Re-Accredited B++ 2.96 CGPA by NAAC
VEER NARMAD SOUTH GUJARAT UNIVERSITY
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વીર નર્મદ દક્ષિણ ગુજરાત યુનિવર્સિટી
યુનિવર્સિટી કેમ્પસ, ઉધના-મગદલ્લા રોડ, સુરત - ૩૯૫ ૦૦૭, ગુજરાત, ભારત.
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-:પરિપત્ર:-

યુનિવર્સિટીના વિજ્ઞાન વિદ્યાશાખા હેઠળના તમામ શૈક્ષણિક વિભાગોના વડાશ્રીઓ અને યુનિવર્સિટી સંલગ્ન વિજ્ઞાન વિદ્યાશાખા હેઠળની તમામ કોલેજોનાં આચાર્યશ્રીઓને જણાવવાનું કે, શૈક્ષણિક વર્ષ ૨૦૨૬–૨૭ થી અમલમાં આવનાર B.Sc. Microbiology Sem.-5 Paper-501(Minor) નો સુધારેલ અભ્યાસક્રમ માઈક્રોબાયોલોજી વિષયની અભ્યાસ સમિતિના ચેરમેનશ્રીએ અભ્યાસ સમિતિવતી અને વિજ્ઞાન વિદ્યાશાખાના અધ્યક્ષશ્રીએ વિદ્યાશાખાવતી મંજૂર કરી એકેડેમિક કાઉન્સિલને કરેલ ભલામણ એકેડેમિક કાઉન્સિલની તા.૨૪/૧૨/૨૦૨૪ ની સભાનાં ઠરાવ ક્રમાંકઃ ૩૫૩ અન્વયે માન.કુલપતિશ્રીને આપેલ સત્તા અંતર્ગત માનનીય કુલપતિશ્રી દ્વારા મંજૂર કરેલ છે, જેનો અમલ કરવા આથી જાણ કરવામાં આવે છે.

(બિડાણઃઉપર મુજબ)

ક્રમાંકઃઓથો./પરિપત્ર/૧૪૭૩૧/૨૦૨૬
તા.૦૧/૦૭/૨૦૨૬

કુલસચિવ

પ્રતિ,
(૧) યુનિવર્સિટીના વિજ્ઞાન વિદ્યાશાખા હેઠળના તમામ શૈક્ષણિક વિભાગોના વડાશ્રીઓ.
(૨) યુનિવર્સિટી સંલગ્ન વિજ્ઞાન વિદ્યાશાખા હેઠળની તમામ કોલેજોનાં આચાર્યશ્રીઓ.
... આપશ્રીના વિભાગ/કોલેજના સંબંધિત શિક્ષકો/વિદ્યાર્થીઓને જાણ કરી અમલ કરવા સારૂ.
(૩) અધ્યક્ષશ્રી, વિજ્ઞાન વિદ્યાશાખા.
(૪) પરીક્ષા નિયામકશ્રી,પરીક્ષા વિભાગ, વીર નર્મદ દ. ગુ. યુનિવર્સિટી, સુરત.

.....તરફ જાણ તેમજ અમલ સારૂ.

[Subject codse-2503000505046001]

MINOR
MB-ME-501

COURSE CODE	MB-ME-501
COURSE TITLE	QUALITY CONTROL & QUALITY ASSURANCE
COURSE LEVEL	300 to 399
COURSE CREDIT	02
TOTAL ENGAGEMENT	02 Credits X 15 hrs. = 30 hrs.
TEACHING PER WEEK	02 Hrs.
MINIMUM WEEKS PER SEMESTER	15 Weeks

COURSE CONTENT:

- This course introduces microbiology students to quality control and assurance in pharmaceutical and laboratory settings. It covers GMP, GLP, regulatory compliance, and microbial safety, ensuring students understand quality standards and their applications in microbiological testing and pharmaceutical production.
- Students will learn to apply quality assurance principles, conduct stability testing, control microbial contamination, and follow biosafety guidelines. The course emphasizes regulatory compliance, risk assessment, and quality audits, preparing them for careers in laboratory management and pharmaceutical quality control.

COURSE OUTCOME: CO1

- Students will develop a strong understanding of quality assurance principles, GMP, and TQM, ensuring adherence to industry standards in pharmaceutical and microbiology laboratories.
- They will also gain insights into accreditation, certification, and regulatory frameworks such as NABL, enabling them to assess and maintain laboratory quality effectively.

COURSE OUTCOME: CO2

- Students will learn to apply Good Laboratory Practices (GLP), hazard analysis, to improve laboratory safety and operational efficiency.
- Additionally, they will acquire expertise in biosafety protocols, sterilization techniques, and microbial contamination control, ensuring safe and effective microbiological testing in pharmaceutical and public health laboratories.

