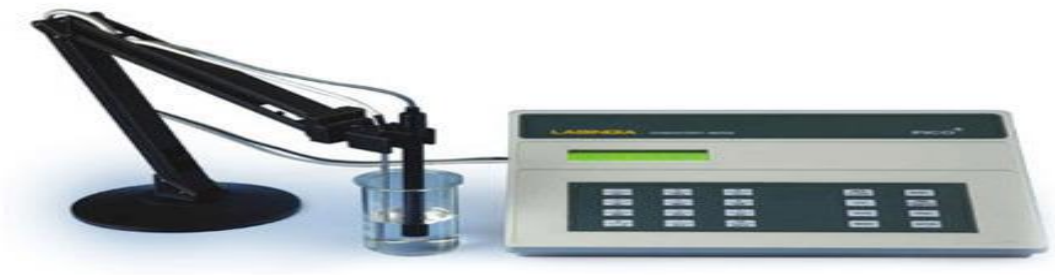


Fig-1(PH meter)

2.2 Conductivity meter

The common laboratory conductivity meters employ a potentiometric method and four electrodes. Often, the electrodes are cylindrical and arranged concentrically. The electrodes are usually made of platinum metal. An alternating current is applied to the outer pair of the electrodes. The potential between the inner pair is measured. Conductivity could in principle be determined using the distance between the electrodes and their surface area using ohm's law but generally, for accuracy, a calibration is employed using electrolytes of well-known conductivity.

Industrial conductivity probes often employ an inductive method, which has the advantage that the fluid does not wet the electrical parts of the sensor. Here, two inductively-coupled coils are used. One is the driving coil producing a magnetic field and it is supplied with accurately-known voltage. The other forms a secondary coil of a transformer.

The potential between the inner pair is measured conductivity could in principle be determined using the difference between the electrodes and their surface area using ohm's law but generally for accuracy a calibration is employed using electrolyte of well known conductivity.

In the microbiology department of the quality control department every day they do the daily calibration of the conductivity meter that time they use two probe for the calibration that is 0.1 and 1.0 buffer which is used for the daily calibration are 147 micro siemen and 1.413 mili siemen.

Fig-2(conductivity meter)

2.3WEIGHING BALANCE

Weighing balance are devices to measure weight.Spring balance or Spring scale calculate weight that is the product of mass into gravity (9.807 m/s^2) on the force on a spring, whereas a balance or pair of scales using a balance beam compares masses by balancing the weight due to the mass of an object against the weight of one or more known masses.

Some of them can be calibrated to read in units of force (weight) such as newtons instead of units of mass such as kilograms. The balance or pair of scales using a traditional balance beam to compare masses may read correctly for mass even if moved to a place with a different non-zero gravitational field strength. Also the spring balances that are designed with reading of weight (force) in mind, would read correctly for weight in a different non-zero gravitational field strength.

In the microbiology department of the quality control department they do daily calibration and balance check of the weighing balance and record it in the weighing balance format.

Fig-3(weighing balance)

2.4 Laminar Air Flow

A laminar air flow is a carefully enclosed bench designed to prevent contamination of semiconductor wafers, biological samples, or any particle sensitive materials. Air is drawn through a HEPA filter and blown in a very smooth, laminar flow towards the user. The cabinet is usually made of stainless steel with no gaps or joints where spores might collect.

Such hoods exist in both horizontal and vertical configurations, and there are many different types of cabinets with a variety of airflow patternsand acceptable uses.

Laminar flow cabinets may have a UV-C germicidal lamp to sterilize the interior and contents before usage to prevent contamination of experiment. Germicidal lamps are usually kept on for 15 minutes to sterilize the interior and no contact is to be made with a laminar flow hood during this time. During this time, scientists normally prepare other materials to maximize efficiency. (It is important to switch this light off during use, to limit exposure to skin and eyes as stray ultraviolet light emissions can cause cancer and cataracts.)

Fig-4(laminar air flow)

2.5Total Organic Carbon

Total organic carbon (TOC) is the amount of carbon found in an organic compound and is often used as a non-specific indicator of water quality or cleanliness of pharmaceutical manufacturing equipment. TOC may also refer to the amount of organic carbon in soil, or in a geological formation, particularly the source rock for a petroleum play 2% is a rough minimum.For marine surface sediments, average TOC content is 0.5% in the deep ocean, and 2% along the eastern margins.

A typical analysis for total carbon (TC) measures both the total carbon present and the so-called "inorganic carbon" (IC), the latter representing the content of dissolved carbon dioxide and carbonic acid salts. Subtracting the inorganic carbon from the total carbon yields TOC. Another common variant of TOC analysis involves removing the IC portion first and then measuring the leftover carbon. This method involves purging an acidified sample with carbon-free air or nitrogen prior to measurement, and so is more accurately called non-purgeable organic carbon (NPOC).

Preparation of standard sucrose solution of 100rpm&500ppb

1-236mg of sucrose+1oo ml water to get 100ppm carbon.

2-take 0.5ml from 100ppm solution in a measuring flask of 100ml.

3-Make solution 100ml by using miliq water this is 100ppb carbon.

Standard 1,4 Benzoquinone

1-15.0mg of 1,4 benzaquinone dissolve 100ml of water.

2-take 0.5ml ppm 100 solution make solution 100ml by milliq water.

System Stability

System stability done every day that is the calibration of TOC analyser.

2.6 Incubator

In biology, an incubator is a device used to grow and maintain microbiological cultures or cell cultures. The incubator maintains optimal temperature, humidity and other conditions such as the carbon dioxide (CO_2) and oxygen content of the atmosphere inside. Incubators are essential for a lot of experimental work in cell biology, microbiology and molecular biology and are used to culture both bacterial as well as eukaryotic cells.

CO2 incubators are typically heated to **37°C** and maintain 95% relative humidity and a CO2 level of 5 percent. Microbiological incubators are essentially temperature-controlled ovens that work within the biological range of 5ºC to 70ºC and are mostly used for growing and storing bacterial cultures.

In biology, an incubator is a device used to grow and maintain microbiological cultures or cell cultures.For other organisms used in biological experiments, such as the budding yeast Saccharomyces cerevisiae, a growth temperature of 30 °C (86 °F) is optimal.

There are two incubator used in microbiology department one is for bacteria and another one is for the fungi.

Fig-5(incubator)

3-Growth Promotion Test

1.Preparation of media:

1.1 Reconstitute dehydrated media as per the manufacturer instructions.
1.2 Record the details for preparation of media.
1.3 Record lot no. for each batch of media sterilized as(Operationof Horizontal Autoclave -Fabwell). Sterilization shall be carried out at 121°C for 15 minutes.
1.4 Each autoclave lot of microbiological media shall be qualified for growth promotion ability.

2.Growth promotion test:

2.1 Select a dilution from a cell suspension tubes with 10- 100 cfu / organism
2.2 Aseptically pipette 1ml of each dilution in pre-sterilized Petri plate in duplicate.
2.3 Pour desired media on the above plates swirl gently.
2.4 Incubate the plates at 30-35ºC for 48 hours in case of bacteria, 20- 25ºC for 72 hours in case of yeast and fungi. Incase of Bioball spread the suspension on agar plates and Incubate the plates at 20-25ºC for 72 hours in case of yeast and fungi and 30-35ºC for 48 hours in case of bacteria. liquid media are suitable if clearly visible growth of the micro-organisms comparable to that previously obtained with a previously tested and approved batch of medium occurs.
2.5 For solid media, growth obtained must not differ by a factor greater than 2 from the calculated value for a standardized inoculum. For a freshly prepared inoculum, growth of the microorganisms comparable to that previously obtained with a previously tested and approved batch of medium occurs and calculation shall be as point no:6.2.6
2.6 Observe the plates for number of colonies, and count the cfu observed on both plates and express the result in cfu by following formula P1 + P2 / 2

Where P1 and P2 are plate 1 and plate 2

Calculate the Microbial recovery in percentage by following equation –

$$\% \text{ Recovery} = \frac{\text{Mean cfu observed}}{\text{Inoculated cfu ml}} \text{ X } 100$$

Recovery should not less than 75%

2.7 Satisfactory growth should be observed within 3 days of incubation in the test. There should not be growth in growth inhibitory test & negative control.
2.8 In case the media passes the growth promotion test, approved remark shall be marked on the media container with signature and date then the same should be used for analysis.

2.9 In case the media fails for the growth promotion test then a rejected remark shall be on the container with signature and date then the same shall be rejected and accordingly the rejection entry should be made in the media preparation log book.
2.10 The rejected media should be discarded.

3.Precaution

3.1 The dehydrated culture media as well as their ingredients are highly hygroscopic and must be stored in a cool dry place away from bright light. These media are meant for laboratory use only and shall never be used for human or animal consumption.

3.2 Use fresh sterile pipette for each transfer.

3.2.1 The medium to be poured in Petri plates should have a temperature of 40 - 45^0C.

3.2.2 The plates should be incubated in an inverted position to prevent collection of condensation on the plate surface.

3.2.3 If any spillage of cultures, immediately wash with 70% IPA solution.

3.2.4 Entire operation inside the microbiology room should be carried out under the laminar airflow chamber using gas burner.

3.2.5 Examine the physical nature of the dehydrated medium. If any unusual colour, odour or physical appearance is noticed, discard the medium.

3.2.6 Always use a dry spoon or spatula for weighing the dehydrated media. The weighing operation shall be completed as quickly as possible to prevent absorption of moisture by the hygroscopic contents. Wear a face mask while weighing the dehydrated media to avoid inhalation of fine particles of media.

3.2.7 All dehydrated media must be retest after the release of three months interval and finally media must be discarded after release of one year.

	Medium	**Property**	**Test strains**
Test for bile-tolerant gram–negative bacteria	Enterobacteria enrichment broth–mossel	Growth promoting	E.coli, P.aeruginosa
		Inhibitory	S.aureus
	Violet red bile glucose agar	Growth promoting + indicative	E.coli, P.aeruginosa
Test for E.coli	Maconkey broth	Growth promoting	E.coli
		Inhibitory	S.aureus
	Maconkey agar	Growth promoting + indicative	E.coli
Test for Salmonella	Rappaport Vassiliadis salmonella enrichment broth	Growth promoting	Salmonella enterica ssp. Enterica serotype typhimurium or salmonella enterica ssp. Enterica serotype abony
		Inhibitory	S.aureus
	Xylose,lysine deoxycholate agar	Growth promoting + indicative	Salmonella enterica ssp. Enterica serotype typhimurium or salmonella enterica ssp. Enterica serotype abony

		indicative	E.coli
Test for Pseudomonas aeruginosa	Cetrimide agar	Growth promoting	P.aeruginosa
		Inhibitory	E.coli
Test for Staphylococcus aureus	Manitol salt agar	Growth promoting + indicative	S.aureus
		Inhibitory	E.coli
Test for Clostridia	Renforced medium for clostridia	Growth promoting	Cl. sporogenes
	Columbia agar	Growth promoting	Cl. sporogenes
Test for Candida albicans	Sabouraud dextrose broth	Growth promoting	Candida albicans
	Sabouraud dextrose agar	Growth promoting + indicative	Candida albicans

4-Handling of Bioball

1. PROCEDURE

Remove the BioBall from the freezer when required Bioball 14 Day Re-Hydration Fluid and allow to them to reach room.

1.1. Carefully handled the Bioball MultiShot under LAF.

1.2. Label the Bioball 14 Day Re-Hydration Fluid include the box of Bioball MultiShot 550.

1.3. Remove the cap of Bioball re-hydration fluid.

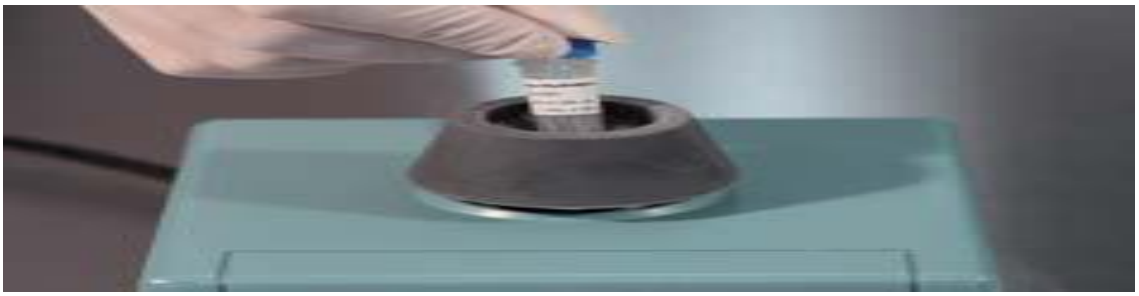
1.4. Remove the stopper from the glass vial containing the Bioball.

1.5. Bioball has a batch mean between 500 and 600, Standard Deviation is less than or equal to 10% of the batch mean

1.6. When re-hydrated with 1.1 mL of re-hydration fluid, each Bioball provides 10 x 100µL doses, each containing 50 cfu

1.7. Tip the BioBall into BioBall 14 days re- hydration fluid.

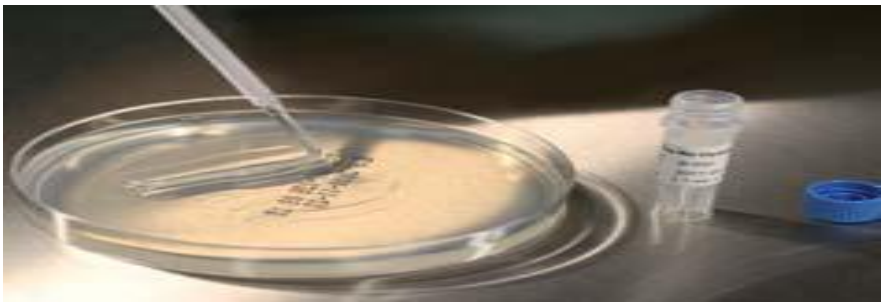
1.8. Vortex 5 seconds



1.9. Draw 100 µL aliquot.

1.10. Pipette 100 µL onto plate

1.11. Spread,dry and incubate



1.12 Determine how many aliquots to be frozen.

1.13 If aliquots are to be used over separate days use a separate microcentrifuge tube for each aliquot. Label the microcentrifuge tubes, mark the date of rehydration and an expiry date

1.14 Pipette 110µL of the remaining Bioball 14 Day Re-Hydration Fluid in to each tube

1.15 Store the microcentrifuge tubes upright within 2 hours of rehydration in a freezer at below -18ºC, this will provide a 14 day stability.

