

# Pharmaceutical Sector Specific Clearances

**Madhya Pradesh**

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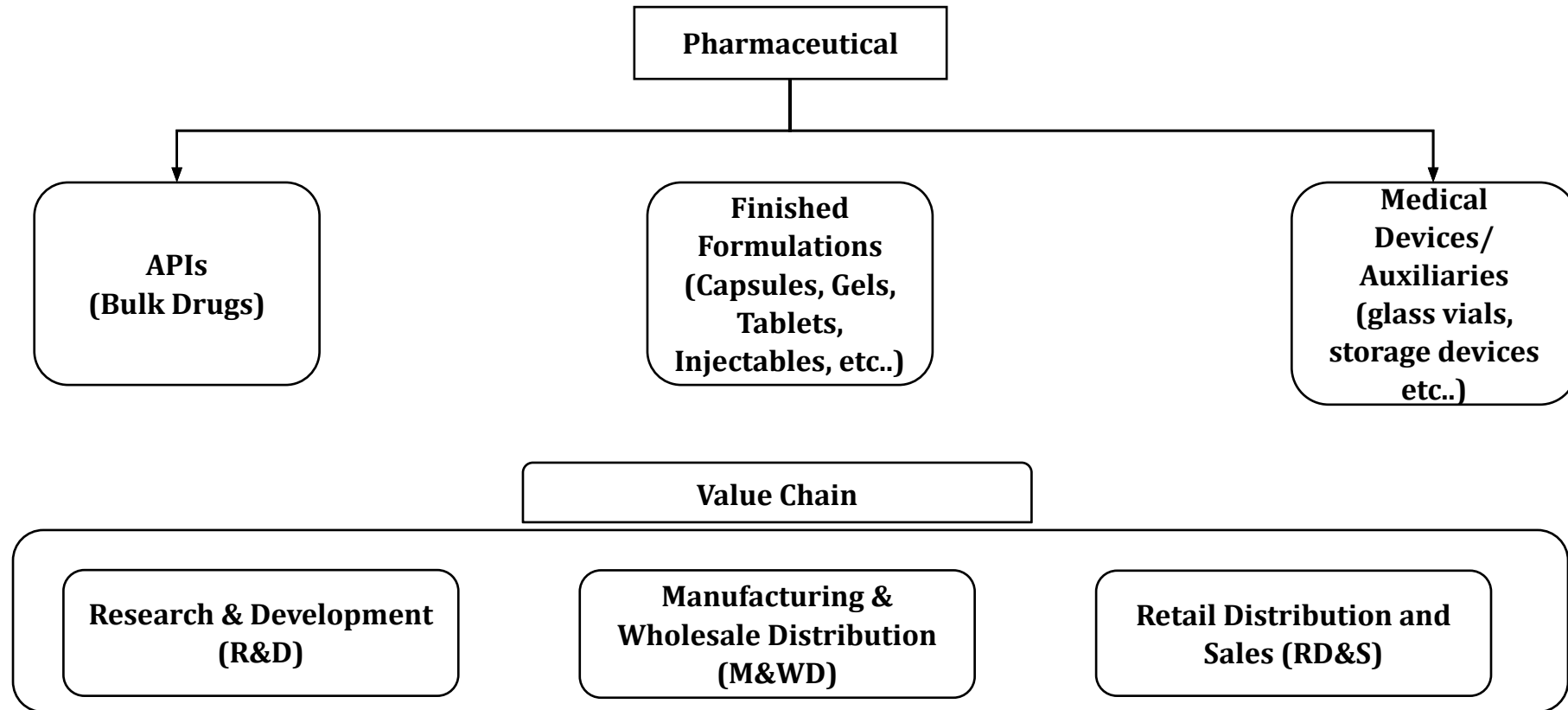
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# Overview of Pharmaceutical Sector

01

Madhya Pradesh

The Pharmaceutical Sector is broadly divided into three major sub-sectors: (a) Active Pharmaceutical Ingredients (API), (b) Finished Formulations, and (c) Medical Devices/Auxiliaries. The Sector Specific Clearances\* for these sub-sectors have been listed in this document. An illustration of the same is presented below along with the value chains that span across the sub-sectors:



The Comprehensive list of clearances provided on the following pages is specific to the Pharma Sector along with common clearances required by any enterprise to establish a unit or Business in Madhya Pradesh. