

F. No. Z30026/02/2017-D
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation

New Delhi, dated the 10th April, 2017

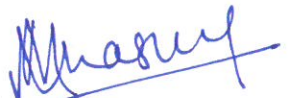
Merit List based on the written examination held on 09.04.2017 at NIB, NOIDA for WHO Rotational Fellowship selection is as under. Marks obtained by the candidates have been mailed to them.

S.No.	Name & Designation	Roll No.
1	Ms. Rubina Bose, DDC(I)	206
2.	Ms. A. Visala, DDC(I)	204
3.	Sh. Praveen A. Jagtap, DI	205
4.	Sh. D.K. Sable, ADC(I)	210
5.	Sh. Shiv Kumar, ADC(I)	212
6.	Sh. Ashish Rai, DI	209
7.	Sh. Navneet Pratap Singh, ADC(I)	226
8.	Sh. Vinay Kumar Gupta, DI	219
9.	Ms. Nisha Sankhwar, DI	217
10.	Ms. Shradha Srivastava, DI	203
11.	Ms. Swati Srivastava, DDC(I)	202
12.	Sh. Abhishek Chawla, DI	225
13.	Sh. Sushant Sharma, ADC(I)	216
14.	Sh. P. Manavalan, DI	211
15.	Sh. Rajesh Kumar Verma, DI	201
16.	Sh. Sanjay Kumar Agarwal, DI	207
17.	Sh. Jayant Kumar, ADC(I)	214
18.	Sh. Nitin M. Jadhav, DI	213
19.	Sh. Gaurav Kumar, ADC(I)	218
20.	Sh. Sidharth Sahai Malhotra, DI	221
21.	Ms. Bharti, ADC(I)	222
22.	Sh. Inderjeet Singh Hura, ADC(I)	220

Officers from S.Nos. 1 to 4 have been selected for the proposed WHO Rotational Fellowship. Officer at S.No. 5 have been kept as reserve.

This examination is going to be a continuous process for selecting officers for these Fellowships. Examination for selecting next batch of

officers for these Fellowships will be held in the coming months. The examination will be of two hours duration and in 3 Parts. Sample Question Papers of all the three parts are also attached for the benefit of officers appearing in the next examination to enable them to prepare for the examination. It is also proposed to make this examination compulsory for all DDC(I)s & ADC(I)s, while it will be optional for Drug Inspectors with requisite experience/age.


(Arun Sharma)
Director(A)

IT Cell, CDCO (HQ) – for placing on the website of CDSCO.



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Part I

[Maximum Mark 30]

[Time permitted 40 Minutes]

Q. 1 Write an essay not exceeding 250 words on how to Leverage comparative cost advantage and quality for increasing the export of pharmaceutical products from India and generating white collar jobs.

[15]

Q.2 Read the following passage and answer the questions given at the end of the passage:

People talk of memorials to him in statues of bronze or marble or pillars and thus they mock him and belie his message. What tribute shall we pay to him that he would have appreciated? He has shown us the way to live and the way to die and if we have not understood that lesson, it would be better that we raised no memorial to him, for the only fit memorial is to follow reverently in the path he showed us and to do our duty in life and in death.

He was a Hindu and an Indian, the greatest in many generations, and he was proud of being a Hindu and an Indian. To him India was dear, because she had represented through the ages certain immutable truths. But though he was intensely religious and came to be called the Father of the Nation which he had liberated. Yet no narrow religious or national bonds confined his spirit. And so he became the great internationalist, believing in the essential unity of man, the underlying unity of all religions, and the needs of humanity and more specially devoting himself to the service of the poor, the distressed and the oppressed millions everywhere.

His death, brought more tributes than have been paid at the passing of any other human being in history. Perhaps what would have pleased him best was the spontaneous tributes that came from the people of Pakistan. On the morrow of the tragedy, all of us forgot for a while the bitterness that had crept in, the estrangement and conflict of these past months and Gandhiji stood out as the beloved champion and leader of the people of India, of India as it was before partition cut up this living nation.

What was his great power over the mind and heart of man due to? Even we realise, that his dominating passion was truth. That truth led him to proclaim without ceasing that good ends can never be attained by evil methods, that the end itself is distorted if the method pursued is bad. The truth led him to confess publicly whenever he thought he had made a mistake – Himalayan errors he called some of his own mistakes. That truth led him to fight evil and untruth wherever he found them, regardless of the consequences. That truth made the service of the poor and the dispossessed the passion of his life, for where there is inequality and discrimination and suppression there is injustice and evil and untruth. And thus he became the beloved of all those who have suffered from social and political evils, and the great representative of humanity as it should be. Because of that truth in him wherever he sat, became a temple and where he trod was hallowed ground.

