File No. 31026/54/2020-Policy
Government of India
Ministry of Chemicals and Fertilizers
Department of Pharmaceuticals

Dated: 27th July, 2020

Guidelines of the Scheme "Promotion of Bulk Drug Parks"

1. Background

1.1. Drugs play a vital role in healthcare delivery in the country. Continuous supply of drugs is necessary to ensure delivery of affordable healthcare to the citizens. Any disruption in supply of drugs can have significant adverse impact on drug security of the country.

1.2. Indian pharmaceutical industry is the 3rd largest in the world by volume and 14th largest in terms of value. India contributes 3.5% of total drugs and medicines exported globally. However, despite these achievements, India is significantly dependent on import of some of the critical basic raw materials, viz., bulk drugs that are used to produce the finished dosage formulations. India imports bulk drugs largely for economic considerations. Bulk drugs accounted for 63% of the total pharmaceutical imports in the country during 2018-19.

1.3. Future growth of pharmaceutical sector is contingent upon our ability to ensure un-interrupted supply of quality bulk drugs and our capacity to upscale their manufacturing during emergency situations. Self-reliance in manufacturing of bulk drugs is, therefore, highly desirable.

1.4. With a view to significantly bring down the manufacturing cost of bulk drugs and thereby increase the competitiveness of the domestic bulk drug industry by providing easy access to standard testing & infrastructure facilities, a Scheme called "Promotion of Bulk Drug Parks" has been approved by the Government of India on 20th March 2020.

1.5. The Scheme has been notified vide Gazette notification no. - 31026/16/2020-Policy, dated - 21/07/2020.

2. Objective

2.1. To promote setting up of bulk drug parks in the country for providing easy access to world class Common Infrastructure Facilities (CIF) to bulk drug units located in the park in order to significantly bring down the manufacturing cost of bulk drugs and thereby make India self-reliant in bulk drugs by increasing the competitiveness of the domestic bulk drug industry.

2.2. To help industry meet the standards of environment at a reduced cost through innovative methods of common waste management system.

2.3. To exploit the benefits arising due to optimization of resources and economies of scale.

3. **Definitions**

3.1. **Active Pharmaceutical Ingredient (API):** Any substance or mixture of substances intended to be used in the manufacture of a drug (medicinal) product and that, when used in the production of a drug, becomes an active ingredient of the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or function of the body.

3.2. **Bulk Drug Park**: For the purpose of this Scheme, a bulk drug park means a designated contiguous area of land with common infrastructure facilities for the exclusive manufacture of APIs or DIs or KSMs.

3.3. **Common Infrastructure Facility (CIF):** The Common facility with capacity commensurate with the expected number of manufacturing units in the bulk drug park, provided by the State Implementing Agency (SIA). Common facilities include:

i. Central Effluent Treatment Plant(s) (CETP)
ii. Solid waste management
iii. Storm water drains network
iv. Common Solvent Storage System, Solvent recovery and distillation plant
v. Common Warehouse
vi. Dedicated power sub-station and distribution system with the necessary transformers at factory gate
vii. Raw, Potable and Demineralised Water
viii. Steam generation and distribution system
ix. Common cooling system and distribution network
x. Internal road network, Compound Wall
Note: The cost of these components (mentioned at serial no. x) shall not exceed 15% of the total project cost.
xi. Common logistics (Clearing and Forwarding, Insurance, Transportation, Customs, Weighbridges, etc.)
xii. Advanced laboratory testing Centre, suitable for even complex testing/ research needs of APIs, including microbiology laboratory and stability chambers
xiii. Emergency Response Centre
xiv. Safety/ Hazardous operations audits centre
xv. Centre of Excellence:
    a) Regulatory awareness facilitation Centre
    b) Technology business incubator

c) Intellectual Property Rights management services
d) Process/ technology development laboratory/ Research Laboratory/ with pilot plants run by eminent scientists with track record of such competitive technology development for import substitution
e) Industry Academia linkage Centre
f) Training centre

3.4. **Drug Intermediate (DI):** A material produced during intermediate steps in the synthesis of an API that must undergo further molecular change or processing before it becomes an API.

3.5. **Key Starting Material (KSM):** A raw material, intermediate or an API that is used in the production of an API and that is incorporated as a significant structural fragment into the structure of the API. KSM can be an article of commerce, a material purchased from one or more suppliers under contract or commercial agreement, or produced in-house. KSMs are normally of defined chemical properties and structure.

3.6. **Preferred Products:** The preferred products are those APIs/DIs/KSMs for which the country is majorly dependent on imports. A list of such products is provided in **Appendix 2.**

3.7. **Proposer:** The proposer for the purpose of the Scheme shall be a State Government.

3.8. **Project cost**: The cost of establishing CIF in the bulk drug park.

3.9. **State**: State or Union Territory of Republic of India

4. **Scope of the Scheme**

4.1. This is a Central Sector Scheme.

4.2. Total financial outlay of the Scheme is Rs. 3000 Crore.

4.3. Three bulk drug parks will be supported under the Scheme.

4.4. Maximum grant-in-aid for one bulk drug park will be limited to Rs 1000 crore.

4.5. The duration of the Scheme is from FY 2020-2021 to FY 2024-2025.

4.6. Under the scheme, a one-time grant-in-aid will be provided for creation of common infrastructure facilities in selected Bulk Drug Park proposed by a State Government.

4.7. The scheme will be implemented through a State Implementing Agency (SIA), a legal entity, set up by the concerned State Government.

4.8. The grant-in-aid will be 70% of the project cost of the common infrastructure facilities (CIF). In case of North Eastern States and Hilly States (i.e Himachal

Pradesh, Uttarakhand, UT of Jammu & Kashmir and UT of Ladakh), the grant-in-aid will be 90% of the common infrastructure facilities.

4.9. The Formulation units shall not be permitted in the Park.

5. Project Management Agency (PMA)

5.1. A Project Management Agency (PMA) will be nominated by Department of Pharmaceuticals (hereinafter referred as DoP) for providing secretarial, managerial and implementation support to DoP for effective implementation of the Scheme.

