ANNEXURE-I
Ref. Clause No. 4. 1 (n) (i) &14.1

DECLARATION

I do hereby declare that I will supply the **Essential Drugs and Medicines** as per the designs in Primary, Secondary packing and labels given in enclosures to this Annexure and as per the instructions given in this regard.

Signature of the Tenderer
Name in capital letters with Designation

Attested by Notary Public.

ANNEXURE-II
Ref. Clause No. 4.1 (n) (ii) and 14.1

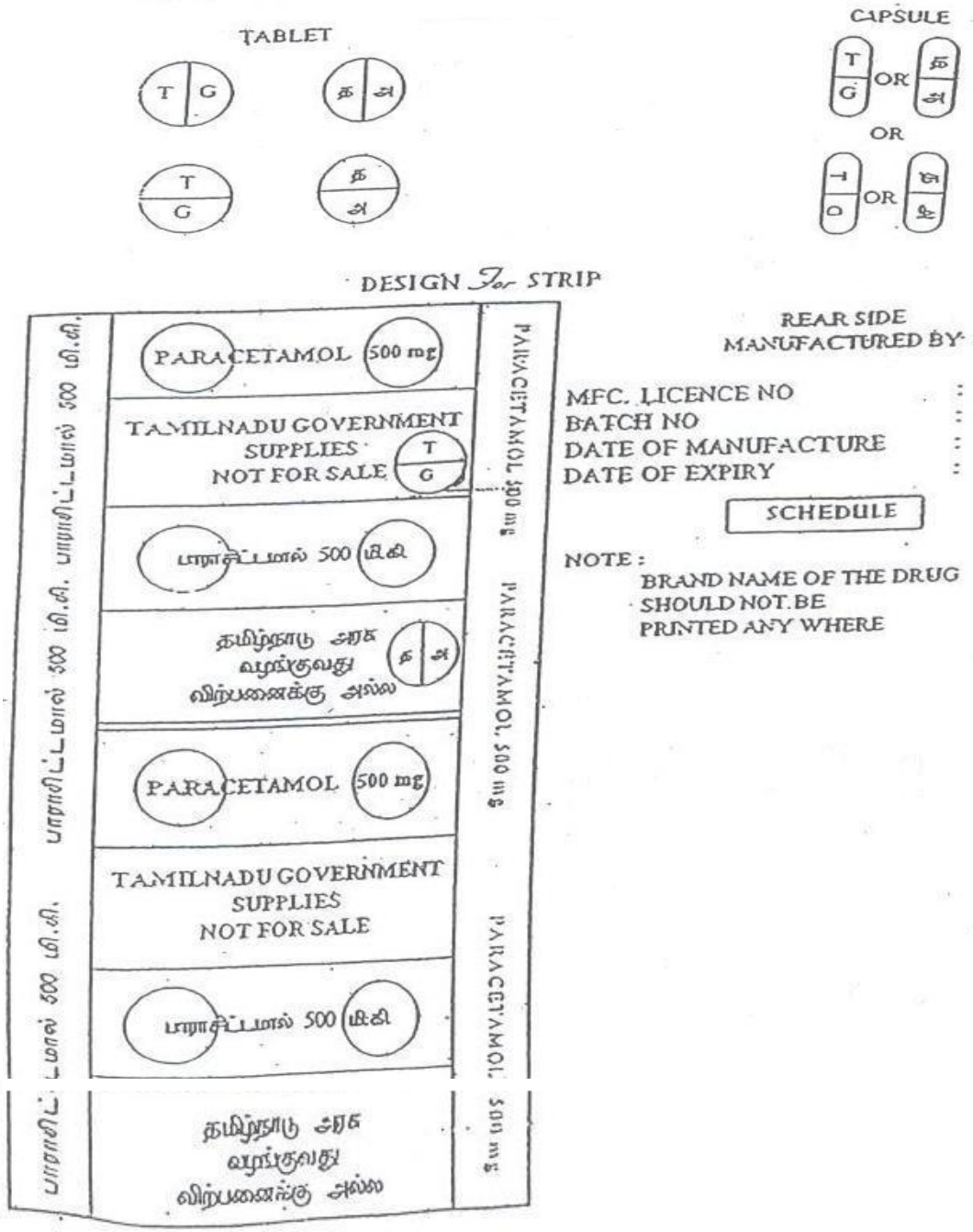
DECLARATION

I / We do hereby declare that I will supply the **Essential Drugs and Medicines** by affixing the logo for Secondary / Primary packing for the imported drugs along with Brand / trade Names as per the designs given in enclosures to this Annexure and as per the instructions given in this regard.

Signature of the Tenderer
Name in capital letters with Designation

Attested by Notary Public.

ENCLOSEURE-I TO ANNEXURE-I and II – REFER CLAUSE NO.4.1.(n)
DESIGN FOR



ENCLOSURE-II TO ANNEXURE-I and ANNEXURE-II
Ref. Clause No. 4.1. (n) & Clause No: 14

DESIGNS FOR LOGORAMS

INJECTIONS

Injection in ampoule form should be supplied in Double constructed neck ampoules with the label bearing the words "**TamilNadu Govt. Supplies - Not for sale**" overprinted and the following logogram which will distinguish from the normal trade packing.

The vials should be supplied with aluminum seals containing the following logogram.

LIQUIDS

Liquid preparations should be in glass bottles with pilfer-proof caps bearing the following logograms:

The top of the cap and the label to be affixed on the containers should bear a distinct colour different from the colour of the label of the trade packs and they should be overprinted in red colour with the words "**TamilNadu Government Supplies – Not for Sale**" and the logogram above.

OINTMENTS

