REGISTERED No. P. 398

THE ORISSA GAZETTE

PUBLISHED BY AUTHORITY

No. 15 CUTTACK, FRIDAY, APRIL 13, 1945

SEPARATE PAGING IS GIVEN TO THIS PART, IN ORDER THAT IT MAY BE FILED AS A SEPARATE COMPILATION

PART IV

Regulations, Orders, Notifications and Rules, of the Government of India, of the Government of Bihar, and of the High Court. Papers extracted from the *Gazette of India* and Provincial Gazettes. Orders of Commandants of Volunteers Corps

FINANCE DEPARTMENT
NOTIFICATION

The 5th April 1945

No. 376 F.3.—The following notification, issued by the Government of India, Finance Department (Communications), is republished for general information.

By order of the Governor
J. E. MAHER
Addl. Secy. to Government

New Delhi, 15th February 1945

No. D.949-PT/45—In exercise of the powers conferred by section 6 of the Post Office National Savings Certificates Ordinance, 1944 (XLII of 1944), the Central Government is pleased to make the following amendment to the Post Office National Savings Certificates Rules, 1944, published with the Notification of the Government of India in the Finance Department (Communications) No. D.8024-PT/44, dated the 9th December 1944, namely :—

In rule A (2) (ix) of the said Rules, for the words—

" Fo the encouragement of thrift and for the mutual benefit of the members ", substitute " of a charitable, religious, educational or recreational nature, or for the encouragement of thrift, provided that the funds are for the mutual benefit of the members, or the general public ".

M. K SENGUPTA
Financial Adviser, Communications

HEALTH AND LOCAL SELF-GOVERNMENT DEPARTMENT
NOTIFICATION

The 4th April 1945

No. 1307-L.S.-G.—The following Order made by the Central Government in the Department of Education, Health and Lands, is republished for general information.

By order of the Governor
M. AZFAR
Secretary to Government

New Delhi, 6th March 1945

No. D. 292-H(c)/45—In exercise of the powers conferred by sub-rule (2) of rule 81 of the Defence of India Rules, the Central Government is pleased to make the following Order, namely :—

The Penicillin Control Order, 1945.

1. (1) This Order may be called the Penicillin Control Order, 1945.

(2) It extends to the whole of British India.

(3) It shall come into force at once.

2. In this Order—

(*a*) " licensing authority " means the Director General, Indian Medical Service ;

(*b*) " penicillin " means the anti-infective organic acid which is known to be produced by *Penicillium notatum* ;

(*c*) " preparation of penicillin " means penicillin (crude filtrate), penicillin (dried crude filtrate) or a penicillin salt or solution thereof ;

(*d*) " penicillin (crude filtrate) " means the solution obtained by the filtration of cultures containing penicillin grown on or in a liquid or other medium, or of extracts from such cultures ; its proper name is " penicillin (crude filtrate) " ;

(*e*) " penicillin (dried crude filtrate) " means the substance obtained by reducing penicillin (crude filtrate) to a dry condition ; its proper name is "penicillin (dried crude filtrate) " ;

(*f*) " penicillin salt " means the substance separated by the application of chemical and physical processes from the culture medium on or in which a mould producing penicillin has been grown, and reduced to a dry condition ; its proper name is " penicillin " followed by a word or words indicating the nature of the preparation, as, for example, " penicillin (sodium salt)".

3. No person shall manufacture for sale any penicillin or preparation of penicillin or any product purporting to be or to have the properties or therapeutic effects of penicillin or of a preparation of penicillin except under, and in accordance with, the conditions of a licence issued by, or under the authority of, the licensing authority.

4. No person shall manufacture for sale, sells offer for sale or distribute any product purporting to be or to have the properties of therapeutic effects of penicillin or of a preparation of penicillin unless it conforms to the provisions of this Order.

5. No person shall sell, offer for sale or distribute, a substance purporting to contain the active principles of penicillin by any name other than the names mentioned in sub-clauses (*b*) to (*f*) of clause 2.

6. The licensing authority shall not issue a licence for the manufacture of penicillin or of a preparation of penicillin unless it is satisfied that the applicant is a fit person and is in a position and willing to observe the conditions of the licence and the provisions of the Order.

7. A licence to manufacture for sale shall be in the Form appended to this Order.

8. A licensee shall—

(*a*) provide and maintain an adequate staff and adequate premises and plant for the proper manufacture and storage of the substance in respect of which the licence is granted ;

(*b*) either

(*i*) provide and maintain an adequate staff and adequate premises and plant for carrying out such tests as may be required to be carried out by him under the provisions of this Order, or

(*ii*) make arrangement with an institution approved by the licensing authority for such tests to be regularly carried out on its behalf by that institution ;

(*c*) employ for the supervision of the processes of manufacture and of the carrying out of the tests a person or persons approved by the licensing authority ;

(*d*) keep permanent records of the details of manufacture of each batch of the substance which is issued for sale and of the application of such tests thereto in such a form as to be available for inspection and to be easily identified by reference to the number of the batch as shown on the lable of each container ;

(*e*) allow any inspector authorised by the licensing authority in that behalf, to enter with or without prior notice any premises where the manufacture is carried on and to inspect the premises, the plant and the process of manufacture and the means employed for standardising and testing the substance and the records relating to the manufacture and sale of the substance ;

(*f*) allow any inspector authorised by the licensing authority to take samples of the manufactured product and supply to such inspector such information as he may require for the purpose of ascertaining whether the provisons of this Order have been observed ;

(*g*) report to the licensing authority any changes in the expert staff responsible for the manufacture or testing of the substance and any material alterations in the premises or plant used for that purpose which have been made

since the date of the last inspection made on behalf of the licensing authority before the issue of the licence ;

(*h*) on request, furnish to the licensing authority or such other authority as the licensing authority may direct, from every batch of the substance or from such batch or batches as the licensing authority may from time to time specify, a sample of such amount as the authority may consider adequate for any examination required to be made and the licensee shall, if so required, furnish full protocols of the tests which have been applied ;

(*i*) if the licensing authority so directs, not sell or offer for sale any batch in respect of which samples protocols are furnished under (*h*) above, until a certificate authorising the sale of the batch has been issued to him by or on behalf of the licensing authority ;

(*j*) on being informed by the licensing authority that any part of any batch of the substance has been found by the licensing authority not to conform with the standards laid down in the Schedule to this Order, and on being directed so to do, withdraw the remainder of that batch from sale and, so far as may in the particular circumstances of the case be practicable, recall all issues made from that particular batch ;

(*k*) maintain such records of the manufacture and sale of penicillin and preparations of penicillin as the licensing authority may direct ;

(*l*) ensure that no substance manufactured under the licence shall be sold unless the precautions necessary for preserving its properties have been observed throughout the period of manufacture ;

(*m*) comply with the provisions of this Order and with such further requirements, if any, as may be specified in instructions issued by the licensing authority from time to time.

9. (1) The licensing authority may suspend for such period as it thinks fit, or cancel, a licence issued under this Order, if in its opinion, the licensee has failed to observe the provisions of this Order or any conditions of the licence.

(2) A licensee whose licence has been suspended or cancelled may, within thirty days of the order, appeal against it to the Central Government whose decision shall be final.

10. No licensee shall cause or permit any preparation of penicillin to be issued or removed from the premises unless samples taken from the batch of which it formed part have been subjected, under the direct supervision of a person approved by the licensing authority, to the tests laid down in the Schedule to this Order and have passed those tests.

11. The container for liquid preparations of penicillin shall be made of glass as respects which the licensee has satisfied himself that it does not lead to the destruction of penicillin.

12. The label on the container shall indicate whether the preparation is suitable for parenteral injection.

13. In the case of preparations of penicillin intended only for local application, the label on the container and the label or wrapper on the package shall bear the words " Not to be injected " clearly printed in a distinctive colour.

