SOP FOR QUOTA ALLOCATION OF CONTROLLED SUBSTANCES FOR EXPORT PURPOSE

1. Application(s) for allocation of controlled substance for export purpose signed by MD/CEO/Authorized Person shall be submitted along with duly filled in checklist and all the required documents/pre-requisites as mentioned in the checklist **(Annexure-II).** However due to unavoidable circumstances, the next senior most management person can be authorized by the MD/CEO to sign the said checklist subject to following conditions:-

a) CEO/ MD of the applicant firm will submit an undertaking on stamp paper attesting the signature of the person being authorized in triplicate.

b) Stating the reason for authorization and taking the full responsibility for such authorization.

c) The authorization shall be valid for that particular case only.

2. Each application will be evaluated initially by the concerned Assistant Director/Desk Officer, Division of Controlled Drugs, DRAP. The shortcomings so observed in the application(s) shall be communicated to the applicant after preliminary evaluation by the Division of Controlled Drugs, DRAP with the approval of Additional/Deputy Director of Division of Controlled Drugs, DRAP within ten working days of receipt of application giving seven days' time to the applicant for submission of reply for further evaluation of the case by the Division of Controlled Drugs, DRAP again. The application so evaluated by the Division shall be scrutinized subsequently by the Scrutiny Committee comprising of officers of Ministry of Narcotics Control, Anti Narcotic Force (ANF) and DRAP.

3. Only those applications shall be included in agenda of meeting of CAQCS for its consideration and decision which have been evaluated by Scrutiny Committee and found complete. However incomplete applications/cases as determined by the Scrutiny Committee along with recommendations shall also be included in the agenda for consideration/endorsement of the CAQCS.

4. The complete case(s) for export of finished product(s) will be presented in the meeting of CAQCS for its consideration in the light of minutes of meeting of Scrutiny Committee. After approval of the minutes of the meeting of CAQCS Allocation Letter and Import Authorization (if applicable) will be issued as per firm's request, accordingly.

5. Recommendation letter, will be forwarded to Ministry of Narcotics Control, Islamabad for further processing of the case i.e. Pre Export Notification and issuance of NOC, in light of application/information for export of finished product submitted by the firm to the Division of Controlled Drugs, DRAP,.

6. After receipt of NOC from Ministry of Narcotics Control, Islamabad, the Export Permit/ Authorization will be issued to the firm/applicant by Division of Controlled Drugs, DRAP, accordingly.

7. The firms shall submit following documents/information duly verified/attested by the Embassy/High Commission of Pakistan in Country of Import and Ministry of Foreign Affairs, Pakistan within 90 days of receipt of the shipment in the Country of Import:-

i. Customs Clearance Documents (Importing Country)
ii. Goods Declaration Form (Importing Country),
iii. Packing List of exported shipment,
iv. Invoices of the shipment Exported,
v. Notarized copies of clearance documents issued by Pakistan Customs

8. The documents annexed with application for Quota Allocation for export purpose and with application for Issuance of NOC shall be notarized by the Notary Public and marked as "Certified True Copy".

9. In case of advisory issued by International Narcotics Control Board (INCB) or emergency/natural calamities declared by the Federal Government the Committee may relax any clause(s) of the SOP to process the export case(s) on fast track.

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Annexure -II

CHECK LIST FOR ALLOCATION OF QUOTA OF CONTROLLED SUBSTANCES FOR EXPORT PURPOSE

Name of applicant firm with complete address_____

Name Of controlled substance: _____Year of Application: _____

Quantity of Controlled Substance in the product(s) to be Exported _____Quantity Demanded _____

Name of Importing Country _____ Import Authorization Number_____

Date of Issuance of Import Authorization_____Date of Expiry of Import Authorization _____

Sr. #		Name of Document	Yes /No	Page #	Remarks
1	1.1	Application for export allocation signed by MD/CEO/Authorized Person			
2	2.1	Undertaking by the firm on stamp paper that they have fulfilled conditions of previous allocation letter as per **Annexure-F1**			
3	3.1	Original Import Permit/Authorization **and/or NOC for Import in case of Ketamine** & other domestically controlled substances, issued by Country of Import in favor of the Importer/Exporter.			
	3.2	Original Purchase Order from Importer. (Notarized from Country of Import)			
4	4.1	Notarized copy of Quota Allocation Letter for Last Export quantity issued by DRAP.			
	4.2	Notarized copy of Export Authorization of last consignment for the concerned country issued by DRAP.			
	4.3	i. Customs Clearance Documents (Importing Country). ii. Goods Declaration Form (Importing Country). iii. Packing List of exported shipment. iv. Clearance documents issued by Pakistan Customs			
	4.4	Notarized Copies of Export Invoice(s) along with NOC from Concerned Area Assistant Director(AD), DRAP			
5	5.1	Manufacturing record for the last export allocation on **Annex-A**.			
6	6.1	Consumption record for the last Allocation on **Annex-B**.			
7	7.1	Consumption certificate from concerned Assistant Director for the **Morphine, Pethidine, Codeine Phosphate, Buprenorphine, Clonazepam, Phenobarbitone, Alprazolam, Diazepam, Pentazocine and Fentanyl** allocated for export purpose only.			
8	8.1	• The firm will have to submit the Undertaking that the quota granted in the last allocation has been used in the licit manufacturing of registered products for export purpose only and new quota will also be used for licit manufacturing and maximum precaution will be taken to avoid any possible diversion. • The quota allocated shall not be used for consumption/sale in local market. • 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. The under signed and the firm M/s…….. shall be held responsible in case any submitted information is found incorrect/misleading and will be liable for legal proceeding/action under the law.(as per **Annexure-F3**)			
9	9.1	Copy of the valid Registration letter of the drug (with status of renewal)			**As per Annexure-E**
10	10.1	Copy of valid Drug Manufacturing License (with status of renewal)			

Name, Seal & Signature
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)
3. BALANCE QUANTITY (Carry Forward) FROM PERVIOUS YEAR …….. …….4. TOTAL QUANTITY ……(Gram/Kg)

Sr. #	Name (Brand) of the Drug	Registration #	Batch #	Pack size	Date of Manufacture	Quantity of Packs Manufactured	Composition for the controlled substance	Quantity of R.M consumed	Remarks

1	Pack size with strength of the Finished Drug of Commercial Packs and Physician sample *	Strength								
		Pack Size								
2	No of Unit Manufactured									
3	Quantity of Controlled Substance Consumed (Gram/Kg)									
4	Yield Loss during Manufacturing percentage and quantity (% & Gram/Kg)									
5	Total Quantity of Controlled Substance Consumed in QC/QA Sample (Gram/Kg)									
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 (Brand) of the Drug	Registration #	Pack Size	Batch Number	Date of Manufacture	Quantity of Packs Manufactured	Name of the Distributor (s) with Address, City and Province	Quantity Sold	Warranty Number/ Sale Invoice with date	Remarks

1	Pack size with strength of Finished Drug of Commercial Packs and Physician sample *	Strength							
		Pack size							
2	Total Unit Packs sold								
3	Quantity of raw material consumed (Gram/Kg)								
4	Total Unit Packs unsold (lying in warehouse)								
5	Quantity of raw material for Unit Packs unsold (Gram/Kg)								
6	Total Quantity of raw material consumed (Gram/Kg)								

Name, Seal & Signature
DIRECTOR/ MANAGER SALES

Name, Seal & Signature
AUTHORIZED WARRANTOR

Name, Seal & Signature
MANAGING DIRECTOR/
CHIEF EXECUTIVE OFFICER

*Add row(s) where required

Annexure-E

MANUFACTURER / IMPORTER DETAIL

Sr. #	Name of Manufacturer with Address	Type Of license	License No.	Date of Issue	Last Renewal	Remarks
1						

BRAND(s) DETAIL

Sr. #	Brand (S)	Registration No	Approved Pack Size	Approved Composition	Date of Registration	Date of Transfer of Registration (If Any)	Last Renewal of Reg.	Remarks
1*								
2								

*Add rows as per brands and pack size if required.

Annexure -F1

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 the conditions of the previous allocation as per DRAP's letter # …….dated……. regarding the controlled substance i.e. ……. quantity allocated…….. in the year……

Name……

Signatures…….

Seal/Stamp……..

Designation: MD/CEO/Authorized Person

Annexure -F3

UNDERTAKING FOR LICIT MANUFACTURING OF CONTROLLED SUBSTANCE FOR EXPORT PURPOSE

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

- The quota granted in the last allocation has been used in the licit manufacturing of registered products for export purpose only and new quota will also be used for licit manufacturing and maximum precaution will be taken to avoid any possible diversion. The quota so allocated shall not be used for consumption/sale in local market.
- 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