5.2. The PMA would be responsible for:

i) Preliminary examination of the proposals received from states and seeking additional information including documents from states, if required for completeness of the proposals.

ii) Appraisal of proposals and making appropriate recommendations to the Scheme Steering Committee (SSC) for approval of proposals under the Scheme.

iii) Appraisal of DPRs including financial viability, commercial sustainability and socio-economic impact of the projects.

iv) Assisting DoP in periodic monitoring of the projects and timely disbursement and utilisation of the funds.

v) Monitoring Bulk Drug Park implementation schedule based on Program Evaluation and Review Technique (PERT), Critical Path Method (CPM) and Gantt Chart and periodic submission of the report to SSC.

vi) Monitoring event report at every stage, an ex-post activity chart with complete breakdown of activities, the original expected dates and actual dates along with the flow of fund requirements.

vii) Periodic physical inspection of the Bulk Drug Parks.

viii) Any other matter pertaining to the Scheme assigned by DoP or SSC.

6. Technical Committee (TC)

6.1. A Technical Committee, constituted by the DoP will assist SSC in discharging its functions. TC will provide comments on any technical matter referred to by the DoP/ SSC.

6.2. Technical committee shall comprise of three experts having knowledge and experience in regulations, process development and R&D of bulk drugs. Out of three, one expert having experience in implementation of infrastructure projects related to development of industrial park/ zone.

7. **State Implementing Agency (SIA)**

7.1. State Implementing Agency (SIA) shall be a legal entity (with minimum 51% equity shareholding of State Government in the paid-up capital of SIA) set up by the State Government for the purpose of implementing the Bulk Drug Park Project.

7.2. SIA shall be responsible for day to day management of Bulk Drug Park.

7.3. The SIA shall be responsible for:

i) Preparing the Detailed Project Report (DPR) covering the technical, financial, institutional and operational aspects of the CIF project of the Bulk Drug Park.

ii) Ensuring and making available balance amount of the Project Cost.

iii) Obtaining all statutory approvals / clearances including all environmental clearances.

iv) Providing single window system for various approvals and testing certificates.

v) Recruiting suitable professionals in order to ensure that the project is executed smoothly.

vi) Implementing various interventions as outlined and approved in DPR.

vii) Preparing event report at every stage, an ex-post activity chart with complete breakdown of activities, the original expected dates and actual dates along with the flow of fund requirements as specified in DPR.

viii) Furnishing regular progress reports of the project to DoP / PMA.

7.4. SIA shall allot land only on long term lease basis.

7.5. SIA shall keep a provision for cancellation of allotment of the land, if the commercial production is not started by the allottee within a period of two years from the date of allotment order unless it extends the time period by one year on valid reasons.

7.6. SIA shall submit any report sought by DoP, from time to time.

8. **Role of State Government**

8.1. State Government shall be responsible for:

i) Submission of Project Report.

ii) Land: State Government will be responsible for providing encumbrances free land for the development of the Bulk Drug Park.

iii) Ensuring and making available balance amount of the Project Cost through budgetary and / or other sources.

iv) Obtaining all statutory approvals / clearances including all environmental clearances.

v) Providing single window system for various approvals and testing certificates.

vi) Providing necessary infrastructure such as access road, power, water supply, etc. up to the park.

vii) Providing all project related clearances expeditiously.

viii) Providing all clearances required by individual bulk drug units expeditiously.

ix) Promoting the Bulk Drug Park at National & International level.

x) Provide necessary electricity supply lines and water supply lines with the necessary infrastructure, upto the project site.

9. **Scheme Steering Committee (SSC)**

9.1. The proposals under the Scheme will be approved by the Scheme Steering Committee (SSC) constituted by DoP.

9.2. The composition of the SSC is as follows:

i) Secretary, DoP - Chairperson
ii) Financial Adviser, DoP - Member
iii) Joint Secretary, Ministry of Environment, Forest and Climate Change - Member
iv) Joint Secretary, Department for Promotion of Industry and Internal Trade - Member
v) Joint Secretary, Ministry of Health and Family Welfare – Member
vi) DCGI, Central Drug Standard Control Organisation - Member
vii) Joint Secretary(Policy), DoP - Convenor

The SSC may invite representatives of Industry Associations, R&D Institutions and other Government / Private sector expert organizations as special invitees as may be necessary from time to time.

9.3. The SSC shall take all decisions required for successful implementation of the Scheme, including any modifications if required.

9.4. The SSC will be assisted by the Project Management Agency (PMA).

9.5. The SSC will meet as often as necessary to ensure timely consideration of proposals and release of instalments of grant-in-aid and to review progress of

the projects under the Scheme. However, it shall hold meeting at least once in 6 months.

10. **Proposer**

10.1 A State Government can make only one proposal of Bulk Drug Park under this Scheme.

10.2 The proposed park shall not be less than 1000 acres in area. For North Eastern States and Hilly States (i.e Himachal Pradesh, Uttarakhand, UT of Jammu & Kashmir and UT of Ladakh), the area of proposed park shall not be less than 700 acres.

10.3 At least 50% of the total area of the Bulk Drug Park shall be made available for allotment to individual bulk drug units.

10.4 The proposer shall have to be in full possession of the land free of all encumbrances proposed for establishing the bulk drug park on the date of submission of proposal.

10.5 The proposer shall submit a Project Report (PR) including the proposed cost of establishing the bulk drug park including cost of CIF.

10.6 The project report shall cover feasibility study establishing viability of the bulk drug park at the identified location. The feasibility study shall cover assessment of environmental risk and associated health risk, business risk and management risk.

10.7 Project cost shall not include the following:

I. Cost of Land,
II. Pre-operative expenses like preparation of Project Report,
III. Administrative and management support expenses.

10.8 The proposer shall give full details of the location of the proposed bulk drug park including land area (in acres), location map and area map.

10.9 The proposer shall provide an undertaking for establishing a single window for all necessary clearances required for the bulk drug units located in the park.

10.10 The proposer shall submit an undertaking to establish a Research and Development facility as a Centre of Excellence in the park. Such facility may be operated by an institution or by a society. Such centre of excellence shall employ competent scientists with suitable experience and promote industry academia linkage. The State Government shall provide sufficient financial and other support for such centre.

10.11 The proposer shall submit an undertaking to ensure availability of funds.

10.12 The proposer may be required to make a presentation on the proposal before SSC.

11. **Proposal**

11.1 The State Government should identify a suitable location for establishment of bulk drug park keeping in mind various factors viz. environmental pollution, assured availability of power, assured availability of water, transport connectivity with railways, national highway, port, airport, etc. The identified location should be well away from eco-sensitive zone of protected areas.