Ointments should be supplied in tubes bearing the following logograms and the words "**TamilNadu Government Supplies – Not for Sale**" overprinted in red colour.

ENCLOSURE-III TO ANNEXURE-II and ANNEXURE-II (A)

SPECIMEN LABEL FOR
OUTER CARTON(20cm x 15cm)

TAMIL NADU GOVT. SUPPLY
NOT FOR SALE

~~~~~~~~~~~~~~~~~~~~~~~~~~~~

ACENOCOUMAROL TAB. I.P

~~~~~~~~~~~~~~~~~~~~~~~~~~~~

10 x 10 TABLETS

Batch. : xxxxxxx **Quantity Packed: 100x10x10**
Mfg Date: JUN- 2021
Exp Date:MAY -2023

Manufactured by:

ANNEXURE-III
Ref. Clause No. 4.1 (j)

DECLARATION

I/We M/s._____ represented by its Proprietor / Managing Partner / Managing Director having its Registered Office at _____and its Factory Premises at _____ do declare that I/We have carefully read all the conditions of tender in Ref.No.**010/M(P)/DRUG/TNMSC/2021, Dated.01.12.2021** for supply of Essential Drugs and Medicines under rate contract system for one year from the date of acceptance floated by the TamilNadu Medical Services Corporation Ltd., Chennai - 600008 and accepts all conditions of the Tender.

I/We declare that we possess the valid licence and GMP Certificate as per revised Schedule-'M'/WHO-GMP issued by the Competent Authority and complies and continue to comply with the conditions laid in Schedule M of Drugs & Cosmetics Act, 1940 and the Rules made thereunder. I/We furnish the particulars in this regard in enclosure to this declaration.

I am/we are aware of the Tender Inviting Authority's right toforfeit the Earnest Money Deposit and/or Security Deposit and blacklisting me/us for a period of 5 years if, any information furnished by us proved to be false at the time of inspection and not complying the conditions as per Schedule M of the said Act for a period of 5 years.

Signature :
Seal Name & Address :

To be attested by the Notary.

