

Seat No.: _____

Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY
Ph.D. COURSE WORK EXAMINATION – 2024 (REMEDIAL)

Subject Code: PHD2201

Date: 01/09/2024

Subject Name: Research Methodology_Pharmacy & Biotechnology

Time: 01:30 PM – 04:30 PM

Total Marks: 70

Instructions:

1. Attempt all questions.
2. Make suitable assumptions wherever necessary.
3. Figures to the right indicate full marks.

- Q.1 (a)** Compare exploratory research vs conclusive research citing appropriate case study **10**
- (b)** Gilead said the COVID-19 pandemic continues to affect its sales, including its treatments for hepatitis C and HIV, due to fewer people going to their doctors. It expects a gradual recovery in underlying market dynamics starting the second quarter of this year. Remdesivir, which is sold under the brand name Veklury, brought in \$1.9 billion in the fourth quarter ended Dec. 31, above analysts' estimates of \$1.34 billion. Excluding Veklury, Gilead said its quarterly sales fell 7%. The company said remdesivir continues to be a critical tool during the COVID-19 pandemic, forecasting 2021 sales of up to \$3 billion for the drug. Gilead Chief Medical Officer Merdad Parsey said that unlike current COVID-19 vaccines and some other drugs, remdesivir does not target the spike proteins of the coronavirus, which are altered in some recently-identified, more transmissible variants of the virus. "We have not so far seen mutations that would impact the efficacy of remdesivir," he said during a conference call. Gilead said it continues to work on an inhaled version of the COVID-19 drug - which is given intravenously to hospitalized patients - but more clinical study is required. For 2021, the California-based company projected an adjusted earnings range with a midpoint of \$7.10 per share, on product sales with a midpoint of \$24.4 billion, ahead of respective Wall Street estimates of \$6.85 per share and \$24.27 billion, according to IBES data from Refinitiv. (source: Gilead forecasts 2021 growth, strong remdesivir COVID-19 sales | Reuters accessed march 2023).

Answer the following questions based on above paragraph

1. Write any three sources of primary data collection and secondary data collection which the company might have relied upon to arrive on the above press release. **6**
2. Based on the above press conference release; which statement signifies a new area of research and what is the research gap they have addressed in this new area of research. **2**
3. Why does the company believes that mutations in coronavirus will have least implications on the forecasted sales of Veklury. **2**

- Q.2 (a)** India is at the cusp of the electric vehicle (EV) revolution and the country now needs innovative ways to use renewable energy for battery storage, Union Road Transport and Highways Minister Nitin Gadkari has said. The battery technology will be in high demand by **2030**, bolstering the ‘Make in India’ initiative. “In the next five years, it is expected that all vehicles will be electric. I encourage everyone involved in the electric vehicle business to work together for the betterment of the country by developing innovative solutions for a clean and green future,” Gadkari said during the ‘India Energy Storage Week 2022 event - organised by the India Energy Storage Alliance (IESA). (ref : Nitin Gadkari: India Needs New Ways to Use Renewable Energy for Battery Storage (news18.com))

Based on above writeup design a questionnaire along with likely response for Hon. minister Shri Nitin Gadkari, addressing following 5 points (need of EV vehicle, make in India, job loss, road conditions, employment opportunities). Also specify the nature of questions (open ended /close ended) and arrange them in appropriate sequence based on the likely answers given by the minister.

- (b)** Artemisinin and its derivatives Artemisinin was first isolated in 1971 by Tu Youyou from the plant *Artemisia annua*, a herb that has commonly been used in Chinese traditional medicine. Due to the great positive impact of artemisinin in combating malaria, Youyou was awarded the joint Nobel Prize in Physiology or Medicine in 2015 for “her discoveries concerning a novel therapy against malaria”. Artemisinin has been shown to be efficacious against all multi-drug resistant forms of *P. falciparum*. The most common derivatives of artemisinin are artemether, artesunate and artemether. These semi-synthetic derivatives are prodrugs which are transformed to the active metabolite, dihydroartemisinin. The use of artemisinins has been integral in the fight against malaria with ACT making up the majority of modern day treatments . Although slow to develop, the first report of resistance to artemisinin was in western Cambodia in 2008 . Ten years later, in February of 2018, a report was published identifying more than 30 independent cases of artemisinin resistance in southeast Asia, specifically with resistance to the dihydroartemisinin–piperaquine combination therapy. The mechanism of action (MoA) through which artemisinin acts has been widely debated. The most accepted theory is that the molecule is activated by haem to generate free radicals, which in turn damage proteins required for parasite survival. Still, evidence for a number of other possible mechanisms have been found. In 2013, a computational approach was taken to determine the MoA based around previous studies which identified haem and PfATP6 (Ca²⁺ transporter) as potential MoAs . More recently in 2015, artemisinin was shown to be associated with the up-regulation of the unfolded protein response (UPR) pathways which may be linked to decreased parasite development . Another study showed that artemisinin was is a potent inhibitor of *P. falciparum* phosphatidylinositol-3-kinase (PfPI3K) (Ref : Tse, E.G., Korsik, M. & Todd, M.H. The past, present and future of anti-malarial medicines. *Malar J* 18, 93 (2019). <https://doi.org/10.1186/s12936-019-2724-z>).