11.2 The proposer State shall submit an undertaking that it shall not increase the land lease rent and utility charges, as declared in the proposal, beyond 5% per annum, for the next 10 years.

11.3 The proposal under the Scheme shall be made within 60 days of issuance of these guidelines, in the format provided at **Annexure 1.**

12. **Selection of Proposal**

12.1 The evaluation criteria provided in **Appendix 1** shall be used for selection of States. The States obtaining top three ranks will be considered for selection under the Scheme.

12.2 In case, the selected State fails to submit the DPR in time or fails to implement the project as per the timelines stated in the DPR, the in-principle approval may be cancelled by the SSC. In such case, State in the ranking may be selected for the purpose of the Scheme.

13. **In-principle approval under the Scheme**

13.1 PMA will evaluate the proposals and give its recommendations to DoP.

13.2 The recommendations of the PMA will be placed before SSC for its consideration.

13.3 After receiving in-principle approval from the SSC, DoP will issue a letter of in-principle approval to the selected States.

14. **Detailed Project Report (DPR)**

14.1 A Detailed Project Report (DPR) shall be prepared and submitted to DoP along with the details as per the format given in **Annexure 2** of these guidelines by the selected State Government within 180 days of date of issuance of in- principle approval letter.

14.2 The DPR shall include, among other things, the following details:

a) Location of the proposed Bulk Drug Park

b) Total land area of the park

c) Total land area of the park available for allotment to units

d) Detailed breakup of the utilisation of the remaining land (Green belt, landscape, CIF, etc.)

e) Project cost

f) Number of projected bulk drug units

g) Proposed time period for obtaining clearances from Central and State Government for establishing the bulk drug park.

- The time period for completing the CIF
- The date at which the plots will be allocated to the bulk drug units

h) Details such as brief description of the CIF, estimated capacity of CIF, justification for arriving at the capacity, cost of CIF, technology used, approximate time to establish the CIF, approval required from different agencies, projected time lines for obtaining approval, for each component of CIF based on the projected number of manufacturing facilities.

i) Detailed viability of the project along with the operational cost and proposed user charges.

j) Provide an analysis of occupational hazards in the park

k) Indicative charges (not higher than those committed in the proposal) to be collected from the bulk drug manufacturing units:

- Land lease rate per square meter
- Utilities charges
  - Power
  - Effluent treatment
  - Water
  - Steam
  - Solid waste treatment
  - Warehouse charges
  - Park maintenance charges
- Quality control testing charges
- Solvent recovery charges

l) Details of all the business processes of the bulk drug park to identify impediments and bottlenecks and to draw action plan for enhancing competitiveness of the units to be set up in the bulk drug park.

m) Mode of funding and phasing of expenditure i.e. contribution of various stakeholders (GoI, State Govt. and others)

n) Financial viability to the extent available i.e. Internal Rate of Return, % occupancy to achieve viability etc.

o) Provide a bulk drug park implementation schedule based on Program Evaluation and Review Technique (PERT), Critical Path Method (CPM) and Gantt Chart.

14.3 Ceiling on the eligible cost of the project

i. Assistance for Administrative and other management support of SIA for the project implementation period shall not exceed 5 % of the grant-in-aid.

ii. Assistance for engaging engineers and other experts for execution of civil works shall not exceed 5 % of the grant-in-aid.

iii. The cost of internal roads and compound wall shall not exceed 15% of the grant-in-aid.

iv. No grant-in-aid shall be given towards construction of buildings. However, as far as various scientific facilities/ centres are concerned, 30% of the estimated cost of respective facility/ centre will be allowed from grant-in-aid towards construction of the building.

15. Final approval under the Scheme

15.1 PMA will appraise the DPR and submit its recommendations to the SSC for its consideration.

15.2 After receiving final approval from the SSC, DoP will issue letter of final approval to the selected State.

16. Post Approval

16.1. The project shall be completed within two years from the date of release of the first instalment of the grant-in-aid, unless the period is extended by the SSC.

16.2. SIA shall furnish a quarterly progress report on the development of the park.

16.3. PMA shall assess the progress of the project from time to time and submit the report to the SSC.

17. Release of funds

17.1. Where bank finance is involved, written commitment of the bank concerned to release proportionate funds shall also be necessary before release of Central Government assistance.

17.2. Grant-in-aid will be released in four instalments in the following manner:

Instalment	Percentage of Funds	Remarks/ Pre-requisite
1st	30	• On final approval of the project by the SSC and after deposit of 30 percent of SIA's share in the project cost in the Trust and Retention Account (TRA) or Escrow or No Lien Account as the case may be, subject to the condition that all relevant environment clearances are in place.
2nd	30	• 60% utilisation of the 1st instalment and after proportionate expenditure has been incurred by the SIA with proportionate physical progress of the bulk drug park as per the DPR • Against the production of Bills
3rd	30	• 100% utilisation of 1st instalment and at least 60% utilization of 2ndinstalment and after proportionate expenditure has been incurred by the SIA with proportionate physical progress of the bulk drug park as per the DPR • Against the production of Bills
4th	10	• 100% utilisation of 2nd and 3rd instalments • SIA has mobilized and spent its entire share in proportion to the grant and completed the project in all respects.

17.3. The SIA shall open a Trust and Retention Account (TRA) or Escrow or No Lien Account as may be decided by the SSC for the purpose of parking the funds received as grant-in-aid from the Central Government under the Scheme and also the State Government share.

17.4. The SIA shall submit the Utilisation Certificate (UC) for the amounts utilized as per the format prescribed in GFR.

17.5. Accounts of SIA shall be subject to audit by the Comptroller & Auditor General of India.

18. **Maintenance /Ownership of Assets**

18.1. SIA shall be responsible for Operation and Management of assets created under the Scheme.

18.2. The assets acquired by the SIA out of Central government assistance shall not be disposed, encumbered or utilized for the purposes other than for which the funds have been released.

18.3. A register of permanent and semi-permanent assets acquired wholly or mainly out of the funds provided by Central government should be maintained as per GFR.

18.4. If, for any reasons, SIA is liquidated, Government of India will have the first right to recover the grant-in-aid released for the project in case any surplus is left in the process of liquidation.

18.5. Escalation in the cost of project, due to any reason, shall be borne by the State government/ SIA. The Central government shall not be responsible for any financial liability arising out of operation of any CIF.