	PSO1	PSO2	PSO3	PSO4	PSO5	PSO6
CO1						
CO2						

UNIT 1	QUALITY ASSURANCE & QUALITY MANAGEMENT CONCEPT
1.1 1.2 1.3 1.4 1.5 1.6	Quality assurance – Objectives of Quality Assurance Current Good Manufacturing Practices Quality Control & Quality Assurance – Objectives of Quality Control Total Quality Management (TQM) -Definitions, Key Elements, Advantages Internal Quality Control Formulating Quality control charts NABL Accreditation
UNIT 2	GOOD LABORATORY PRACTICES & GUIDELINES
2.1 2.2 2.3 2.4 2.5 2.6 2.7	WHO good practices for pharmaceutical microbiology laboratories Biosafety Guidelines for Public Health Laboratories. General Principles of Biosafety Biosafety Cabinets Good Microbiological Techniques-Safe laboratory procedures Sterilization and Disinfection Procedures Biomedical Waste Management

REFERENCES:

- Organization, W. H. (2024). Quality assurance of pharmaceuticals: a compendium of guidelines and related materials. Volume 2. Good manufacturing practices and inspection. World Health Organization.
- Godkar, P. B. and Godkar, D. P. (2014). Textbook of Medical Laboratory Technology,3rd Ed., Volume 1, Bhalani Publication House Mumbai, India.
- Baird, R. M., Hodges, N. A. and Denyer, S. P. (2006). Handbook of Microbiological Quality Control, Special Indian Ed., CRC Press.
- Hewitt, S. (2003). Microbiological Assay for Pharmaceuticals Analysis: A Rational Approach, CRC Press.
- Tambwekar, S. (2009). Handbook of Quality Assurance in Laboratory Medicines, B. I. Publications.

E-RESOURCES:

- https://www.njlm.net/articles/PDF/2351/40437_CE%5BRa1%5D_F(SHU)_PF1(AG_OM)_PFA(SHU)_PB(AG_OM)_PN(SHU).pdf&ved=2ahUKEwic7_qbt_KLAxWvumMGHSpxGpMQFnoECDsQAQ&usg=AOvVaw04AHdfRHkECY1aEBnCPK2p
- https://www.cdc.gov/labs/pdf/SF__19_308133-A_BMBL6_00-BOOK-WEB-final-3.pdf
- https://ncdc.mohfw.gov.in/wp-content/uploads/2024/04/File608.pdf
- SWAYAM (https://swayam.gov.in/)
- SWAYAM Plus (https://swayam-plus.swayam2.ac.in)

[Subject code-2503000505046002]

PRACTICALS

MBP-ME-501

COURSE CODE	MB-ME-501
COURSE TITLE	QUALITY CONTROL & QUALITY ASSURANCE PRACTICALS
COURSE LEVEL	300 to 399
COURSE CREDIT	02
TOTAL ENGAGEMENT	02 Credits X 15 hrs. = 30 hrs.
TEACHING PER WEEK	04 Hrs.
MINIMUM WEEKS PER SEMESTER	15 Weeks

COURSE OUTCOME:

CO1: Students shall develop an insight regarding the quality control and become proficient to prepare and interpret the quality of data from Levey-Jennings Chart.
CO2: Students shall gain skills to perform the Sterility Testing of Pharmaceutical Products and determine the sterility of the product.
CO3: Students shall become aware regarding the Microbial Limit Testing of Non-Sterile products.
CO4: Students shall develop skill to monitor the environment of Pharmaceutical Labs.
CO5: Students shall develop skill to monitor the Quality Control of Water for Pharmaceutical use.
CO6: Students shall become skillful in documentation Practices and learn validation of analytical methods.

	PSO1	PSO2	PSO3	PSO4	PSO5	PSO6
CO1 to CO6						

CONTENT

1. Interpretation and reporting of sterility of pharmaceutical product
2. Preparation and Interpretation of Levey-Jennings Chart.
3. Environmental Monitoring in Pharmaceutical Labs: Air sapling by settling plate method
4. Microbial Limit Testing of Non-Sterile Products by plate count method (Intrepretation & reporting)
5. Good Documentation Practices and Validation of Analytical Methods.

REFERENCES:

1. Godkar, P. B. & Godkar, D. P. (2014). Textbook of Medical Laboratory Technology, 3rd Ed., Volume 1, Bhalani Publishing House, Mumbai.
2. WHO (2024). Quality Assurance of Pharmaceuticals: A Compendium of Guidelines and Related Materials, Volume 2. WHO Technical Report Series.

3. USP (United States Pharmacopeia) 43-NF 38. Microbiological Examination of Nonsterile Products: Microbial Enumeration Tests.
4. Baird, R. M., Hodges, N. A., & Denyer, S. P. (2006). Handbook of Microbiological Quality Control: Pharmaceuticals and Medical Devices, CRC Press. (Page No. 221-238).
5. WHO (2024). Quality Assurance of Pharmaceuticals: Water for Pharmaceutical Use, WHO Technical Report Series.
6. Hewitt, S. (2003). Microbiological Assay for Pharmaceutical Analysis: A Rational Approach, CRC Press.