5-Water testing

1.Introduction:

The tests are intended for detecting the Total Viable Count and the absence of specified pathogenic microorganism (i.e. Escherichia coli, Salmonella, Pseudomonas aeruginosa, Staphylococcus aureus and shigella) in a water sample.

Type of Water	Microbiological Analysis Required	Method of Test	Sample Volume	Limits	
Purified Water	Total Aerobic Microbial Count	Membrane filtration	1 ml	**Alert**	10 CFU/ml
				Action	20 CFU/ml
	Specified Organisms(Pathogens) E. coli, Salmonella, P. aeruginosa, S. aureus shigella	Enrichment	100 ml	Should be Absent / 100ml	

1.1 Test for Total Aerobic Microbial Count:

1.1.1 Perform the test by Membrane Filtration Method for all Purified Water Samples.

1.1.2 Arrange the Milliflex filtration assembly, close all knobs and connect with vacuum supply by sterile rubber tube.Place a sterile 0.22µ / 0.45µ filter aseptically on the mesh disc of filtration unit.

1.1.3 Filter 1 ml of purified water sample (take 1 ml of purified water sample and make it up 100ml by using sterile water then filter it , if necessary) and transfer the membrane to labeled R2A Agar and Incubate at 30-35^{0}C for 120 hours in duplicate. Following the incubation, examine the plates for growth, count the number of colonies, express the results as number of Colony Forming Unit (CFU) per ml of sample. If no microbial colonies are recovered from the dish, express the result, as ND (not detected).

1.1.4 Simultaneously Filter 1 ml of purified water sample (take 1 ml of purified water sample and make it up 100ml by using sterile water then filter it , if necessary) and transfer the membrane to labeled PCA Agar and Incubate at 30-35^{0}C for 72 hours in duplicate.Following the incubation, examine the plates for growth, count the number of colonies,express the results as number of Colony Forming Unit (CFU) per ml of sample. If no microbial colonies are recovered from the dish, express the result, as ND (not detected).

1.2 Tests for Specified Organisms (Pathogens):

Enrichment:

Filter not less than 100ml of sample through 0.45 / 0.22µ membrane filter (diameter 47mm) and transfer the membrane into 100 ml Soyabean Casein Digest Medium and incubate the tube at 30-35^{0}C for 18-24 hours. Examine the medium for growth (turbidity in medium), and carry out the primary test.

1.2.1 Test for Escherichia coli:-

Selection and subculture:- After 24 hours of incubation of Soybean-Casein Digest Broth, shake the container and aseptically transfer1 ml of Soybean-Casein Digest Broth to 100 ml of MacConkey broth and incubate at 42-44 °C for 24-48 hours. After 48 hours of incubation, subculture on a plate of MacConkey agar at 30-35 °C for 18-72 h.

Interpretation:- Growth of gram negative rods with brick red colonies surrounded by bile precipitate indicates the possible presence of E. coli. This is confirmed by identification tests. The product complies with the test if no colonies are present or if the identification tests are negative.

Identification tests: If the colonies are matching with the description above, streak a loopful of colonies from the surface of MacConkey Agar medium on to the surface of Levine Eosin-Methylene Blue agar medium, cover and invert the plates and incubate at 30°C-35°C for 48 hours.

Indole test: Transfer 1.0ml from MacConkey Broth to 5ml Peptone water (1%). Incubate at 30-35°C for 24 hrs. After incubation period add 0.5 ml Kovac's reagent, shake well, allow to stand for 1minute. The product complies with the test if no Red colour ring is produced in reagent layer.

Observation and Results: Upon examination, if none of the colonies exhibits both a characteristic metallic sheen under reflected light and a blue black appearance under transmitted light, then the specimen meets the requirements for the absence of Escherichia coli. Along with sample test parallely Carry out the;

-Negative control test.
-Growth promotion, inhibitory and indication properties of the media.

1.2.2 Test for Salmonella :-

Selection and subculture: After 24 hours of incubation of Soybean-Casein Digest Broth, transfer 0.1 ml o Soybean-Casein Digest Broth to 10ml of Rappaport Vassiliadis Salmonella Enrichment Broth and incubate at 30-35 °C for 18-24 hours. Subculture on plates of Xylose Lysine Deoxycholate Agar and incubate at 30-35°C for 18-48 hours.

Interpretation: The possible presence of salmonellae is indicated by the growth of well-developed red colonies with or without black centers. This is confirmed by identification tests. The product complies with the test if colonies of the types described below are not present or if the confirmatory identification tests are negative.

Medium	**Characteristic colonial morphology**

Xylose Lysine Deoxycholate Agar	well-developed, red colonies, with or without black centers

Identification tests: If colonies of Gram negative rods matching the description in above mentioned table then further subculture on to triple sugar iron agar butt-slant, first streaking the surface of slope and then make a stab culture with the same inoculating needle. Incubate the slant at 30-35°C for 48 hrs. If upon examination, there is no evidence of tubes having alkaline (red) slants and acid (yellow) butts (with or without blackening of the butt i.e. Hydrogen Sulfide production), the product meets the requirements of the test for the absence of Salmonella species Along with sample test parallely Carry out the;

-Negative control test.
-Growth promotion, inhibitory and indication properties of the media.

1.2.3 Test for Pseudomonas aeruginosa:-

Selection and subculture: After 24 hours of incubation of Soybean-Casein Digest Broth, streak a loopful of enriched culture on a plate of Cetrimide agar. Incubate the plates at 30-35^{o}C for 18 – 72 hours.

Interpretation: Growth of colonies indicates the possible presence of P.aeruginosa. This is confirmed by identification tests. The product complies with the test if the colonies are not present or if the confirmatory identification tests are negative.

Identification tests: Subculture any colony showing greenish colony on to the surface of Pseudomonas Agar medium for detection of Pyocyanin and Pseudomonas Agar medium for detection of fluorescin, cover and invert the plates, and incubate at 35-37^{0}C for not less than three days.

Observation and Result: Examine the streaked surfaces under UV light to determine whether the colonies are having characteristics given below.

Morphological characteristics: Morphological characteristics of Pseudomonas Agar medium for detection of Fluorescin shows generally colourless to yellowish colonies and yellowish Fluorescence in UV light. Morphological characteristics of Pseudomonas Agar medium for detection of Pyocyanin show generally greenish colonies and Bluish Fluorescence in UV light. Confirm any suspect colonial growth by means of 42omogen test.

Medium	**Characteristic Colonial Morphology**	**Fluorescence in UV light**

Pseudomonas Agar medium for detection of Fluorescin	Generally colourless to yellowish colonies	Yellowish
Pseudomonas Agar medium for detection of Pyocyanin	Generally greenish colonies	Blue

Oxidase test: If growth of suspect colonies occurs, smear the suspected colony on homogen disc. If there is no development of purple colour within 30 seconds, sample meets the requirement for the test for the absence of Pseudomonas aeruginosa. Along with sample test parallely Carry out the;

-Negative control test.
-Growth promotion, inhibitory and indication properties of the media.

1.2.4 Test for Staphylococcus aureus:-

Selection and subculture: After 24 hours of incubation of Soybean-Casein Digest Broth, streak a loopful of enriched culture on a plate of Mannitol salt agar Incubate the plates at 30-35^{o}C for 18 – 72 hours.

Interpretation: The possible presence of S.aureus is indicated by the growth of yellow or white colonies surrounded by a yellow zone. This is confirmed by identification tests. The product complies with the test if the colonies of the types described are not present or if the confirmatory identification tests are negative.

Identification tests: In case the colonies characteristics matches with the description as mentioned above, then confirm the presence with coagulation test. Along with sample test parallely Carry out the;

-Negative control test.
-Growth promotion, inhibitory and indication properties of the media.

1.2.5 Test for Shigella:-

After 24 hours of incubation of Soybean-Casein Digest Broth, shake the container and aseptically transfer1 1ml of Soybean-Casein Digest Broth to 100 ml of GN broth and incubate at 30-35 °C for 24-48 hours. After 48 hours of incubation, subculture on a plate of Xylose Lysine Deoxycholate Agar and incubate at 30-35°C for 24-48 hours.

Interpretation:- The possible presence of Shigella is indicated by the growth of red colored translucent colonies without black centers indicate possibility of presence of shigella. This is confirmed by identification tests. The product complies with the test if colonies of the types described below are not present or if the confirmatory identification tests are negative.

Medium	**Characteristic colonial morphology**
Xylose Lysine Deoxycholate Agar	red colored translucent colonies without black centers

Name of Organism	**Media**	**Characteristic Growth / Observation**
E. coli	MacConkey Agar	Red, non-mucoid colonies with precipitated
Salmonella	Rappaport Vassiliadis Salmonella Enrichment Broth	Turbidity in Medium
	Xylose-Lysine- Desoxycholate Agar	Red colonies with or without black centers
	Triple Sugar Iron Agar	Change of color of slant from red to yellow with formation of acid & gas in stab culture
P. aeruginosa	Cetrimide Agar	Greenish Colonies
	Pseudomonas Agar for detection of Flourescin	Yellowish colonies with Yellow fluorescence in UV light
	Pseudomonas Agar for detection of Pyocyanin	Greenish colonies with Blue fluorescence in UV light
S. aureus	Mannitol- Salt Agar	Yellow Colonies with Yellow zone
Shigella	Xylose-Lysine- Desoxycholate Agar	Red colored translucent colonies without black centers

Alert and Action Plan

Whenever the count exceeded Alert Limit the Quality Assurance,An investigation must be conducted and corrective action should be taken whenever required but water can be used.

PRECAUTIONS

- Always perform analysis of water sample within 1hour after sampling otherwise store at 2-8^0 for not more than 5 hours and perform analysis after bringing the sample to room temperature.

- Always perform analysis after bringing the samples to room temperature.

- Media used should comply with the Growth Promotion test (GPT) and sterilization assurance (media negative control) carried out before or in parallel with the Test.

- Always perform positive controls along with secondary and confirmatory test.

- Always handle viable cultures carefully under LFH or in Bio Safety Cabinet.

- Overheating of the culture media should be avoided.

- Colony count should be checked after observation.

6-Sampling of water

Purified Water

1.clean the sampling bottles.
2.autoclave it at 121 degree c for 15min 15lbs(loose the cap)
3.wear sterile gloves.
4.open sampling valve allow water drain for 1 min.
5.collect water then close the cap don't touch by hand.
6.sampled water should be analyzed with in 2hr after sampling. Store it in 2-8 degree not more than 6-8 hrs.
7-Due to sop of the company production have 30 points in purified water they do water testing on daily and cover it in 15 days.
8-TOC and Conductivity have daily observed.

Raw water

1-There are 9 point in raw water on the daily basis S2 point is testing in the microbiology laboratory.
2-Other points are S3,S4,S6,S7,S8,S9,S10,S11 shall be covered once in 15 working days.
3-Only S2 has required ph. balance.

Sampling of Raw water

1-clean the sampling bottles and sterilize it.
2-Wear sterile gloves and open sampling valves allow water drain for 3 min.
3-Collect water then close the cap don't touch by hand.
4-Sampled water should be analyzed with in 2hrs after sampling. Store it in 2-8 degree not more than 6-8 hr.

Drinking water

1-There are 5 points in drinking water S5,S37,S38,S39,S40 testing should be covered in a week.
2-Ph. should be performed.

Sampling of Drinking water

1-clean the sampling bottles and sterilize it.
2-Wear sterile gloves and open sampling valves allow water drain for 3 min.
3-Collect water then close the cap don't touch by hand.
4-Sampled water should be analyzed with in 2hrs after sampling. Store it in 2-8 degree not more than 6-8 hr.

7-Environmental Monitoring Program

Environmental Monitoring Program is a proceduralized recurring set of activities for evaluating air and surfaces (including personnel, where applicable) for viable or non viable particles as well as other environmental variables. For completeness for coverage, EMP compasses the following:

1) Defined fined space temperature, relative humidity, pressure differential, HEPA filtered air velocity, non viable particulate counts, viable active air counts and viable passive air counts.

2) Surface and personnel viable particle counts.

These EMP measurements are performed in real time or non real time and online or offline with respect to the manufacture, packaging orholding of active pharmaceutical ingredients (APIs). Environmental monitoring is distinct from environmental control, with the latter of referring to facility and equipment design, qualification and maintenance that collectively provide varying degrees of protection from microbial and other particulate contamination. Environmental control devices such as heating, ventilation and air conditioning (HVAC), high efficiency particulate air (HEPA) filters, water and pure steam generation systems are covered in dealing with facilities, equipment, infrastructure and utilities. Environmental monitoring works in parallel with clean room facility qualification. Clean rooms are classified according to the maximum count per cubic meters of particles at or above a specified diameter. Most of the world's pharmaceutical clean room regulations and guideline recommend the use of international standard ISO-14644-1 and related ISO standards. Viable and non viable particulate monitoring is described to check the amount of contamination. Regarding "action levels," these are usually interpreted as the regulatory limits reproduced in the given below, whereas "alert levels" are statistically based environmental monitoring, early warning out-of-trend values.

7.1 Role of EMP

A) Informational feedback on the effectiveness or adequacy of the following:

1. Environmental control

2. Disinfection and sanitization activities

3. Personnel gowning, hygienic, and where necessary, aseptic practices.

7.2 How does EMP work?

Types of Environmental Monitoring

1. Total Airborne (Non-Viable) Particulate Monitoring

2. Active Viable Air Monitoring

3. Passive Viable Air Monitoring

4. Surface Monitoring

5. Personnel Monitoring

7.3 PROCEDURE

1.1 Enter the area for which the environmental monitoring has to be done by following entry and exit procedure.
1.2 Carry out the environmental monitoring as per any one of the following method.

