

## The Health Master

### Area required for manufacturing of Drugs, Cosmetics, Homoeopathic and Blood Centre

Manufacturing area / section	Area prescribed for basic installations (Square Metre)	Ancillary Area prescribed (Square Metre)	Total Area required (Square Metre)
<b><u>Allopathic drugs</u></b>			
External Preparations	30	10	40
Oral Liquid Preparations	30	10	40
Tablets (uncoated) Non-Beta Lactum (Granulation + compression + packaging etc)	60	20	80
Coating (Non-Beta Lactum)	30	10	40
Tablets (uncoated) Beta Lactum (Granulation + compression + packaging etc)	60	20	80
Coating (Beta Lactum)	30	10	40
Powders (oral)	30	-	30
Hard Gelatin Capsules (Beta-lactam)	25	10	35
Hard Gelatin Capsules (Non Beta-lactam)	25	10	35
Ophthalmic Preparation	25	10	35
Eye ointment, Eye lotion	25	-	25
Pessaries	20	-	20
Inhalers & Vitraliae	20	-	20
Re-packing of drugs	30	-	30
Parenteral (Small Volume Parenteral)	150	100	250
Parenteral (Large Volume Parenteral)	150	150	300
Plastic (LVP) by Form-Fill-Seal / Blow, Fill –Seal technology	250	150	400

<b><u>Homoeopathic</u></b>			
Mother tincture and mother solutions	55	-	55
Potentization section	20	-	20
Trituration, Tableting, Pills and Globules section	55	-	55

## The Health Master

Syrups & other oral liquids	20	-	20
Ointments & lotions section	20	-	20
Ophthalmic Preparations	20	-	20
Packing & labelling	50	-	50

<b><u>Cosmetics</u></b>			
A. Powders	15	-	15
B. Skin powder for infants	15	-	15
C. Creams, Lotions, Shampoo, Shaving Creams, Hair Oils, Emulsions, Pastes, Cleansing Milk, Pomade	25	-	25
D. Nail Polish and Nail Lacquers	15	-	15
E. Lipsticks and Lipgloss	15	-	15
F. Depilatories used for eyes	10	-	10
G. 1. Eyebrows, Eyelashes, Eyeliners	10	-	10
2. Kajal and Surma	10	5	15
		For base sterilization	
H. Aerosols	15	-	15
I. Alcoholic Fragrance Solutions	15	-	15
J. Hair Dyes	15	-	15
K. Tooth powders general	15	-	15
L. Toilet Soaps	100	-	100

<b><u>Blood Bank / Centre</u></b>			
Blood Bank / Centre (only for Whole Human Blood)	100	-	100
Blood Component	50	-	50
Blood Bank / Centre including Blood Components	150	-	150
Apheresis	10	-	10

## The Health Master

<b><u>Medical Devices</u></b>
Area not prescribed in MDR 2017 for manufacturing of Medical Devices
<b><u>Medicinal Gas</u></b>
Area not prescribed for manufacturing of Medicinal gases
<b><u>Disinfectant</u></b>
Area not prescribed for manufacturing of Disinfectants
<b><u>API (Bulk drug)</u></b>
Area not prescribed for manufacturing of API (Bulk drugs)
<b><u>Empty Capsule Shell</u></b>
Area not prescribed for manufacturing of Empty gelatin Shell
<b><u>Soft Gelatin Capsules</u></b>
Area not prescribed for manufacturing of Soft Gelatin Capsules
<b><u>Cytotoxic substances / Sex hormones</u></b>
Same area required as defined for tablet section
<b><u>Laboratory</u></b>
Area for Commercial Laboratory or Laboratory for manufacturing units not prescribed

**Note:** Requirement of ancillary area shall not apply to the units registered before 30-06-2005

Compiled by:

**Lalit Kr. Goel**, DSDC, **FDA Haryana**

**Rakesh Dahiya**, SDCO, **FDA Haryana**