Enclosure to Annexure – III Clause 4(1) (j)

DECLARATION FOR COMPLIANCE OF cGMP/WHO-GMP
(In Case of Loan Licensee, the following details to be provided for the Manufacturing Facility)

01. Name and Address of The Firm :

02. Name of Proprietor / Partner / Director :

03. Name and Designation of Person Present :

04. GMP Certificate **As per Revised Schedule "M"/WHO GMP**

05. Details of Licenses Held With Validity :

06. Number of Workers Employed :Ladies :
Gents :

07. Whether Workers Provided with Uniform : Yes / No

08. Whether Medical Examination done for the Workers : Yes / No

09. **Hygienic Condition**

(I) Surrounding : Satisfactory / Not Satisfactory

(II) Production Areas : Satisfactory / Not Satisfactory

(III) Other Areas : Satisfactory / Not Satisfactory

10. Provision For Disposal of Waste : Yes / No

11. Heating System : Yes / No

12. Whether Benches Provided in all Working Area : Yes / No

13. <u>Water Supply</u>

(A) Source :

(B) Storage Condition : Satisfactory / Not Satisfactory

(C) Testing
(With reference to Pathogenic Organization) : Yes / No

(D) Cleaning Schedule In Water Supply
System With Proper Records : Yes / No

(E) Type of Machinery installed as to Semiautomatic or Fully Automatic plant for water purification system along with cost and whether this is working, and if so he flow rate of Pharmaceutical water to must the requires preparation :

14. Air handling system along with list of machine and cost of the unit. Separately for sterile and non sterile preparation :

15. Whether the pollution control clearance is valid for Air and Water and if so the period upto which valid (copy of the certificate to be enclosed) :

16. Raw Material Storage Area
(Storage Facilities / Hygienic Condition) :

(I) Quarantine : Provided / Not Provided

(II) Passed Materials : Provided / Not Provided

(III) Rejected Materials : Provided / Not Provided

17. Finished Product Storage Area
(Hygienic / Storage) :

(I) Quarantine : Provided / Not Provided
(II) Released Material : Provided / Not Provided

18. Details of Technical Staff

Name	Qualification	Experience

For Manufacturing :

For Testing :

19. Testing Facilities (List of Equipments to be furnished Separately in the format to meet the bench mark vide Annexure)

Chemical Method : Yes / No

Instrumental : Yes / No
(Type of Instrument Provided as indicated in Annexure)

Biological : Yes / No

Micro Biological : Yes / No

Animal Testing : Yes / No

20. Remarks

(A) Whether Products Quoted to TNMSC are Endorsed in the Licence : Yes / No

(B) Whether the drugs Quoted to TNMSC have been Manufactured Earlier (Last 3 Years) : Yes / No

If Yes, Details Like

Sl.No	Date of Manufacturer	Name of the Drug	Batch No.	Batch Size	Date of Release

(C) Production Capacity (Section Wise)

PRODUCTION CAPACITY:

Tablet Section

Type of Equipments (1)	No. of Equipments (2)	Production Capacity of all the Equipments in column 2 per shift (3)	No of shift (4)	Production Capacity allotted for TNMSC (5)
Planatery mixer				
Fluidized bed drier				
Tray drier				
Mechanical shifter				
Multi mill				
Tablet compression machine				
1) With _____ number of station				
2) With _____ number of station				
3) With _____ number of station				
4) With _____ number of station				
Coating pan.				
Blister Packing machine				
Strip packing machine				

Capsule Section

Type of Equipments (1)	No. of Equipments (2)	Production Capacity of all the Equipments in column 2 per shift (3)	No of shift (4)	Production Capacity allotted for TNMSC (5)
Double cone blender				
Automatic capsule filling machine				

Type of Equipments (1)	No. of Equipments (2)	Production Capacity of all the Equipments in column 2 per shift (3)	No of shift (4)	Production Capacity allotted for TNMSC (5)
Semi-Automatic Capsule filling machine				
Hand filling machine				
Blister packing machine				
strip packing machine				