- Jawahar Lal Nehru

Question

1. About whom is the passage written? [1]
2. Why does Nehru make the difference about being a "Hindu" and an "Indian"? Is there any difference really? [Not more than three sentence] [2]
3. What great lesson did this great man show us for life? [Two sentences] [2]

4. Mention some of the virtues of 'the great internationalist'?
[Not more than three sentence] [2]
5. Nehru seems to suggest that his hero was 'the beloved champion and leader of the people of India' only before the partition of Pakistan and India. Do you agree with that? Explain
[In Three sentences] [2]
6. What did 'truth' mean to this great man? [1]
7. Give the meaning of the following in the context of the passage: memorials, immutable, essential, estrangement, spontaneous, discrimination, dominating, Himalayan. [4]
8. What could, according to Nehru be the best tribute to the great man after his death? [1]



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PART – II

Time: 40 Min
[Marks: 40]

1. Arrange the following drug discovery process in the order of concept to product life cycle. [1]

- a) Compound screening or lead optimization
- b) Human Pharmacology trials
- c) Preclinical Pharmacology
- d) Therapeutic exploratory Trials
- e) Post Marketing Surveillance Study
- f) Therapeutic Confirmatory Trials

Identify the correct order/sequence given below:

- | | |
|----------------------|----------------------|
| i) a, c, b, d, f, e | ii) a, b, e, d, f, c |
| ii) b, e, a, d, f, c | iv) a, b, e, c, f, d |

2. The study of the use and effects/side-effects of drugs in large number of people with the objective of supporting rational and cost-effective use of drugs in the population and thereby improving health outcomes, is called _____. [1]

3. What is the frequency of PSUR submission to Licensing Authority after New Drugs approval as per Schedule Y of Drugs and Cosmetics Rule 1945? [1]

4. Reverse Osmosis is the phenomenon of diffusion of solvent through semi-permeable membrane from lower concentration gradient to higher concentration gradient under the influence of high pressure. [True/False] [1]

5. Match the correct method of sterilisation for following below mentioned materials: [2]

Table I	
Materials	
i)	Glass Vial
ii)	Aqueous thermo labile solutions
iii)	Aqueous thermo stable solutions
	Radiation
iv)	Orthopaedic implants

Table II	
Method of Sterilisation	
a)	Steam sterilization
b)	Dry Heat sterilization
c)	Exposure to ionizing
d)	Filtration

Write the roman no. and alphabet in respect of table I and table II respectively -

(i) (ii) (iii) (iv)

6. Define the periodicity of the environmental parameters monitoring for sterile manufacturing area as per Schedule M of Drugs & Cosmetics Rules, 1945. [3]

a) Particulate monitoring in air

b) HEPA filter integrity testing (smoke testing)

c) Air pressure differentials

d) Air Changes Rates

e) Temperature and Humidity

f) Microbiological monitoring by settle in aseptic area

7. Write the name of four degradation studies performed during analytical method validation. [3]

8. Match the bio indicators used and sterilization techniques: [4]

Method of Sterilisation	Bio indicator strain proposed for validation of the sterilization process
a. Steam sterilization	i. spores of <i>Bacillus subtilis</i>
b. Filtration	ii. spores of <i>Bacillus stearothermophilus</i>

c. Exposure to ionizing Radiation	iii. microbiological challenge of 10^7 CFU of <i>Brevundimonasdiminuta</i> per cm^2 of the filter surface
d. Dry Heat sterilization	iv. spores of <i>Bacillus pumilus</i> or spores of <i>Bacillus cereus</i> or <i>Bacillus sphaericus</i>

Write alphabet for method and roman numeral for bio indicator.

a b c d

9. Which of the following is a polysaccharide vaccine: [1]

- a) Anthrax vaccine
- b) Rabies vaccine
- c) Hepatitis A
- d) Hib vaccine

10. Current WHO guidelines recommending the dead leg of continuous water circulation loop should be less than. [1]

- a) 5D
- b) 8D
- c) 6D
- d) 3D

11. What does Sensitivity mean in validation of an analytical procedure? [1]

- a) The ability to measure an analyte free of interference from other components

- b) The degree of agreement among the test results
- c) The closeness of the results to the true value.
- d) The ability to produce results directly proportional to the analyte concentration.
- e) The capacity to record small variations in concentration.