1.2.1 By plate exposure
1.2.2 By air sampling.

1.3 By plate exposure:

1.3.1 Wear the sterile gloves.
1.3.2 Clean the area where plate exposure has to be carried out with fresh 70% IPA before exposing the plates.
1.3.3 Ensure that the AHU system is ON.
1.3.4 Expose the preincubated Soyabean casein digest agar medium plates in as per the sampling points in the layouts for microbiology area and Production area by removing the lid and placing the same at the edge of the bottom dish.
1.3.5 Expose the plates for 2 hour with proper labeling.
1.3.6 Collect the plates by closing the lid starting from the plate of initial exposure.
1.3.7 Bring the exposed plates in incubation area.
1.3.8 Cover the plates with Aluminum foil.
1.3.9 Incubate the plates at 30-35 degree centigrade for 48 hours.
1.3.10 Incubate the same plates for further 72 hours at 20-25 degree centigrade.
1.3.11 Count the Bacterial and fungal colonies on plates.

Fig-6- settle plate

By air sampling:

1.4.1 Carry out the air sampling by using either SAS (Pbi) air sampler or Millipore air sampler. Operate SAS (Pbi) air sampler and Millipore air sampler.

1.4.2 For SAS (Pbi) air sampler use pre incubated Soyabean casein digest agar medium plates for sampling the air. Sample air volume of 1000 liters.

1.4.3 For Millipore air sampler use pre filled cassettes of media. Sample 1000 liters.

1.4.4 Incubate the sampled plates first for 30-35 degree centigrade for 48 hours.

1.4.5 Incubate the same plates for further 72 hours at 20-25 degree centigrade.

1.4.6 Count the Bacterial and fungal colonies on plates.

1.4.7 Fill the corrected count after observe count by considering the correction factor as per correction table attached with this SOP.

Fig-7-air sampler

1.5 The environmental monitoring shall be done once in fifteen days or “when required”.

1.6 Identify type of organism and record the cfu units with type of organism.

1.7 The schedule for environmental monitoring shall be difference between actual date and planed date shall be three days.

1.8 The trend data should be trended once in a year after year end for both method Air sampling and Settle Plate.

8-Environmental Monitoring Of Surface Sampling

swab sampling detect microorganism contamination in the immediate vicinity of the work area.

8.1 Swab Sampling

Swabs are sterile and stored in a suitable sterile liquid or other diluents. The swabs are rubbed over the test surface. It can be used to sample irregular or constrained surfaces such as equipment, filling nozzles, tubing, or corners. They are useful for sampling large areas, such as after cleaning or sanitization procedures. They are also used for surfaces that are not flat, and can be used to sample hard to reach areas of machinery that could not be sampled with a contact plate.

The microbiologist can determine the type of microorganisms on the swab by sub culturing it to media. Swabbing is more qualitative than quantitative.

The recovery of microorganisms from swabs should be validated, including the chosen sampling method, the suitability of the swab moisturizing liquid, and the transfer of microorganisms to growth media. Normally > 50% of microorganisms should be recoverable during validation studies. If the area to be sampled is large but not standardized, no regulatory limits are applicable to swabs. However, the detection of microorganisms using this method should be investigated as part of batch release.

Procedure-

1. Prepare 10ml saline(0.9%) or peptone water tubes.
2. Sterilize the tubes and cotton swabs in autoclave at 121 c for 15 min at 2.1 bars pressure.
3. Carry the swabs sterilize saline or peptone water tubes to be area where surface monitoring to be done.
4. Wear sterile hand gloves.
5. Disinfect the 5×5cm stainless steel template with 70% IPA.
6. Swab the 5×5cm area with the help of stainless steel template and sterile cotton swabs by horizental and vertical strokes.
7. Clean the area after swabing with 70% IPA.
8. Dip the same swab in 10ml saline or peptone water tubes immediately plug the tube with sterile cotton and label it as name of area,date,sign.

9. Filter the sample using sterile cellulose nitrate membrane filter.
10. Mark the plate with respective sampling area,date and sign.
11. Incubate at 32.5c+2.5c 48 hr.
12. then incubate at 22.3c +/- 2.5c 72hr.
13. After incubation count the colony.

Fig-8-swab sampling

8.2Contact Plates

Contact plates should be used to detect microorganisms on surfaces that could lead to product contamination. These surfaces may include working surfaces, equipment surfaces, and walls and ceilings of unidirectional air flow systems. When spills dropped materials are likely to contaminate floors, these should be sampled. When operators work in close proximity to exposed product, such as in an open flow hood, gown fronts, sleeves, masks, or other representative areas should be sampled.

Contact samples should be taken after completion of production activities or in such a way that contamination of sterile areas by monitoring does not occur. Samples should be taken before sanitization of the area. Where frequent sanitization (e.g., through spraying with alcohol solutions) occur, samples should be taken prior to the sanitation procedure to maximize the likelihood that microorganisms are detected. Where surfaces are still wet with sanitization solutions, contact plate measurements are invalid.

These are monitored on a regular basis for viable counts by using specially designed contact plates that contain a growth medium called Soyabean casein digest agar medium(SCDA)

Insert timer in RODAC weight.

Programme the timer for 2min using min button on the time.

Insert the contact plate at the back side of RODAC weight.

Remove plates then press stop button.

Then incubate at 30-35 degree Celsius which is mainly the optimal growing temperature for most environmental bacteria, and 20-25 degree Celsius which is the optimal growing temperature for most mold and yeast species.

Fig-9-contact plate

8.3Personnel Monitoring

Personnel are the biggest source of contamination in clean areas. Personnel harbour millions of bacteria, carrying them with them everywhere they go. Gowning is the most effective way to protect the clean room environment from ourselves. To assess the effectiveness of the gowning program personnel may be monitored on a regular basis for viable counts. Personnel monitoring employ contact plates to assess microbial contamination of clean room personnel. The contact plates monitor areas of the body that may interact with the sterile field or product exposure areas. These may include gloved hands, forearms or other areas. Personnel monitoring is a good

indication of how well personnel are gowning when they enter the clean room. Many companies utilize this testing for proficiency based training programs for clean room personnel.

Glove Prints (Finger dabs)

Fingertips are the most likely area to come into contact with microbial contamination on work surfaces, on materials, or arising from the operator and then be transferred to products. Glove prints including all five fingers should be taken to monitor this possibility.

Sampling should be conducted before routine sanitization of gloves with alcohol, or before changing of outer gloves in cases where double-gloving is used.

8.4 Alert and Action levels for environmental monitoring

An **Alert level** in EM is that level of microorganisms that shows a potential drift from normal operating conditions. Exceeding the alert level is not necessarily grounds for definitive corrective action, but it should be at least prompt a documented follow-up investigation that could include sampling plan modifications.

An **Action level** in EM is that level of microorganisms that when exceeded require immediate follow up and if necessary, corrective action.