14. The following particulars shall be clearly and indelibly marked on the label of the container and the wrapper :—

(*a*) the proper name of the substance ;

(*b*) name of the manufacturer ;

(*c*) a distinctive batch number by reference to which the details of manufacture and tests of the particular batch from which the substance in the container is taken are permanently recorded and available for inspection ; and

(*d*) the date on which the tests prescribed in the Schedule to this Order were completed.

15. If a preparation of penicillin as issued for sale is combined with any substance other than a simple diluent, the exact nature and strength of that diluent shall be stated on the label of the container.

16. Any person who sells penicillin or a preparation of penicillin shall maintain a record of all purchases and sales including the following particulars :—

(*i*) name and address of the persons from whom it was purchased and to whom it was sold ;

(*ii*) name of the manufacturer ; and

(*iii*) batch number ;

and such record shall be made available for inspection by any person authorised in this behalf by the licensing authority or the Provincial Government.

17. (1) Any person authorised by the licensing authority or the Provincial Government in this behalf may enter and inspect any premises where he has reason to believe

(*a*) that penicillin or a preparation of penicillin is being manufactured, stocked or sold, or

(*b*) that an article purporting to be or to possess the properties or therapeutic effects of penicillin or of a preparation of penicillin is being manufactured, stocked or sold in contravention of this Order, and take samples thereof.

(2) Such person may, if he has reason to believe that any stocks are not in comformity with the standards or do not satisfy the tests laid down in the Schedule to this Order, direct that pending the orders of the licensing authority or the Provincial Government such stocks shall not be sold or distributed.

18. The licensing authority or the Provincial Government may prohibit the distribution or sale, and order the seizure, of the substance which forms part of a batch of which a sample has been reported on a test at a laboratory approved by the Central Government or Provincial Government to be not in conformity with the standards or as not satisfying the tests laid down in the Schedule and Annexures I and II to this Order.

FORM

Licence to manufacture for sale Penicillin and preparations of Penicillin.

Number of licence and year of issue.....
.....is hereby licensed to manufacture for sale at the premises situated at.....
Penicillin and preparations of Penicillin.

2. Names of approved expert staff.....

3. The licence will be in force for a period of two years from the date of issue unless it is previously cancelled.

4. The licence is subject to the condition stated below and to the provisions of the Pencillin Control Order, 1945.

Signature.....

Designation.....

Date of issue.....

CONDITION

The licence and any certificate of renewal in force shall be kept on the approved premises and shall be produced at the request of any person deputed by the licensing authority under the Penicillin Control Order, 1945.

SCHEDULE

Standard preparation

1. The standard preparation is a quantity of a dry penicillin salt kept at the National Institute for Medical Research, Hampstead, London.

Unit of standardisation

2. The unit of penicillin for the purpose of these regulations is the activity contained in such an amount of the standard preparation as may be indicated from time to time by the Medical Research Council in the United Kingdom

Tests of Potency

3. A preparation of pencillin shall be tested for potency in units, which shall be determined, by comparative tests in relation to penicillin which has been standardised in relation to the standard preparation ; by a method approved by the licensing authority. The potency so determined shall be expressed in units per c. c. in the case of liquid preparations and in units per milligramme in the case of solid preparations.

Quality

4. (1) Penicillin (crude filtrate) containing less than 10 units per c.c. and penicillin (dried crude filtrate) containing less than 0·75 units per milligramme, shall not be issued.

(2) A preparation of penicillin intended for use in making solutions for parenteral injection shall contain not less than 150 units of penicillin per milligramme

Tests for sterility.

5. (1) The provisions of Annexure I to this Schedule relating to the application of tests for sterility shall apply to preparations of penicillin with such modifications, if any, as the licensing authority may from time to time approve.

(2) The provisions of Annexure II to this Schedule shall apply to a preparation of penicillin which is alleged to contain *Penicillium Notatum*, or any other organism in living condition.