1. Based on the above writeup prepare a historical timeline and relevant key findings related to discovery of artemisinin and its derivatives. **6**
2. Enlist the key objective of carrying out Historical research on Artemisinin and its derivatives based on above writeup. **2**
3. Malaria is considered to be a problem of developing nations and Multinational companies are not very keen on developing a vaccine for a **2**

disease which does not affect their population. Justify using brief explanation whether I can deduce this hypothesis based on above writeup.

or

- (a)** At the first United Nations (UN) high-level meeting on TB in 2018, Member States committed to a global target of providing TB preventive treatment to at least 30 million people in the 5-year period 2018–2022: 6 million people living with HIV, 4 million children aged under 5 years who are household contacts of people diagnosed with TB, and 20 million household contacts in older age groups . At the UN high-level meeting on HIV and AIDS held in June 2021, countries committed to ensuring that 90% of people living with HIV receive TB preventive treatment by 2025. The global number of people living with HIV and household contacts of people diagnosed with TB who were provided with TB preventive treatment increased from 1.0 million in 2015 to 3.6 million in 2019, with a particularly large increase (1.4 million) between 2018 and 2019). However, this positive trend reversed between 2019 and 2020, probably reflecting disruptions to health services caused by the COVID-19 pandemic. The total number of people provided with TB preventive treatment in 2020 was 2.8 million, a 21% reduction compared with 2019. Progress made in the past 3 years lags far behind that needed to reach the global target set at the UN high-level meeting on TB: the combined total of 8.7 million in 2018–2020 is only 29% of the target of 30 million for the 5-year period 2018–2022. BCG vaccination is recommended as part of national childhood immunization programmes, in line with a country’s TB epidemiology. Of countries reporting BCG coverage data in 2019, 31 reported a reduction in coverage of 5% or more in 2020 compared with 2019; 24 did not report data. This decline was greater than that seen in previous years, and may reflect disruptions to health services caused by the COVID-19 pandemic. (ref : 4. TB prevention (who.int) accessed March 2023)

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| 1. Based on the above writeup prepare a historical timeline and relevant key findings related to global target of providing TB preventive treatment. | 6 |
| 2. Enlist the key objective of carrying out Historical research on global target of providing TB preventive treatment based on above writeup. | 2 |
| 3. Covid 19 disrupted global target of providing TB preventive treatment to at least 30 million people in the 5-year period 2018–2022. Justify using brief explanation whether I can deduce this hypothesis based on above writeup. | 2 |

- (b)** The 76th World Health Assembly (WHA), which will be held in Geneva from May 21–30, will be attended by Union Health Minister Mansukh Mandaviya. The Union Health minister will undertake several bilateral talks with his colleagues from other nations, including Singapore, France, and the Netherlands. Minister Mandaviya will also take part in activities like “Heal in India” and “Heal by India,” “climate change and health,” “Together we fight against TB,” and meetings with Indian-origin health innovators headquartered in Switzerland. “Use of technology and Digital Health Tools are an enabler and equalizer which can facilitate strengthened health service delivery and aid in the achievement of Universal Health Coverage. The COVID-19 pandemic has catalyzed the use of technology in health service delivery and also highlighted the need to focus on an enabling framework to bridge the digital divide across the countries specifically amongst low-and-middle-income countries.” Mandaviya said in Japan. (ref: Union Minister Mansukh Mandaviya to attend World Health Assembly in Geneva from May 21 - (newsx.com)) **10**

Based on above writeup design a questionnaire along with likely response for Hon. minister Shri Mansukh Mandaviya, addressing following points(need of universal health coverage, Heal in India, heal by India, climate change and health, digital health tools). Also specify the nature of questions (open ended /close ended) and arrange them in appropriate sequence based on the likely answers given by the minister.

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| Q.3 | (a) Explain the drawback of conducting telephonic interview vs personal interview as means of primary data collection. | 05 |
| | (b) A Biotech company intends to manufacture a vaccine for HIV and needs to collect secondary data before venturing into the market. Suggest likely internal and external sources of collecting secondary data which the company can follow | 05 |
| Q.4 | (a) Explain HARKing, Cherry-Picking, P-Hacking, Fishing Expeditions, Data Dredging and Mining | 05 |
| | (b) Describe the impact of performing sensitivity analysis in clinical trials | 05 |
| Q.5 | (a) Explain the concept of true score and error score while measuring reliability | 05 |
| | (b) Describe the concept of test retest reliability and parallel form reliability citing suitable case study | 05 |
