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 , 2013			……. KG
	(b)	Quota allocation letter for the year , 2012			……. KG
	(c)	Quota allocation letter for the year , 2011			……. KG
	(d)	Copies of ADC attested invoices			
5	(a)	Manufacturing record for the year , 2013 as per **Annex-A**.			……. KG
	(b)	Manufacturing record for the year , 2012 as per **Annex-A**			……. KG
	(c)	Manufacturing record for the year , 2011 as per **Annex-A**			……. KG
6	(a)	Consumption for the year 2013 supported by documents of sales record as per **Annex-B**.			……. KG
	(b)	Consumption for the year 2012 supported by documents of sales record as per **Annex-B**.			……. KG
	(c)	Consumption for the year 2011 supported by documents of sales record as per **Annex-B**.			……. KG
	(d)	Average consumption for the three years			……. KG
7		Consumption certificate from concerned ADC or DDG for the **Morphine, Pethidine, Codeine Phosphate, Buprenorphine, Phenobarbitone, Alprazolam, Diazepam, Pentazocine.**			
8		The undertaking on stamp paper 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 precautions will be taken to avoid any possible diversion.			
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)			

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 ……

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	Total Quantity of Controlled substance consumed (Kg)	
4.	Quantity of raw material in balance (Kg)	

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 ……

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