Action and Alert limit-

Area grade	Settle Plate	Air Sampler
A	<1	<1
B	<5	<10
C	<50	<100
D	<100	<200

8.5 Investigations

There should be a detailed SOP on how to investigate and react to an environmental excursion. This should be recorded and documented; the event should be investigated and the results of the investigation recorded; and an unbiased, scientific decision should be made whether the excursion could negatively affect the products purity, potency, safety, or efficacy.

Batch release by QA should be delayed until investigations have been successfully completed and the result of the investigation indicates that no unacceptable risk to the product or patient exists as a result of the environmental excursion.

A thorough investigation into the cause of the environmental excursion should be carried out. The results of the investigation should be documented and reviewed as part of batch release.

The impact of the environmental excursion on all batches produced in the area while the condition existed must be considered. Companies often make the mistake of sampling too infrequently, and then ignoring the fact that the area could have been continuously out of compliance for weeks or even months. Practically, if a malfunctioning filter or area contamination with a pathogenic microorganism has been discovered, all batches produced in the area since the last successful result was obtained are considered suspect. Batch failures and recall procedures for all such released batches must be specifically considered in the investigation, and failure to do so represents a severe failure in the manufacturer's quality assurance system.

When a process generates particles or microorganisms (such as a process where an aerosol of a live bacterial vaccine is generated), it may be difficult or even impossible to demonstrate compliance with EM requirements. In such cases a detailed validation study should be conducted that demonstrates that the nature of the product alone is responsible for these results. This may take the form of repetitive simulation studies (e.g., using an innocuous replacement of product such as growth media) where all EM results are found to be acceptable.

Where EM excursions have been obtained and clean room design and function do not meet specifications, this should generally result in batch failure. If a piece of equipment does not meet specifications (e.g., HVAC systems, autoclaves, fermenters, or lyophilizers cannot be qualified, or operating parameters cannot be validated) and they are possible causes of the EM excursions, this should generally result in batch failure. Where the clean room grade of the area in which the excursion occurred does not comply with GMP requirements, this should be reported in each investigation summary.

9-Introduction of Isolation of Bacteria in Environmental core Area

The microbiological quality of air, surface and working personnel in a pharmaceutical industry was investigated. Bacterial isolates recovered from the processing environment were also identified. Phenol co-efficient of commonly used disinfectants such as sodium hypochlorite, savlon (chlorhexidine gluconate 0.3% w/v and cetrimide 3% w/v), ethanol, methanol and isopropyl alcohol were determined using standard methods against the most predominant organisms. This study reveals that the personnel involved in manufacturing were the main source of contamination and the common organisms found from samples of air, surface, and working personnel monitoring area were Staphylococcus sp., Pseudomonas sp. and Escherichia sp. Among the used disinfectants of this study, sodium hypochlorite showed the highest potency. Phenol coefficient of sodium hypochlorite, savlon, isopropyl alcohol, methanol and ethanol were 5.55 and 4.44; 2.77 and 2.22; 0.22 and 0.33; 0.33 and 0.44; 0.11 and 0.16 for Staphylococcus sp. and Pseudomonas sp., respectively. To reduce the risk of contamination, working personnel should follow the rules of cGMP (current good manufacturing protocol) and the disinfectants should be used in appropriate concentration for the beneficial cost effect of the pharmaceutical industry and also for a clean environment.

Microorganisms regarded as an important bioresource of our environment because they can be obtained in large quantities using cultural techniques within a shortest possible time by established fermentation methods, and they produce a regular and abundant supply of the desired product. Because of the presence of microbes in all walks of human life, there is constant interaction between microbes and humans. The vast majority of the bacteria in the body are rendered harmless by the protective effects of the immune system, and a few are beneficial. In fact, the relationship between microbes and humans is delicate and complex.

Microorganisms found in the manufacturing environment, water for pharmaceutical use, raw materials and ingredients, intermediates, and finished products are frequently identified to assist in product investigations.The value of the data from an environmental monitoring program is greatly reduced if the microorganisms isolated are not characterized to some degree. Identification of isolates is an essential part of understanding the microbial ecology of a manufacturing facility, monitoring the effectiveness of microbiological control in aseptic environments and investigating of normal microbial populations or sterility failures.Routine investigation might include characterization by colony and cellular morphology, gram reaction, and key enzyme activities. This information may be sufficient to confirm that the bacteria found in the sample are typical for that material or manufacturing area or to indicate the effectiveness of environmental control in an aseptic process

10-PROFILING OF MICROORGANISMS ISOLATED IN THE LABORATORY

1.0 PROCEDURE

1.1 The microbial colonies observed on the plates shall be studied for the predominant types.

1.2 The colonies of the predominant and other types shall be studied for the cultural characteristics (shape, size, margin, consistency, color, etc.) and microscopic characteristics (by Gram's staining or special staining techniques).

1.2.1 **Method For Gram-Staining:-**

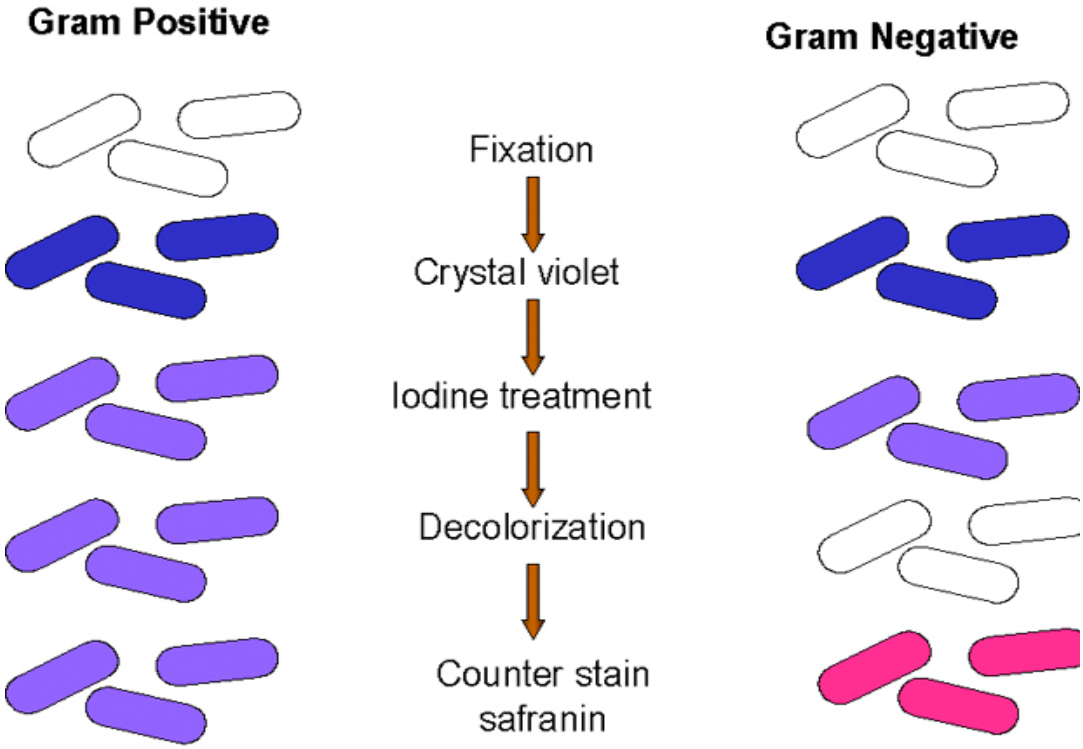
1.2.2 Staining reactions.

