Subject:- **GUIDELINES /STANDARD OPERATINMG PROCEDURE FOR QUOTA ALLOCATION OF CONTROLLED SUBSTANCES.**

1. a) Applications of controlled substances shall be submitted for each year by the firm/applicants by 7th January, with data consumed till 31st December of previous year.
   b) Checklist submitted with application shall be duly signed by MD / CEO / authorized senior representative and should also clearly indicate percentage of consumption (manufacturing and sale).
   c) Applications complete in all respects with 75% consumption in manufacturing and 65% sales will be considered by COACD in 1st meeting. Meeting of COACD will be held preferably every month.
   d) A Committee comprising of officers of Ministry of Narcotics Control, ANF and DRAP would scrutinize the application and shortcomings of incomplete applications will be conveyed to the applicants within one week after meeting giving 15 days time period.

2. Only those firms will be granted quota of Controlled Substances who have fulfilled the conditions/procedures as laid down in the quota allocation letters including information which is to be submitted to the field offices after procurement and sale etc.

3. The firms having sales reported in the IMS should submit the relevant IMS data along with their application dossier. The IMS data will be considered for framing ALR.

4. All firms to submit detailed consumption record of last import authorization along with import invoices. ADC consumption certificate (where applicable) and consumption record of material should be made basis for the allocation of new quota.

5. The detail of the last three year quota allocation and its consumption will also be submitted by the firms along with related documents (quota allocation letter, ADC attested invoices etc.)

6. The firms will have to provide supporting documents to justify their existing quota by submission of manufacturing for last three years on **Annex-A** and sales record reflected in the IMS, exports (if any) as on **Annex-B** for last three years. No signature shall be accepted on behalf of any authorized person. However, MD / CEO shall authorize senior representative on stamp paper who would sign on his behalf / absence on the relevant documents. His specimen signature in triplicate shall be attested by MD/CEO himself and oath commissioner for record purpose**.**

7. The quota for the firms who have applied for the first time will not exceed the maximum slab fixed for the molecule as at Annex. C.

8. The submission of the consumption certificate from concerned ADC or DDG would be mandatory for following controlled substances namely Morphine, Pethidine, Codeine Phosphate, Buprenorphine, Phenobarbitone, Alprazolam, Diazepam, Pentazocine.

9. The firm will have to submit the Undertaking that the quota granted in the last years has been used in the licit manufacturing of registered products and new quota will also be used for licit manufacturing and maximum precaution will be taken to avoid any possible diversion.

10. All documents attached with the application are true copies of the original and the same have been notarized from notary public as “Certified True Copy”

11. The committee may decide enhancement cases applied by the firms from July onward at any time every year, provided that the enhancement will be granted once in a year after consumption of 75% manufacturing & 65% sales and providing consumption of the last allocation.

12. Firms to indicate proportion of their quota required for export. The enhancement of quota will be considered on the basis of export orders provided by the firms.

13. Enhancements and allocations applications will also be considered in case of natural calamities or other emergency need.

14. While providing source for import, in cases where manufacturer and exporter are different, the firms/importer should provide name and address of both in writing for mentioning in import permit.

****

Annex-II

CHECK LIST FOR ALLOCATION OF QUOTA OF CONTROLLED SUBSTANCES

S#		Document	Yes/No	Page#	Remarks
1		Whether application is for routine allocation or for enhancement.			Routine/ First time / Export / Enhancement
2		Undertaking by the firm on stamp paper that they have fulfilled conditions of previous allocation letter.			
3		Sales reported in the IMS alongwith IMS data, if applicable.			
4	(a)	Quota allocation letter for the year , 2015			……. KG
	(b)	Quota allocation letter for the year , 2014			……. KG
	(c)	Quota allocation letter for the year , 2013			……. KG
	(d)	Copies of ADC attested invoices			
5	(a)	Manufacturing record for the year , 2015 as per **Annex-A**.			……. KG
	(b)	Manufacturing record for the year , 2014 as per **Annex-A**			……. KG
	(c)	Manufacturing record for the year , 2013 as per **Annex-A**			……. KG
6	(a)	Consumption for the year 2015 supported by documents of sales record as per **Annex-B**.			……. KG
	(b)	Consumption for the year 2014 supported by documents of sales record as per **Annex-B**.			……. KG
	(c)	Consumption for the year 2013 supported by documents of sales record as per **Annex-B**.			……. KG
	(d)	Average consumption for the three years			……. KG
	(e)	*Percentage (%) of Consumption of pervious allocation (Manufacturing and Sales)*			
7		Consumption certificate from concerned ADC or DDG for the **Morphine, Pethidine, Codeine Phosphate, Buprenorphine, Phenobarbitone, Alprazolam, Diazepam, Pentazocine.**			
8		• The firm will have to submit the Undertaking that the quota granted in the last years has been used in the licit manufacturing of registered products and new quota will also be used for licit manufacturing and maximum precaution will be taken to avoid any possible diversion. • All documents attached with the application are true copies of the original and the same have been notarized from notary public as "Certified True Copy" • All other submitted information is true.			
9		Proportion of the quota indicated by firms required for exports.			
10		Copy of the valid Registration letter of the drug (with status of renewal)			
11		Copy of valid Drug Manufacturing Licence (with status of renewal)			

Name, Seal & Signature
MANAGING DIRECTOR/
CHIEF EXECUTIVE OFFICER

ANNEX-A

MANUFACTURING RECORD FOR THE PREVIOUS YEAR'S ALLOCATION TO BE SUBMITTED ALONGWITH THE APPLICATION FOR CURRENT YEAR' ALLOCATION.

1. NAME OF THE CONTROLLED SUBSTANCE …… 2. QUANTITY ALLOCATED (Year)……
3. BALANCE quantity FROM PERVIOUS YEAR …….. ……. 4. TOTAL QUANTITY ……Kgs

S#	Name (Brand) of the Drug	Registration #	Batch Number	Date of Manufacture	Quantity/ Units Manufactured	Composition for the controlled substance	Quantity of R.M consumed	Remarks

1	Pack Size of the Finished Drug	
2	Total Unit Packs Manufactured	
3	Yield Loss during Manufacturing	
4	Total Quantity of Controlled Substance Consumed in Samples	
5	Total Quantity of Controlled Substance Consumed	
6	Quantity of raw material in balance (Kgs)	

Name, Seal & Signature
PRODUCTION MANAGER

Name, Seal & Signature
QUALITY CONTROL MANAGER

Name, Seal & Signature
MANAGING DIRECTOR/
CHIEF EXECUTIVE OFFICER

ANNEX-B

SALES RECORD FOR THE PREVIOUS YEAR'S ALLOCATION TO BE SUBMITTED ALONGWITH THE APPLICATION FOR CURRENT YEAR'S ALLOCATION.

NAME OF THE CONTROLLED SUBSTANCE …… CARRY OVER FINISHED STOCKS FROM PERVIOUS YEAR ……Kgs

S#	Name (Brand) of the Drug	Registration #	Batch Number	Date of Manufacture	Quantity/ Units Manufactured	Name of the Distributor (s) with Address	Quantity Sold	Warranty Number/ Sale Invoice with date	Remarks

1	Total Unit Packs sold	
2	Total Quantity of raw material consumed (Kg)	
3	Total Unit Packs unsold (lying in warehouse)	
4.	Quantity of raw material for Unit Packs unsold (Kg)	

Name, Seal & Signature DIRECTOR/ MANAGER SALES	**Name, Seal & Signature** AUTHORIZED WARRANTOR	**Name, Seal & Signature** MANAGING DIRECTOR/ CHIEF EXECUTIVE OFFICER