18.6. For successful implementation and operation of the Bulk Drug park, agreements shall be entered into between Government of India (GoI) and the State Government on one hand and between State Government and SIA on the other hand. The draft agreements will be circulated along with the letter of final approval.

18.7. In addition to the CIF, the SIA and the State shall actively facilitate common services/utilities required for smooth running of businesses such as petrol pumps, banks, cafeteria, business centre, parking for trucks, convenience stores, medical service centre etc.

18.8. SIA, while allocating the land, shall give priority to applicants proposing to manufacture preferred products listed in **Appendix 2** of these guidelines.

18.9. SIA shall constitute a management committee comprising of the representatives of the State Government, SIA, two representatives nominated from among the manufacturing units situated in the park and State Drugs Controller, for monitoring operation and maintenance of the park after completion of the project.

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New Delhi, Dated:27th July, 2020

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2. All States / Union Territories
3. Cabinet Secretariat
4. PMO
5. NITI Aayog
6. Comptroller and Auditor General of India
7. AS&FA, Department of Pharmaceuticals
8. Industry Associations
9. Internal Circulation

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Appendix 1

Evaluation Criteria for Selection

S. No.	Parameter	Maximum Marks
1	Utility charges (rates) as per proposal submitted by State Govt. (the State quoting the lowest rate will be awarded full marks and others will be rated pro-rata): i. Power (10) ii. Effluent treatment (7) iii. Water (3) iv. Steam (3) v. Solid waste treatment (3) vi. Warehouse charges (2) vii. Park maintenance charges (2)	30
2	Total area of the proposed park 1. The hilly States, as defined in the guidelines, shall get 2.5 marks for every additional 175 acres over and above 700 acres minimum stipulated land 2. Other States shall get 2.5 marks for every additional 250 acres of land over and above 1,000 acres minimum stipulated land	10
3	Land lease rate to be offered to individual units of bulk-drugs to be set up in the park - the lease rent shall be compared based on the NPV of the upfront lease payment and/or periodic lease/ maintenance charges per sq. meter, discounted at SBI 1 Year MCLR applicable on the date of evaluation (the State quoting the lowest lease rent per sq. meter on NPV basis, shall be awarded full marks and others will be rated pro-rata).	10
4	Uninterrupted 24*7 availability, with committed source and necessary infrastructure, of (Yes/ No): i. Power (5) ii. Water supply (5)	10
5	Suitability of location of the park from environmental angle. • Near the coast (within 20 Km of coastline) or zero liquid discharge effluent treatment plant* (5) • Outside the municipal limits (5) * The cost of such zero liquid effluent plant shall not form part of project cost and shall be financed by the State separately.	10

6	Policy incentives of State government applicable for Bulk Drug industry i. Interest Subvention Scheme (5) – (the State quoting highest percentage of interest subvention for a period of 10 years from the date of operation of the park, shall be awarded highest marks and others shall be rated pro-rata) ii. GST reimbursement, subsidy, incentive etc. against investment (5) - (the State quoting highest percentage of the reimbursement of investment, for a period of 10 years from the date of operation of the park, shall be awarded highest marks and others shall be rated pro-rata).	10
7	Connectivity of the Park i. National Highway within 25 km from site (2) ii. Air Cargo / Airport within 50 km from site (2) iii. Sea Port / In-land waterway/ Dry port within 100 km from site (2)	6
8	Full exemption of Stamp Duty and Registration charges (Yes/No)	5
9	Latest Ease of Doing Business Ranking of the State – The marks shall be awarded based on the slabs of ranking: • Rank 1 to 5 = 5 Marks • Rank 6 to 10 = 4 Marks • Rank 11 to 15 = 3 Marks • Rank 16 to 20 = 2 Marks • Rank 21 to 25 = 1 Mark • Rank below 25 = 0 Mark	5
10	Availability of Technical Manpower in the State i. No. of specialised research institutes in Pharmaceutical sector ≥ 1 (1) ii. No. of Medical, Bio-Technology and Pharmacy colleges ≥ 30 (1)	2
11	Number of Pharma and chemical clusters in the State i. Pharma Clusters ≥ 01 (1) ii. Auxiliary units chemicals used in Pharma ≥ 02 (1)	2
	Total	**100**

Appendix 2

Preferred Products

Sr. No.	Name of API	Sr. No.	Name of API
1.	5-Fluorouracil	2.	Acyclovir
3.	Abiraterone Acetate	4.	Amoxicillin
5.	Acarbose	6.	Amphotericin B
7.	Acetazolamide	8.	Alfacalcidol
9.	Ampicillin	10.	Sulbactum Sodium
11.	Amprolium HCl	12.	Alpha Lipoic Acid
13.	Alcaftadine	14.	Antipyrine HCl
15.	Aspirin	16.	Arbekacin Sulfate
17.	Atorvastatin	18.	Artemether
19.	Alprazolam	20.	Artemisinin
21.	Alfuzosin Hydrochloride	22.	Asparaginase
23.	Amantadine HCl	24.	Amiodarone hydrochloride
25.	Atracurium besylate	26.	Atropine Sulfate
27.	Amikacin Sulphate	28.	Azithromycin
29.	Artesunate	30.	Aztreonam
31.	Potassium Clavulanate	32.	Atoshban Acetate
33.	Bedaquline Fumarate	34.	Baclofen
35.	Benzathine Benzylpenicillin	36.	Beclomethasone
37.	Bacitracin	38.	Betaxolol HCl
39.	Betahistine Dihydrochloride	40.	Bromocriptine mesylate
41.	Betamethasone	42.	Budesonide
43.	Bifonazole	44.	Buspirone Hydrochloride
45.	Bimatoprost	46.	Butaphosphan
47.	Bisoprolol fumarate	48.	Butorphanol tartrate
49.	Bleomycin Sufate	50.	Carboplatin
51.	Cabergoline	52.	Carboprost tromethamine
53.	Caffeine	54.	Cefadroxil
55.	Calcitriol	56.	Cefalexin
57.	Calcium D-Pantothenate	58.	Cefatazidime
59.	Calcium folinate	60.	Cefazolin
61.	Calcium Gluconate	62.	Cefepime
63.	Calcium Lactate Pentahydrate	64.	Cefoperazone
65.	Calcium Levulinate	66.	Ceftiofur Soduim Sterile
67.	Capreomycin sulphate	68.	Ceftizoxime sodium
69.	Captopril	70.	Ceftriazone Sodium
71.	Carbamazepine	72.	Ceftriaxone Sodium
73.	Carbidopa	74.	Ceftriazidine