Tests for freedom from abnormal toxicity

6. Preparations of penicillin intended for use by parenteral injection shall be subjected to the following test for absence of abnormal toxicity :—

A quantity of the preparation containing not less than 1,000 units of penicillin, in a volume not exceeding 0·5 c.c. of a water solution, shall be injected intravenously into each of five normal mice each weighing approximately 20 grammes. The sample shall be treated as having passed the test if either—

(*a*) The injection does not cause death in any of the mice within twenty-four hours from the injection, or

(*b*) the injection having caused death in one only of the mice within that period, further such injections in five other such mice do not cause the death of any of these mice within twenty-four hours from the injection.

Tests for freedom from pyrogenic substances

7. Preparations of penicillin intended for use by parenteral injection shall be subjected to the following tests for absence of pyrogenic substances :—

A quantity of the preparation containing not less than 10,000 units of penicillin, in a pyrogen-free watery solution, shall be injected intravenously into each of three normal healthy rabbits each weighing not more than 2·5 kilograms. The body temperature of the rabbits shall be recorded one and one-half hours before the injection and either continuously for three hours after the injection or at the end of one, two and three hours after the injection. The sample shall be treated as having passed the test if the average maximum temperature increase of the three rabbits does not exceed 1·2°C.

ANNEXURE I

Tests

I. The tests shall be applied—

(*a*) to samples taken from each batch of the substance before the operation of filling and sealing the containers in which it is to be issued has commenced ; and

(*b*) to the contents of sample containers when ready for issue.

Amount of samples

II. The samples required to be taken under the last preceding article shall be taken in the following proportions :—

(*a*) In the case of samples taken from the batch, the quantity taken shall be not less than 0·1 per cent of the total volume of the batch if the volume is not more than 10 litres, and not less than 10 c. c. if the volume is 10 litres or more, but shall in no case be less than 1 c.c. :

Provided that if, at the time when the test is made, the batch is contained in a number of bulk containers, samples in the foregoing proportions shall be taken from each of such bulk containers and be separately tested ;

(*b*) in the case of the contents of sample containers the number of containers taken for test shall be not less than 1 per cent of the total number filled from the batch if this number is not more than 1,000 and not less than 10 containers if the total number is more than 1,000.

Method of preparing and using media

III. (1) The tests shall be made on fluid media, the quantity of medium contained in each tube or other vessel used in the test being such as to secure that any phynolic antiseptic present in the sample is diluted to less than 0·01 per cent.

(2) In the case of a test for aerobic organisms the medium shall consist either of a meat extract with the addition of 1 per cent of peptone, or of such an equivalent as can be prepared by the tryptic digestion of muscle. After the final sterilisation the hydrogen-ion concentration of the medium shall be between the limits represented by pH = 7·2 and pH = 7·8.

(3) In the case of a test for anaerobic organisms the medium shall consist of a nutrient broth similar to that used in testing for aerobic organisms, with the addition of heat coagulated muscle of an amount sufficient to occupy a depth of not less than 1 centimetre at the bottom of the tube. After the final sterilisation the hydrogen-ion concentration of the medium shall be between the limits represented by pH = 7·2 and pH = 7·8. Before the test inoculation the medium shall be heated to 100°C. for a period sufficient to free it completely from dissolved oxygen, and then be cooled to 37°C. or lower.

(4) The licensing authority may, at the request of any licensee authorise the use, for the test prescribed under either paragraph (2) or (3) of this paragraph, of any other specified medium or method of using a specified medium, on being satisfied that its use affords equal certainty in the detection of the presence of living aerobic or anaerobic organisms as the case may be.

Method of testing

IV. (1) In the case of samples taken from the batch each sample shall be inoculated into tubes or other vessels containing the media, one-half of the total volume of the sample being used for the aerobic and one-half for the anaerobic test.

(2) In the case of the contents of sample containers the contents of each container shall be subjected to the test for aerobic and the test for anaerobic organisms. When the volume in the container is 2 c.c. or more, 1 c.c. shall be used for each test. When the volume in the container is less than 2 c.c. the contents shall be divided into two approximately equal parts, one part being used for the aerobic and the other for the anaerobic test.