12. The high-level document that summarizes the manufacturer's overall philosophy, intentions and approach, to be used for establishing performance adequacy is called
_____ [1]

13. The document which defines what the system is intended to do i.e. basic needs or functionality of the system from the end user's perspective and also describe the capacity, safety and control requirements is called
_____ [1]

14. The test to verify the proper functioning of an operating system, i.e., the electronics, the equipment, the specimens and the analytical operations is called
_____ [1]

15. Write at least three parameters which should be validated during analytical method in case of the cleaning validation.
[3]

16. Which type of tablets are exempted from Disintegration testing?
[1]

17. Air re-circulation:
[1]

- a) Is allowed if there is no danger of cross-contamination.
- b) Is always the preferred setup for air handling systems.
- c) Is allowed only if terminal HEPA filters are installed.
- d) Is allowed provided that the make-up fresh air is more than 15%.

Indicate the correct options-

18. Air diffusers should be of the low induction type so that:
[1]

- a) Laminar (uni-directional) flow can be maintained in clean rooms.
- b) Circulation of dust in the room is minimized.
- c) So that drafts are not created.
- d) Proper room flushing is ensured.

19. _____ are the examples of live attenuated vaccines. [1]

- a) Oral polio vaccine and Varicella-Zoster virus vaccine (VZV)
- b) Pertussis vaccine, Inactivated Polio Vaccine (IPV)
- c) Haemophilus influenzae PRP conjugate vaccine and Pneumococcal conjugate vaccine
- d) Tetanus toxoid and Diphtheria toxoid

20. Expand the following [3]

a) VVM

b) OOS

c) OOT

d) TRS

e) CPCSEA:

f) RCGM

21. _____ % fall of assay value of any product with respect to initial value is considered as the significant change during conduct of stability studies. [1]

- a) 0.5%
- b) 5%
- c) 5.5%
- d) None of the above

22. Match the following: [4]

S.N.	Table I	S.N.	Table II
a)	Special Courts	i)	Section 35
b)	Power of central Government to give directions	ii)) Section 34
c)	Publication of sentences passed under D&C Act	iii)	Section 36AB
d)	Offences by companies	iv)	Section 33 P

- a)
- b)
- c)
- d)

23. Swasthya Adhikar Manch V/s Union of India is a case filed in the Court and relates to [1]

24. Section_____ of the Drugs and Cosmetics Act, 1940 provides power to the Central Government to regulate, restrict manufacture, etc., of drug and cosmetic in public interest. [1]

25. The science and activities relating to detection, assessment, understanding and prevention of adverse effects or any other drug-related problem is called as _____ . [1]



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Part III

[Maximum Marks – 40]

[Time 40 Minutes]

Q.1 Fill in the Blanks:

[11]

- (I) Placebo is a Latin name which means.....
- (II) Anticoagulant interacts with food high in
- (III) Digoxin interacts with Food item called
- (IV) Paracentesis is the insertion of a needle into.....
..... for removal of.....
- (V) Shigella is a micro-organism that causes gastroenteritis through.....
- (VI) Repeated use of excessive doses of drugs belonging to the group.....
causes kidney damage.
- (VII) Thyroids hormone regulates the rate of.....
- (VIII) Growth hormones is produced in gland
and it controls growth
of.....
production.
- (IX) Renin hormone is produced in and
controls.....

- (X) Leptin is a hormone which is produced in and controls
- (XI) Dyspepsia refers to pain in.....

Q.2 Write the route through which the following drugs are taken: [10]

Drug	Route	Side Effect [Maximum Two]
Isoniazid		
Rifampin		
Pyrazinamide		
Ethambutol		
Streptomycin		

Q.3 Match the infection in table A with Host in table B

[5]

S.No.	Table A	S.No.	Table B
1.	Epidemic typhus	a)	Sheeps, cattle and goats
2.	Murine tphus	b)	Rodents
3.	Scrub typhus	c)	Rodents
4.	Rickettsialpox	d)	Cats, rodents, and opossums
5.	Q fever	e)	Human beings

Ans. **1.....**

4.....

2.....

5.....

3.....

Q.4 Explain in one sentence or phrase the following terms

[5]

(i) Paracoccidioidomycosis –

(ii) Cryptococcosis –

(iii) Hypertrichosis –

(iv) Alopecia –

(v) Actinomycosis –

Q.5 Write generic names of the following:

[9]

Chemical Name	Generic Name
N-(4-hydroxyphenyl) acetamide	
7-chloro-1, 3-dihydro-1-methyl-5-phenyl-2H-1, 4-benzodiazepin-2-one	
4-[4-(p-chlorophenyl)-4-hydroxypiperidino]-4'-fluorobutyrophenone	
5-thia-1-azabicyclo[4.2.0]-oct-2-ene-2 carboxylic acid, 7-[(aminophenylacetyl)amino]-3-methyl-8-oxo, monohydrate	
dl-threo-2-(methylamino)-1-phenylpropan-1-ol	
N''-cyano-N-methyl-N'-[2-[1(5-methyl-1H-imidazol-4yl)methyl]thio]]ethyl]guanidine	