Sr. No.	Name of API	Sr. No.	Name of API
75.	Carbocisteine	76.	Citric Acid
77.	Cefixime	78.	Ciprofloxacin
79.	Celecoxib	80.	Cisatracurium Besylate
81.	Cephalexin	82.	Cisplatin
83.	Cerebroprotein Hydrosalate	84.	Citicoline
85.	Cetiofur Sodium	86.	Clarithromycin
87.	Cetoperazone Sodium	88.	Clavulanate Potassium
89.	Chloramphenicol	90.	Clemastine fumarate
91.	Chlordiazepoxide Hydrochloride	92.	Clindamycin
93.	Chlorpromazine HCL	94.	Clobazam
95.	Chlortetracycline Hydrochloride	96.	Clopidol
97.	Cefuroxime	98.	Cloprostenol Sodium
99.	Chondroitin Sulfate Sodium	100.	Clorpromazine Hcl
101.	Chorionic Gonadotrophin (HCG)	102.	Clotrimazole
103.	Ciclopirox Olamine	104.	Clozapine
105.	Cimetidine	106.	Colesevelam Hydrochloride
107.	Cinchonidine	108.	Colistimet Sodium
109.	Codeine Phosphate	110.	Cyclamic Acid
111.	Colistin Sulphate	112.	Cyclizine Hcl
113.	Cortisone Acetate Micronised	114.	Cycloserine
115.	Cyacloserine	116.	D- Penicillamine
117.	Cyproterone Aceate	118.	Dimenhyrinate
119.	Cystamine Hcl	120.	Dinoprostone (Prostaglandin E2)
121.	Dactinomycin	122.	Diosmin
123.	Daidzein	124.	Diphenhydramine
125.	Dapagliflozin	126.	Divalproex Sodium
127.	Daptomycin	128.	Dihydroergotamine Mesylate
129.	D-A-Tocopheryl Acetate	130.	Docetaxel
131.	D-Biotin	132.	Dopamine HCl
133.	Desogestrel	134.	Doramectin
135.	Desonide Micronized	136.	Doxorubin
137.	Dexamethasone	138.	Doxycycline
139.	Dexmedetomidine	140.	Doxylamine
141.	Diatriazoic Acid	142.	D-Panthenol
143.	Diazepam	144.	Dried Aluminium Hhydroxide Gel
145.	Dicloxacillin Sodium	146.	Drospirenone Micronised
147.	Dienogest Micronized	148.	Docusate Sodium
149.	Difluprednate	150.	Dofetilide
151.	Dabigatran Etrxilate Mesylate	152.	Domperidone

Sr. No.	Name of API	Sr. No.	Name of API
153.	Dextran	154.	Diclofenac
155.	Dextrose	156.	Estradiol Hemihydrate
157.	Dydrogesterone	158.	Eszopiclone
159.	Efavirenz	160.	Ethambutol Hydrochloride
161.	EHG Capsules	162.	Ethinylestradiol
163.	Eloctate	164.	Ethionamide
165.	Enalapril Maleate	166.	Ethosuximide
167.	Enoxaparin sodium	168.	Etomidate
169.	Enrofloxacin	170.	Etoposide
171.	Enzogenol	172.	Evogliptin Tartrate
173.	Ephedrine Sulfate	174.	Exemestane
175.	Epirubicin Hydrochloride	176.	Escitalopram
177.	Epopresional sodium	178.	Esculin (Esculoside)
179.	Ergocalciferol	180.	Esmolol Hydrochloride
181.	Ergometrine	182.	Estradiol
183.	Erythromycin	184.	Famciclovir
185.	Erythylsuccinate, Erythromycin Ethylsuccinate	186.	Famotidine
187.	Flucinolone Acetonide	188.	Faropenem Sodium
189.	Flucloxacillin Sodium	190.	Fegfilgrastem
191.	Flunixin Megulmine	192.	Ferrous Fumarate
193.	Fluocinolone acetonide	194.	Filgotinib
195.	Fluoromethalone	196.	Finasteride
197.	Fluoxetine HCL	198.	Fosfomycin
199.	Fluphenazine Deconate	200.	Framycetin Sulfate
201.	Flurometholone	202.	Furosemide
203.	Fluticasone propionate	204.	Fusidic Acid
205.	Folic acid	206.	Gliclazide
207.	Gabapentine	208.	Glimepiride
209.	Galantamine	210.	Glipizide
211.	Gallic Acid	212.	Gramicidin
213.	Gentamicin	214.	Glucosamine Sulfate
215.	Griseofulvin	216.	Hydrochlorothiazide
217.	Guanidine Hydrochloride	218.	Hydrocortisone
219.	Halobetasol Propionate	220.	Hydroxy Ethyl Starch
221.	Heparin	222.	Hydroxypropyl Methylcellulose
223.	Hesperidin	224.	Hydroxyzine HCl
225.	Himatoprost	226.	Ibuprofen
227.	Hyoscine butyl bromide	228.	Idebenone

Sr. No.	Name of API	Sr. No.	Name of API
229.	Indapamide	230.	Ifosfmide
231.	Indomethacine	232.	Isoflurane
233.	Inositol	234.	Isoniazid
235.	Iodixanol	236.	Isopropanol
237.	Iodomethyl Sulbactam	238.	Isotretinoin
239.	Iohexol	240.	Itraconazole
241.	Iopamidol	242.	Ivermectin
243.	Ipratropium bromide	244.	Kanamycin
245.	Irbesartan	246.	Lactulose
247.	Lactic Acid	248.	Lamivudine
249.	Lactitol Monohydrate	250.	Levamisole HCL
251.	Latanoprost	252.	Levodopa
253.	Lenvatinib	254.	Levofloxacin
255.	Leuprorelin acetate	256.	Lincomycin HCl
257.	Levonogestrel	258.	Lithium carbonate
259.	Ethinyl Estradiol	260.	Loperamid
261.	Levothyroxine Sodium	262.	Loratadine
263.	Lumefantrine	264.	L-Ornithine monohydrochloride
265.	Losartan	266.	Lopinavir
267.	Lyophillisate	268.	Levetiracetam
269.	Mannitol	270.	L-Ornithine-L-Aspartate
271.	Mebevarine HCl	272.	Meprobamate
273.	Methylcobalamine	274.	Meropenam
275.	Medroxoyprogesterone acetate	276.	Mesalamin
277.	Mefenamic Acid	278.	Mesna
279.	Meglumine	280.	Metamizole sodium
281.	Methyl Prednisolone	282.	Metformin
283.	Methyl Salicylate	284.	Methionine
285.	Methylcobalamin	286.	Methotrexate
287.	Metoprolol Tartarate	288.	Methyldopa
289.	Metronidazole	290.	Methylergometrine maleate
291.	Mexiletine Hydrochloride	292.	Methylprednisolone
293.	Mitomycin	294.	Midazolam
295.	Mometasone Fuorate	296.	Mifepristone
297.	Mycophenolate Mofetil	298.	Miglitol
299.	Mycophenolic Acid	300.	Miltefosine
301.	Mupricocin	302.	Minocycline Hydrochloride
303.	Naloxone Hydrochloride	304.	Misopristol
305.	Neomycin	306.	Nevirapin

Sr. No.	Name of API	Sr. No.	Name of API
307.	Netilimycin	308.	Niacin
309.	Netilmiin	310.	Nicergoline
311.	Nifuroxazide	312.	Norgestrel
313.	Nilotinib	314.	Nortriptyline HCL
315.	Nitrofurantoin	316.	Nothindrone
317.	Nizatidine	318.	Norethindrone Acetate
319.	Nor-Adrenaline Bitartrate	320.	Norethisterone
321.	Ofloxacin	322.	Norfloxacin
323.	Olmesartan	324.	Nystatin
325.	Orpendrine citrate	326.	Ornidazole
327.	Oxcarbazepine	328.	Otilonium Bromide
329.	Paclitaxel	330.	Oxaliplatin
331.	Pancuronium bromide	332.	Oxytetracycline
333.	Paracetamol	334.	Phenytoin Sodium
335.	Paricalcitol	336.	Pholcodine
337.	Paroxetine HCL	338.	Phthalimide Potassium
339.	Pegfilgrastim	340.	Piperacillin Sodium
341.	Praziquantel	342.	Pilocarpine
343.	Prednisolone	344.	Pimavanserin Tartate
345.	Prednisone	346.	Perindopril Erbumine
347.	Pregabalin	348.	Prochlorperazine
349.	Premarin	350.	Prochlorperazine Malete
351.	Piracetam	352.	Progesterone
353.	Piribedil	354.	Propofol
355.	Polymyxin B Sulfate	356.	Protaglandin E1
357.	Ranitidine Hcl	358.	Pseudoephedrine
359.	Rebamipide	360.	PVP IODINE
361.	Ribaviren	362.	Pyridostigmine bromide
363.	Riboflavine	364.	Pyridoxine HCl
365.	Ritonavir	366.	Quinine Sulfate
367.	Rifampicin	368.	Rosuvastatin Calcium
369.	salicylic acid	370.	Roxithromycin
371.	Secnidazole	372.	Rocuronium Br
373.	Sevoflurane	374.	Simvastatin
375.	Sodium fusidate	376.	Sirolimus
377.	Sodium Hyaluronate	378.	Sodium Gluconate
379.	Sodium Valproate	380.	Sodium Alginate
381.	Solifenacin Succinate	382.	Sodium ascorbate
383.	Sorafenib	384.	Sodium Bicarbinate

Sr. No.	Name of API	Sr. No.	Name of API
385.	Sotalol HCL	386.	Sodium Cromoglycate
387.	Spectinomycin	388.	Streptomycin
389.	Spiramycin	390.	Sucralfate
391.	Spironolactone	392.	Sulbutamine
393.	Sulfadiazine	394.	Sulfaoamide
395.	Sulfadimidine	396.	Sulfachloropyrazine sodium
397.	Sulfaquinoxaline Sodium	398.	Sulphaclozine
399.	Sulphachloropyridazine Sodium	400.	Sulphadoxine
401.	Tamoxifen Citrate	402.	Sulpiride
403.	Taurine	404.	Teicoplanin
405.	Tazobactum Sodium	406.	Telmisartan
407.	Tofisopam	408.	Terbinafine HCl
409.	Thiamine HCL	410.	Tetracycline
411.	Thiocolchicoside	412.	Theophylline Anhydrous
413.	Tiamulin fumarate	414.	Toltrazuril
415.	Tianeptine sodium	416.	Topiramate
417.	Tibolone	418.	Topotecan HCL
419.	Ticarcillin sodium	420.	Tramadol HCl
421.	Tilmicosin Phosphate	422.	Tranexamic Acid
423.	Tinidazole	424.	Travaprost
425.	Tobramycin	426.	Tretinoin
427.	Tricoplanin	428.	Triamcinolone
429.	Trihexylphenidyl HCL	430.	Trimethoprime
431.	Trimetazidine	432.	Tryptophan
433.	Tyrosine	434.	Tylosin Tartrate
435.	Ulipristal Acetate	436.	Ursodeoxychlolic Acid
437.	Valsartan	438.	Valiolamine
439.	Verapamil	440.	Vancomycin HCl
441.	Vinblastine sulfate	442.	Vardenafil
443.	Vinorelbine	444.	Various Amino Acids
445.	Various Vitamins	446.	Vasopressin
447.	Zidovudine	448.	Xaluprine
449.	Zinc Bacitracin	450.	Zolpidem Tartrate
451.	Zopiclone	452.	Any other API/KSM/DI

Sr. No.	Name of KSM/DI	Sr. No.	Name of KSM/DI
1.	OTBN	2.	Artemisinin
3.	Sabam HCl	4.	2-MNI (2-methyl-5-Nitro-Imidazole)
5.	MICA ester	6.	ATS-8
7.	Non Sterile Ceftriaxone Sodium	8.	2-Keto-Gluconic Acid
9.	Tazo Acid,	10.	BCFI
11.	Piperacilline Acid	12.	Diacetyl acyclovir
13.	Meropenem Crude	14.	10-MISB
15.	LEVO ACID	16.	Heparin (Crude)
17.	Cipro Acid	18.	Salicylic Acid
19.	O-Acid	20.	Para amino phenol
21.	Cycloproplylamine	22.	2,6-Dichlorophenol
23.	1,1 cyclohexane Diacetic Acid (CDA)	24.	Dicyandiamide (DCDA)

Annexure 1

Proposal Form

1. Instructions

1.1. The proposal shall be duly signed by the authorized signatory.

1.2. Proposers are advised to go through the guidelines carefully before submitting the proposal.

1.3. Proposers shall follow the format provided in this proposal form for submitting the proposals. Proposers shall provide information and enclose all the supporting documents as detailed.

1.4. All proposals will be submitted to the DoP in physical form and soft copy (pen drive/ CD) in a sealed envelope, addressed to Dr Sumit Garg, Deputy Secretary (Policy), Department of Pharmaceuticals, Ministry of Chemical & Fertilizers, Room No. 228, A-Wing, Shastri Bhawan, New Delhi – 110001.

1.5. Proposal has following two sections:

I. Proposer Details

II. Details of the Proposal

2. Section I – Proposer Details

2.1 Name of the State

2.2 Authorised Signatory Details – Name, Designation, Contact No. (Mobile and Office Landline No.), Email and complete office address.

3. Section II - Details of the Proposal

3.1 Cost of Development of the Park & tentative source of funds (Rs. in crore):

i. Cost of Development of the Park (estimated)
ii. Central Government Share (Grant-in-Aid)
iii. State Government /Union Territory share with source of funds for share of State Govt./ Union Territory

3.2 Details of Land: Total land area (in acres) of the proposed park and estimate of area available for allotment to bulk drug manufacturing units (which shall be not less than 50% of the total land area).

The State is required to furnish the details on the following specific points (in case, any of the following is applicable to the land, including part of the land, proposed for the park):

a) Location of the land on google map, mapping of the land and land survey report

b) Status of ownership, possession and mutation of the land in the revenue records

c) Status of any encroachment, unauthorised possession or habitation on the land (including part of the land) proposed for the park

d) Whether the land (including part of the land) is subject to any rehabilitation requirement etc. The status, procedure and timelines of the same should be clearly mentioned

e) Whether there is any compensation related issue which is pending for the land (including part of the land)

f) Whether there is any legal dispute or claim, pending in any court of law with any party for the land (including part of the land). If yes, detail about nature of dispute, forum where pending and any timelines for closure to be furnished.

g) Any other known encumbrance, restriction or relevant information which may have an impact on timely completion of development of the Park, please furnish the details.

3.3 Land Lease Rate

Please specify the land lease rate *(annual rent per square meter in Rs.)* to be offered to bulk drug manufacturing units to be set up in the park. The state is required to clearly mention the upfront fee payable by the manufacturing unit and all subsequent payment with the periodicity and duration of payment.

The lease rent referred to above shall be a comprehensive levy for allotment of land.

3.4 Commitment to provide 24*7 availability of power and water supply

The State is required to give a commitment with broad details for sourcing continuous power and water supply, which shall be considered for the evaluation of the proposal. However, the selected States will be required to provide detailed justification and feasibility for sourcing continuous power and water supply in the Detailed Project Report.

3.5 Location of the park vis-à-vis connectivity

The State should specify the distance (in km) of proposed Park from the following:

a) Nearest National Highway
b) Nearest Air Cargo/ Airport
c) Nearest Sea Port / In-land waterway/ Dry Port

Please specify the location and name the National Highway, Air Cargo and Nearest Sea Port/ In-land waterways and Dry Port.

3.6 Location of the park vis-à-vis eco-sensitive zone of protected area

Whether the land is in proximity to any of the eco sensitive zone of protected area. The state is required to furnish the detail of distance (in km) of proposed park from nearest such zone.

3.7 Location of the park vis-à-vis environmental aspects

a) Please specify the distance (in km) of the proposed park from the nearest coast

b) Whether State proposes to install Zero Liquid Discharge effluent treatment plant.

c) Whether the proposed park is outside the municipal limits. Please specify the distance (in km) of the proposed park from the nearest municipal limits.

3.8 Policy incentives given/proposed by the State government for Bulk Drug industry

a) **Interest subvention scheme:** Whether the State has/proposes any interest subvention scheme on the loan availed by the Bulk Drug manufacturing units. State is required to provide the detail of percentage of interest rate subvention for a period of 10 years from the date of operation of the park.

b) **Incentive in the form of GST reimbursement, subsidy etc. against investment:** The State is required to submit detail of all incentives by way of GST reimbursement/ subsidy or any other form of incentive, as a % of the total investment made by Bulk Drug manufacturing unit. State is also required to submit the calculation of such % of incentive against investment.

c) Whether State commits to exempt the Stamp Duty and Registration Charges for bulk drug manufacturing units (Yes/ No).

Please submit the relevant supporting documents.

3.9 Utility Charges

State is required to submit the following utility charges to be charged from Bulk Drug manufacturing units. The said charges will have to be committed by the State and undertaking in this regard shall be submitted as appended in this Proposal Form.

Utility	Units (for specifying the charges)
Power	kWh
Effluent treatment	Per kilo litre
Water	Per kilo litre
Steam	Per Tonne
Solid waste treatment	Per Tonne
Warehouse	Monthly charges per square meter
Park maintenance charges	Annual charges per square meter

3.10 Availability of technical manpower

a) Specialised research institutes in Pharmaceutical sector- Number, Name, Address and recognition status

b) Medical, Bio-Technology and Pharmacy colleges- Number, Name, Address and recognition status

Institute recognised by concerned State or Central body only shall be considered.

3.11 Number of Pharmaceutical and Auxiliary clusters in the State

a) Pharmaceutical Clusters – Name and location of each cluster in the State

b) Auxiliary units of chemicals used in pharmaceutical sector – Name and location of approved units engaged in the manufacturing of pharmaceutical sector

3.12 Latest Ease of Doing Business Ranking of the State

Undertaking

In connection with our application for development of a Bulk Drug Park as notified vide notification no. - 31026/16/2020-Policy, dated - 21/07/2020 and guidelines thereunder, the State of ..... acting through authorised signatory Sh..... do hereby undertake unconditionally and irrevocably that the State of ..... shall ensure to:

i) adhere to the roles and responsibilities of the State as outlined under these guidelines and fulfil all the commitments made in the proposal.

ii) set up a State Implementing Agency (SIA) with the roles and responsibilities, as outlined in the Guidelines of the Scheme "Promotion of Bulk Drug Parks".

iii) make available balance amount of Project Cost without any delay, as may be required for completion of development of Bulk Drug Park, through budgetary and/or other sources, as may be necessary.

iv) not increase the land lease rent and utility charges, as declared in the proposal, beyond 5% per annum, for the next 10 years.

v) establish a Research and Development facility as a Centre of Excellence in the park to be operated by an institution or by a society. Such centre of excellence shall employ competent scientists with suitable experience and promote industry academia linkage. The State Government shall provide sufficient financial and other support for such centre.

vi) adhere to the responsibilities as specified in these guidelines and also the SIA, as appointed, and implementing agency, if any, as appointed, shall also adhere to the roles and responsibilities specified in these guidelines.