Parenteral Section

Type of Equipments (1)	No. of Equipments (2)	Production Capacity of all the Equipments in column 2 per shift (3)	No of shift (4)	Production Capacity allotted for TNMSC (5)
Small volume Parenteral				
Mixing Vessel				
Laminar Flow unit				
Filtration unit				
Ampoule filling machine (with No of head)				
Vial filling Machine (with No of head)				
Vial sealing machine				
Powder filling machine				
Autoclave for terminal Sterilization				
Ampoule labeling machine				
Vials labeling machine				

Large Volume Parenterals

Type of Equipments (1)	No. of Equipments (2)	Production Capacity of all the Equipments in column 2 per shift (3)	No of shift (4)	Production Capacity allotted for TNMSC (5)
Mixing vessel				
Filtration Unit.				
Filling Machine Autoclave for terminal Sterilization				
Labeling Machine				

Ointment/ Cream

Type of Equipments (1)	No. of Equipments (2)	Production Capacity of all the Equipments in column 2 per shift (3)	No of shift (4)	Production Capacity allotted for TNMSC (5)
Stream jacket vessel for mixing				
Ointment/cream filling machine				

Liquid Section

Type of Equipments (1)	No. of Equipments (2)	Production Capacity of all the Equipments in column 2 per shift (3)	No of shift (4)	Production Capacity allotted for TNMSC (5)
Bottle washing machine				
SS tank with capacity				
Filter press				
Colloidal mill				
Bottle Filling Machine				
Labeling Machine				

External Preparation

Type of Equipments (1)	No. of Equipments (2)	Production Capacity of all the Equipments in column 2 per shift (3)	No of shift (4)	Production Capacity allotted for TNMSC (5)
Mixing Vessel				
Filling machine				
Labeling machine				

(D) Any, Not Of Standard Quality Reports Of Product Quoted/ Approved By TNMSC (If Not, Nil Statement) : Yes / No

(E) Any Prosecution After Submission of Tender Documents. (If Not, Nil Statement) : Yes / No

(F) Chances Of Cross Contamination at Raw Materials/In Process/ Finished Product Stages And Steps/Facilities : Yes / No

(G) Validation of Equipments done : Yes / No

(H) Cleaning Schedule

(I) For Premises :

(II) For Equipments :

(I) Adverse Reaction, If Any and Reported :

Sl.No.	Description	Remarks
1	Whether any drug(s) manufactured by the tenderer has / have been recalled during last five years? If yes given details	

Sl.No.	Description	Remarks
2	What are the results of investigations on the recalled drug(s)?	
3	What action have been taken to prevent recurrence of recall of drug(s) on that particular account?	

(J) Complaints Received If Any and Steps taken. :

Sl.No.	Description	Remarks
1	Whether any drug(s) manufactured by the tenderer has / have been recalled during last five years? If yes given details	
2	What are the results of investigations on the recalled drug(s)?	
3	What action have been taken to prevent recurrence of recall of drug(s) on that particular account?	

Signature and Seal of
Proprietor / Partner / Director

To be attested by the Notary.

Annexure

Sl. No. (1)	Name of the Instruments (2)	No. of Instruments (3)	Cost of Instruments (4)	Whether it is in working condition (5)
1	Analytical Balance			
2	Infra-Red Spectrometer			
3	Karl Fisher Tritator			
4	Melting Point			
5	Brookfield Viscometer			
6	Polarimeter			
7	Autoclave			
8	Refractometer			
9	Sampling Booth			
10	UV-Vis Spectrometer			
11	HPLC			
12	Muffle Furnace			
13	Fuming Cupboard			
14	Micrometer			
15	Dissolution Tester			
16	Disintegration Tester			
17	Friability Tester			

Sl. No. (1)	Name of the Instruments (2)	No. of Instruments (3)	Cost of Instruments (4)	Whether it is in working condition (5)
18	Vernier Calipers			
19	IR Balance			
20	Hardness Tester			
21	Leak Test Apparatus			
22	Laminar Air Flow			
23	BOD Incubator			
24	Vacuum oven			
25	Bulk Density Apparatus			
26	Water Activity Meter			
27	Anaerobic System			
28	Gas Chromatograph			
29	LAL Kit			
30	Sterility Test Kit			
31	Particle Counter			
32	Air Sampler			
33	Flame Photometer			
34	Tap Density Tester			