1.2.2.1 Incinerate the inoculation loop.
1.2.2.2 Prepare a thin smear of the organism from the culture source on a clear, dry, grease free glass slide in the laminar air flow station using the incinerated inoculation loop.
1.2.2.3 Allow it to dry and fix by gentle heat .Incinerate the inoculation loop.
1.2.2.4 Flood the slide with crystal violet solution and allow it to remain for a period of 1 minute.
1.2.2.5 Wash the slide with purified water.
1.2.2.6 Flood the smear with gram's iodine solution and allow it to remain for a period of 1 minute.
1.2.2.7 Decolorize with decoloursing agent-Ethyl alcohol-95% until the blue dye no longer flows from the smear.
1.2.2.8 Wash the slide with purified water.
1.2.2.9 Flood the slide with the counter stain safranin and allow it to remain for a period of 1 minute.
1.2.2.10 Wash the slide with purified water.
1.2.2.11 Allow the slide to air dry or blot dry.
1.2.2.12 Flow chart shall be as per annexure IV Gram Staining.

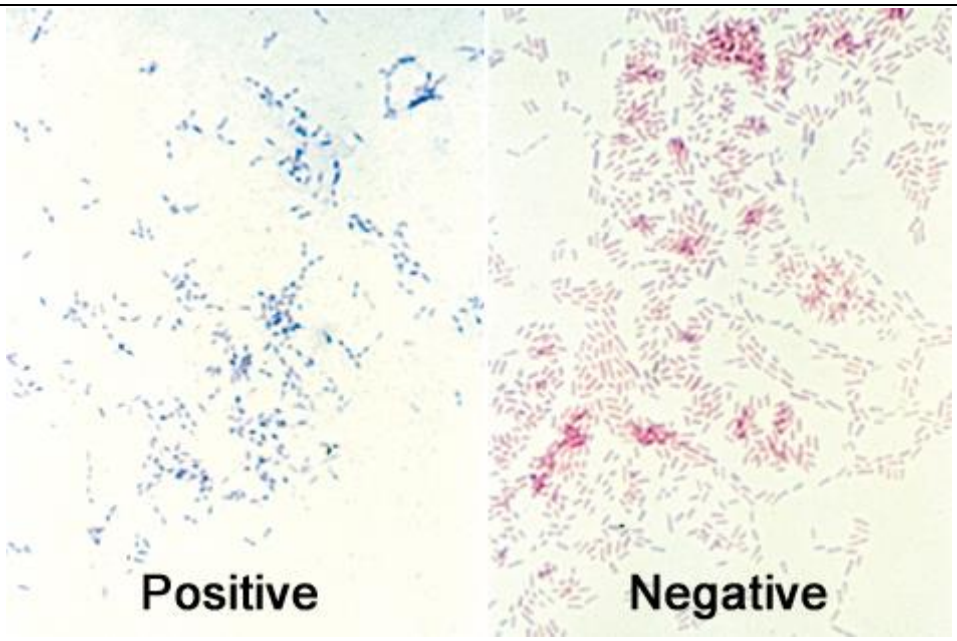
1.2.3 **Microscopic observations**.

1.2.3.1 Observe the slide under the microscope under oil immersion objective.
1.2.3.2 Bluish purple colour stained cells indicates gram positive organism.
1.2.3.3 Pinkish red colour stained cells indicates gram negative organism.

1.2.4 **Diagrammatic representation of Gram staining**



1.2.5 **Bacterial cells under Microscopy.**



1.3 The predominant types shall be further cultivated on selective culture media.

1.4 The microbiologist shall draw inference up to the genus and species of the organisms.

1.5 Further confirmation shall be done, where necessary using biochemical testing and other confirmatory tests and record as per annexure I.

1.6 In case of pathogens, the isolates shall be properly handled to avoid infection and contamination.

1.7 The microbiologist shall recommend control measures for eradication of the predominant types and objectionable microorganisms.

1.8 The objectionable organisms shall include, but not limited to:

1.8.1 E. Coli
1.8.2 Salmonella species
1.8.3 Shigella species
1.8.4 Staphylococcus aureus
1.8.5 Pseudomonas species
1.8.6 Streptococcus species
1.8.7 Klebsiella species
1.8.8 Aspergillus niger
1.8.9 Candida albicans
1.8.10 Clostridium sporogenes

1.9 The culture bank shall be prepared for all isolates recovered from environmental, water or any other samples and slant shall be prepared and preserved for one year at 2 ^{o}C to 8 ^{o}C .Stored Isolates shell be verified on monthly basis

11-RESULTS

Samples were mainly obtained from the core area of the pharmaceutical company using three techniques: Settle plate, Air sampling and personal monitoring. After sampling of core area, the plates were incubated in the incubators 22.5±2.5°C and 32.5±2.5°C for 72 hrs and 48 hrs respectively. The colonies developed on these plates were eventually observed after 120 days. The shape, size, color and morphology of these colonies were noted.

Figure-10 to the left and right shows the colonies obtained from the core area of the facility.

Figure- 11(right) encircled colony indicates the colony of interest and further isolated.

Colonies were further streaked on the SCDA plates for better isolation. The fresh streaked plates were incubated in 32.5±2.5°C for 48 hrs.

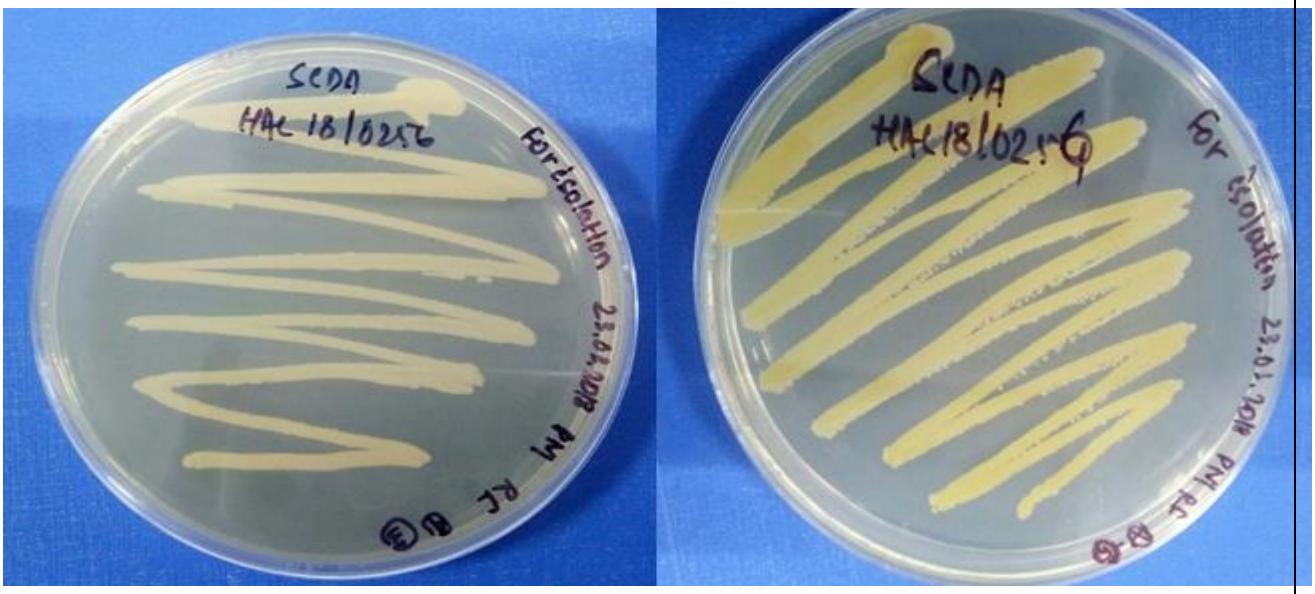


Figure-12and 13 to the left and right shows the two different colonies further isolated on SCDA plates and observed after 48 hrs.

After colonies were isolated, their gram characteristics were done using Gram Staining. On gram staining these colonies we found that all the colonies belonged to gram positive strain.

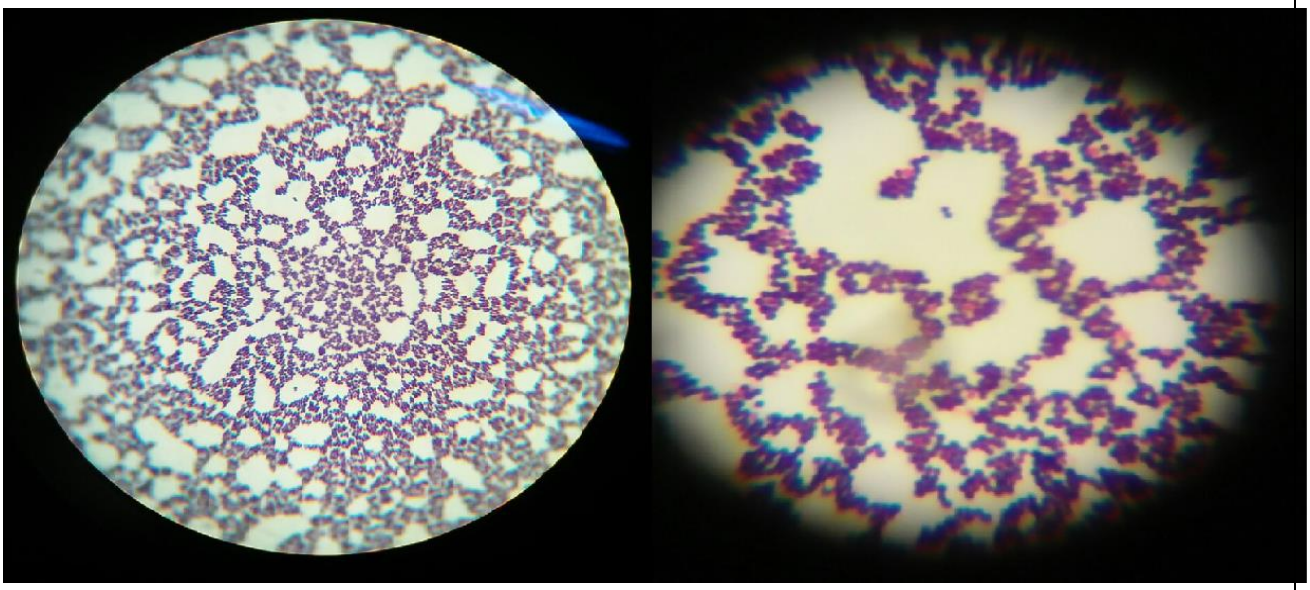


Figure-14 and 15 to the left and right shows the gram staining results obtained from two different colonies obtained from the core area of the facility.

Once completing the gram staining, further characterization of these microorganisms was done using profiling kits. Using these kits, we were able to identify the microorganism up to species level. The two main species we found were bacillus and streptococcus.

There are profiling kit for the further identification is the catalase kit and oxidase kit from these ki we identify the charcterization.

12-DISCUSSION

Based on the results we obtained, we were able to deduce that the source of these microorganisms isolated from the core area of the facility were mainly human interventions. The microorganisms were mainly isolated from core area. We were able to isolate them and characterize them based on their species. It was also deduced that these microorganisms didn't seem to affect the quality of the product in whatsoever way.

This study is of utmost importance as this study shows what kind of microorganisms might be present in the facility and what impact they might have on the product. Identifying these microorganisms is the first step in identifying any potential hazards present in the core area and only by identifying them we can take various actions which might help us get rid of these hazards.

Working in close quarter with pharmaceutical industry, I feel it is really important to eliminate any possible source of contamination which might be potential source of infection for the consumer consuming the product.

All of the air delivered to a clean room passes through HEPA filters, and in some cases where stringent cleanliness performance is necessary, ULPA filters are used.

Temperature should be maintained: 16 to 19 degree Celsius.

50% humidity is maintained in clean room.

Pressure is maintained in according to classification of clean rooms. Pressure is high in Grade A than B. Pressure is low in Grade D.

Personnel selected to work in clean rooms undergo extensive training in contamination control theory. They enter and exit the clean room through airlocks, air showers and/or gowning rooms, and they must wear special clothing designed to trap contaminants that are naturally generated by skin and the body.

13-CONCLUSION

These results are in agreement with the findings of other workers.It was found that *Staphylococcus* and spore-forming *Bacillus* were more resistant to UV than the other vegetative bacteria.

To ensure a clean room conforming to the designated classification, constant monitoring of contaminant sources and identification of the predominant contaminant bacteria is usually necessary.This study found that the predominant contaminant bacteria were a group of Gram positive bacteria either spore-forming *Bacillus*, or nonsporulating *Staphylococcus.*

This study found that 8 bacterial genus identified isolates were Gram positive bacteria, either spore-forming *Brevibacillus*, which is known to confer resistance to extreme environmental conditions, or non-sporulating *Staphylococcus* and *Micrococcus*, which have a thick cell wall and the rest of the bacterial genus also.

The thick wall of a cell or spore is a reasonable explanation for resistance to UV irradiation because this kind of non-ionizing radiation penetrates weakly. However, to 70% IPA and hydrogen peroxide solutions, the cell wall could not be a reasonable explanation for retarding disinfectant entrance.

Maintaining the integrity of a clean room is a constant battle.

There are 3 prime sources of contamination. The first is from human errors. To control this source of contamination, human hands must be washed with disinfectant. 70% IPA is the widely used skin disinfectant because of its mild nature. Contamination may also result from the room surface areas. To avoid such contamination, floors, walls and ceilings must be swept with disinfectants. The third contamination source is from the room air. UV irradiation is the most convenient way to sterilize room air although it is advised the fumigation with suitable disinfectant periodically reduce and limit the microbial load in the production area at pharmaceutical industry

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Microbial identification in pharmaceutical industry

Scott v.w sutton,phd and anthony m.cundeli,phd usp expert committee on analytical microbiology

Bacterial isolates from pharmaceutical industry enviornment and water system

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