(3) The inoculated tubes shall be incubated at 37°C. for five days and be examined after incubation, permanent records being kept of the examination of each tube.

V. (1) If at this examination no growth of micro-organisms is found in any tube, the sample may be treated as having passed the test.

(2) If at the examination a growth of micro-organisms is visible further samples may be taken and the tests may be repeated on the further samples so taken ; but no container the contents of which form part of the batch shall be issued until such further samples have passed the test. The process of taking samples from the batch for a test may, if necessary, be repeated twice :

Provided that if the same organism is visible in more than one test, the batch shall be treated as not sterile and the material contained in the batch shall not be issued or used as part of a further batch unless and until it has been re-sterilised and has passed the tests.

ANNEXURE II

A preparation of penicillin, which is alleged to contain *Penicillium notatum* or any other organism in living condition shall be tested, in such manner as the Licensing Authority shall approve, for the purpose of determining :—

(*a*) that the substance contains, in living condition, *Penicillium notatum* or any other organism which it is alleged to contain ;

(b) that its administration is free from danger ;
(c) that it is free from living organisms other than those which it is alleged to contain.

S. H. Y. OULSNAM
Joint Secretary to the Government of India

DEPARTMENT OF SUPPLY AND TRANSPORT

NOTIFICATION

The 4th April 1945

No. 7455-S.T.—The following notifications issued by the Government of India in the Department of Industries and Civil Supplies, are republished for general information.

By order of the Governor
C. S. JHA
Secretary to Government

New Delhi, 3rd February 1945

No. 106-TA/44—In exercise of the powers conferred by rule 20 of the Defence of India Rules, the Central Government is pleased to direct that the following further amendment shall be made in the Cotton Cloth and Yarn (Transmission by Post) Prohibition Order, 1944, namely :—

In the Schedule to the said Order, under the heading " Authorities empowered to despatch or receive cotton cloth or yarn by post ", for entry 3 the following entry shall be substituted, namely :—

" 3. Chief Inspector of Cotton Textiles, Bombay and branches including I. C. T. Laboratories, Ahmedabad and I. G. S. Outstation Laboratories, Madras ".

New Delhi, 17th February 1945

No. 106-TA/44—In exercise of the powers conferred by rule 20 of the Defence of India Rules, the Central Government is pleased to direct that the following further amendment shall be made in the Cotton Cloth and Yarn (Transmission by Post) Prohibition Order, 1944, namely :—

In clause 7 of the said Order, after the word " Commissioner " the words " Bombay, or any other officer authorised by him in this behalf " shall be inserted.

J. D. KAPADIA
Deputy Secy. to the Govt. of India

CENTRAL BOARD OF REVENUE

ORDER

The 21st March 1945

C. No. 30-Admn(Per)/45—The following officers have been posted to the Ranges noted against them in the Bihar and Orissa Income-tax Department, with effect from the dates noted :

Mr. H. M. Patnaik, Appellate Assistant Commissioner of Income-tax.	Central Range, Patna.	2nd March 1945.
Mr. K. P. Sinha, officiating Additional Appellate Assistant Commissioner of Income-tax.	Darbhanga ..	7th March 1945.

RANGANATHAN
Secretary, Central Board of Revenue

GOVERNMENT OF INDIA

FINANCE DEPARTMENT (CENTRAL REVENUES)

NOTIFICATION

INCOME-TAX ESTABLISHMENT

The 24th March 1945

No. 17-Camp.—In exercise of the powers conferred by sub-section (3) of section 5 of the Indian Income-tax Act, 1922 (XI of 1922), the Central Government has been pleasd to appoint Mr. H. M. Patnaik as an Appellate Assistant Commissioner of Income-tax, with effect from the 2nd March 1945.

RANGANATHAN
Dy. Secy. to the Govt. of India

CUTTACK : Printed and Published by S. E. Khan, Superintendent, Govt. Press. O. G. 2—393—13-4-1945