ANNEXURE-IV
Ref. Clause No. 2 (f)

DECLARATION

I _____ Managing Director / Director / Partner / Proprietor of M/s._____ having its manufacturing or import unit / registered office at_____ do hereby declare that we have not been blacklisted either by Tender Inviting Authority or by any State Government or Central Government Organization for the following products quoted in the tender. We are eligible to participate in the tender Ref. No. **010/M(P)/DRUG/TNMSC/2021, Dated.01.12.2021** for the following products.

Sl. No.	Drug Code	Name of the Drug

M/s._____

Company seal

To be attested by the Notary.

ANNEXURE-V
Ref. Clause No.7.1 (a)

DETAILS OF E.M.D. SUBMITTED

We herewith submit the E.M.D. of Rs._____ in the form of Demand Draft bearing No._____ Dated: _____ drawn on _____ Bank _____Branch in favour of TNMSC for the following drugs of drugs.

Sl. No.	Drug Code*	Name of the Drug	Amount of E.M.D.
		Total :	

*in ascending order as in **Annexure-IX.**

Signature & Seal

ANNEXURE-VI
Ref. Clause No. 7.2(ii)

NOTARISED UNDERTAKING

(In 20- Rupees stamp paper)

I _____, S/o _____, Proprietor / Partner / Managing Director of _____ (Proprietary Concern / Firm / Company Ltd.) execute this Undertaking for myself and on behalf of _____ (Proprietary Concern / Firm / Company Ltd.).

2. Whereas, TNMSC Ltd., (Tender Inviting Authority) has invited Tender for supply of Essential Drugs and Medicines under rate contract system for one year from the date of acceptance and in pursuant to the conditions in the tender documents. M/s._____ (Proprietary Concern/ Firm / Company Ltd.), having its Office at _____ _____ is exempted from payment of Earnest Money Deposit as indicated in the Annexure-IX of tender document.

3. And whereas, in pursuant to the conditions in Clause Nos. 7.2&7.3(viii) of the tender, the sum equivalent to the Earnest Money Deposit can be forfeited by the Tender Inviting Authority in case of violation of any of the conditions and for non-performance of the obligation under tender document.

4. In consideration of exempting M/s._____ (Proprietary Concern/ Firm / Company Ltd.) from payment of Earnest Money Deposit as indicated in the Annexure-IX of tender document, I undertake to pay the said sum without any demur on receipt of demand issued by the tender inviting authority.

M/s _____

for Self and Firm / Company Ltd.

Signature and Seal

Witness:-

(1)

(2)

ANNEXURE-VII
Ref. Clause No. 4.1 (h)

PROFORMA FOR PERFORMANCE STATEMENT

(FOR A PERIOD OF LAST 3 YEARS)
(2018-2019, 2019-2020 AND 2020-2021)

Name of firm_____

Sl.	Name of the product	Year	No. of batches manufactured / imported & supplied.	Batch No.	Name and full address of the purchaser
	1	2	3	4	5
1.					
2.					
3.					

Note : Proof for the manufacturing (BMR) / importing of the drug quoted to be produced.

Signature and seal of the Tenderer_____

ANNEXURE-VIII
Ref. Clause. 4.1 (k)

ANNUAL TURN OVER STATEMENT

The Annual Turnover of M/s._____ for last 3 years are given below and certified that the statement is true and correct.

Sl.No.	Financial Year		Turnover in Lakhs (Rs)
1.	2018 - 2019	-	
2.	2019 - 2020	-	
3.	2020 - 2021	-	
	Total	-	Rs. _____ Lakhs.

Average turnover per annual - Rs._____ Lakhs.

Date:

Signature of Auditor/
Chartered Accountant
(Name in Capital)

Seal: