STANDARD OPERATING PROCEDURE (SOP) FOR QUOTA ALLOCATION OF CONTROLLED SUBSTANCES FOR BASIC/SEMI BASIC MANUFACTURING/PRECURSORS BY THE COMMITTEE FOR ALLOCATION OF QUOTA OF CONTROLLED SUBSTANCES (CAQCS)

1. The licensed firm(s) shall apply on the letter head by the MD/CEO of the firm along with documents as per Checklist of the SOP and the prescribed fee as per SRO.

2. The application will be evaluated by the concerned Assistant Director (CD) Division within 10working days and will issue the short coming(s) letter (if any) after taking approval from the Deputy Director/Additional Director/Director.

3. The firm can apply after consumption of previous allocation i.e. 75% in manufacturing and 65% in sales for locally purchased controlled substances and/or 65% in manufacturing and 55% in sales for imported controlled substances.

4. In case of complete application as per SOP the inspection letter will be issued to the panel to inspect the firm for verification of previous consumption (if any) / recommendation of new quantity for import/local purchase.

5. The panel may comprise of the following members:

i. Additional Director (E&M), DRAP

ii. Area Federal Inspector of Drugs / Assistant Director, DRAP

iii. Representative from Division of Controlled Drugs, DRAP

6. The panel will submit the inspection report mentioning the clear and candid recommendation to the Division of Controlled Drugs, DRAP for further processing of the case. In case of any violation / observation the Area FID will take immediate action as per DRAP Act 2012/Drugs Act 1976 and rules framed thereunder under intimation to the Division of Controlled Drugs DRAP.

7. The Division of Controlled Drugs DRAP will issue recommendation letter after evaluation of the case/inspection report to the Ministry of Narcotics Control, Islamabad. In case of any violation/observation the matter will be brought before the Ministry of Narcotics Control for further necessary action (if any) under the Control of Narcotic Substances Act, 1997.

8. The Ministry of Narcotics Control will issue the NOC as per procedure adopted at the time of issuance.

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Annexure -I

CHECK LIST FOR ALLOCATION OF QUOTA OF CONTROLLED SUBSTANCE(S)
(Basic Manufacturing/Semi Basic Manufacturing/Precursor(s))

Name of Applicant firm with complete Address_____
Name of Controlled Substance: _____ Year: _____
Quantity Demanded_____

Sr. #		Name of Document			Yes /No	Page#	Quantity (where applicable)	Remarks
1	1.1	Application is for	**I**. Routine allocation □	**II.** First Time □				
2	2.1	Notarize Undertaking on stamp paper for fulfillment of conditions of previous allocation letter as per **Annexure-F4**						
4	4.1	Notarized Copies of the Inspection/verification report by panel of DRAP.						
	4.2	Notarized copy of the recommendation latter(s) from DRAP						
	4.3	Notarized Copy of the Registration Certificate issed by the Ministry of Narcotics Control						
	4.4	Notarized copies of the NOC for Import/Export of the basic raw material/API.						
5	5.1	Year wise manufacturing record for the last allocation as per **Annex-A**.						
6	6.1	Year wise sales record for the last allocation as per **Annex-B**.						
	6.6	Percentage (%) of Consumption of last allocation (Manufacturing and Sales)						
7	7.1	Undertaking on stamp paper for licit manufacturing as per **Annex-F5**						
8	8.1	Copy of valid Drug Manufacturing License (with status of renewal)						
	8.2	Registration/permission/grant of active pharmaceutical product manufacturing letter.						
	8.3	NOC issued by the MNC after combined ground check of DRAP & ANF.						

Name, Seal & Signature of
MD/CEO/Authorized Person

Annexure -A

MANUFACTURING RECORD FOR THE YEAR_____(w.e.f. 1ST JANUARY TO 31ST DECEMBER)
TO BE SUBMITTED ALONG WITH THE APPLICATION OF QUOTA ALLOCATION FOR THE YEAR_____

1. NAME OF THE CONTROLLED SUBSTANCE …… ……2. QUANTITY ALLOCATED (Year)…… (Gram/Kg/Litre)
3. BALANCE QUANTITY (Carry Forward) FROM PERVIOUS YEAR …….. …….4. TOTAL QUANTITY ……(Gram/Kg/Litre)

Sr. #	Name of the Controlled Substances	Batch #	Date of Manufacture	Quantity Manufactured	Quantity of the basic material/Precursor Added	Quantity of the basic material/precursor Recovered (If any)	Quantity of the basic material/precursor Consumed	Remarks

1	Quantity of the Controlled Substances Added (Grams/Kg/Liter)	
2	Quantity of the controlled substance Recovered (Grams/Kg/Liter)	
3	Quantity of the controlled substance Used (Grams/Kg/Liter)	
4	Yield Loss during Manufacturing percentage and quantity (Grams/Kg/Liter)	
5	Total Quantity of Controlled Substance Consumed in QC/QA Sample (Grams/Kg/Liter)	
6	Total Quantity of Controlled Substance Consumed (Gram/Kg)	
7	Quantity of raw material in balance (Gram/Kg)	

Name, Seal & Signature
PRODUCTION MANAGER

Name, Seal & Signature
QUALITY CONTROL MANAGER

Name, Seal & Signature
MANAGING DIRECTOR/
CHIEF EXECUTIVE OFFICER

*Add row(s) where required.

Annexure -B

SALE RECORD FOR THE YEAR_____ (w.e.f. 1ST JANUARY TO 31ST DECEMBER)
TO BE SUBMITTED ALONG WITH THE APPLICATION OF QUOTA ALLOCATION FOR THE YEAR_____

NAME OF THE CONTROLLED SUBSTANCE ……CARRY OVER FINISHED STOCKS FROM PERVIOUS YEAR ……Kg/Gram

Sr. #	Name of the Controlled Substance	Batch Number	Date of Manufacture	Quantity Manufactured	Name of the purchasing firm with complete address as per drug Manufacturing License.	DRAP Allocation/ Recommendation Letter No. with date	MNC NOC Number with date	Quantity Sold	Warranty Number/ Sale Invoice with date	Remarks

1	Standard Batch Size (Grams/Kg/Liter)	
2	Total Batches Manufactured (Grams/Kg/Liter)	
3	Total Batches Sold (Grams/Kg/Liter)	
4	Quantity of raw material consumed (Grams/Kg/Liter)	
5	Quantity of raw material in balance (Grams/Kg/Liter)	

Name, Seal & Signature
DIRECTOR/ MANAGER SALES

Name, Seal & Signature
AUTHORIZED WARRANTOR

Name, Seal & Signature
MANAGING DIRECTOR/
CHIEF EXECUTIVE OFFICER

*Add row(s) where required.

UNDERTAKING FOR FULFILLMENT OF CONDITIONS OF PREVIOUS ALLOCATION OF CONTROLLED SUBSTANCE

I……..……. CNIC # …… resident of…….. hereby undertake, on behalf of M/s…….. Drug Manufacturing License No..... situated at ……., that the firm has fulfilled all the conditions of the previous allocation as per DRAP's/MNC's letter # …….dated……. regarding the controlled substance i.e. ……. quantity Allocated…….. in the year……

Name……

Signatures…….

Seal/Stamp……..

Designation: MD/CEO/Authorized Person

Annexure -F5

UNDERTAKING FOR LICIT MANUFACTURING OF CONTROLLED SUBSTANCE

I……..……. CNIC # …… resident of…….. hereby undertake, on behalf of M/s…….. DML#..... situated at ……., that

- The quota of controlled substance i.e. ……. granted in the last allocation i.e. year……. as per DRAP's letter # …….dated……. has been utilized in the licit manufacturing of registered product(s) (Product Name) and new quota will also be used for licit manufacturing of the said registered product(s) and maximum precautions 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 and marked as "Certified True Copy".
- All other submitted information is true and correct.

The under signed and the firm M/s…….. shall be held responsible and shall be liable for legal proceeding/action under the law in case any submitted information is found incorrect/misleading at any stage.

Name……

Signatures…….

Seal/Stamp……

Designation: MD/CEO/ Authorized Person

END OF DOCUMENTS