To be signed by the Authorised Signatory

Mention name and designation

Annexure 2

Detailed Project Report (DPR)

1. The DPR should include the following information among other details.

2. **Proposed State Implementing Agency (SIA) -** Type of organisation, legal status, shareholding pattern (give detail of any private participation such as PPP agreement, MoU etc. with model terms and structure), functions and responsibilities, budgetary allocation (if any), administrative dept. of the State for SIA.

   a. **Governing Body:** Constitution of governing body of the SIA.

   b. **Key Personnel Details:** Contact details of three senior officials of the proposer. Details would include Name, Designation, Address, phone, email

   c. **Contact Details of Authorized Representative:** Details would include Name, Designation, Address, phone, email

   Documents to be furnished: all applicable documents.

3. **Description of the Park:**

   a. Details of area of land allocated for Park, address and location

   b. Land Acquisition details with Survey nos.

   c. Any change in the status of encumbrance, pending legal dispute etc. submitted earlier in the proposal form

   d. Connectivity and linkage (distance from the nearest National Highway, Airport, Sea Port, Railway Station, residential area, etc.)

   e. Strength of the project location, description of the terrain, natural water resources available, type of land (Forest, agriculture, etc.) and other relevant detail, if any.

   f. Specify the useable land (Industrial Plots and plotting pattern based on number and size of plots), number of projected manufacturing facilities, internal roads, green buffer, open space, social infrastructure, support facilities and CIF.

   Document to be furnished: *Layout of the proposed bulk drug park and Geotagging details*

4. **Cost estimation & source of funds:**

   a. Furnish detailed head-wise cost of:

- **Development of the Park:** Provide breakup of cost into land development, green belt, internal roads, sewage, culverts, RCC drains, compound wall, street lighting, support facilities & misc. Provide cost of each building proposed in the Park with purpose of such building.
- **Development of CIF:** Provide break-up of cost of every project/ facility covered under common infrastructure facility.

b. Give Source of funds under the following broad heads:

- Share of Central Govt. (grant-in-aid)
- Share of State Govt. (Please specify details of Budgetary Allocation, Equity, Loan or any Other form of funding)
- Other Source of funds – (Please specify the source as bank loans, public bonds, private participation etc.)

c. Specify whether external funds, if any, shall be raised by the State of SIA and proposed model of fund raising.

d. Give phase-wise disbursement schedule of funds from all the sources till completion of the Park.

5. **Source of Revenue:** Furnish the detailed sources of revenue, with estimated annual revenue from each source.

a. Budgetary Allocation from the State
b. Land lease
c. Utility Charges
d. Any other source of revenue envisaged

Revenue Head	Charge per unit	Annual Revenue (Rs. In crore)
Land Lease	per sq. meter	
Power	kWh	
Effluent treatment	Per kilo litre	
Water	Per kilo litre	
Steam	Per Tonne	
Solid waste treatment	Per Tonne	
Warehouse	Monthly charges per square meter	
Park maintenance	Annual charges per square meter	
Any other	Specify nature and unit	

6. **Development of Common Infrastructure Facility (CIF):** The State is required to submit the detail for individual project item/ facility under CIF, as defined in the guidelines.

   a. Brief description the project item/ facility,
   b. Estimated capacity with detailed justification for arriving at such capacity considering area of the Park, proposed number of manufacturing units etc.
   c. Cost of each project item/ facility
   d. Comment on the technology applied with technical feasibility
   e. Timelines for starting the construction and completion of individual project item/ facility
   f. Phasing of individual project item/ facility, based on the estimated allotment of land to manufacturing facilities

7. **Infrastructure Support by the State:** The DPR should contain the following for support infrastructure to be provided by the State with timelines of completion:

   a. **Power & Water:** Detailed plan for committed source of water and power supply with capacity and adequacy to support the size of park and projected number of manufacturing units. Provide details of any necessary infrastructure to be created by the State like sub-station, transmission line, dedicated water reservoir and pipe-line etc. with timelines.

   b. **Ancillary Infrastructure:** All ancillary infrastructure like road, sewage, sanitation and social infrastructure to be developed by the State. Give size and scale of such ancillary infrastructure and proposed timelines of completion.

8. **Schedule for completion of the Park**

   a. Provide the Park implementation schedule based on Program Evaluation and Review Technique (PERT), Critical Path Method (CPM) and Gantt Chart including financial expenditure plan for each activity with proposed starting and completion date.

   b. Provide the "Schedule Date of Commercial Operations of the Park".

9. **Single Window Mechanism:**

   a. Provide details of single window mechanism proposed to be set-up in the park for giving clearance to the manufacturing units.

   b. Mention if any clearance under the proposed single window mechanism is to be given by Central Govt.

c. Provide details, if any clearance is not proposed to be kept under the single window mechanism and the reason for the same.

10. **Financial viability of the Park**:

a. Provide detailed market survey with respect to existing status of pharmaceutical sector in the State, strategic and locational advantage of the Park for new investment, policies of the State Govt. to attract FDI/ Domestic investment in the Sector, any MoU/ commitment from the interested investors to set-up units in the proposed Park etc.

b. Provide financial projection taking into account projected revenue, budgetary allocation, estimated occupancy, operational expenses, interest expense (if any) and other relevant factors.

c. Provide projected P&L, Balance Sheet, Cash Flow projection with detailed assumption and key ratio such as IRR, NPV, minimum occupancy for Break Even etc.

11. Regulatory Approvals:

Provide detail of all regulatory approvals and clearances required from State Govt. and Central Govt. with timelines, procedure and also whether the proposed Park and construction plan as per DPR is in compliance with the applicable regulations and standards.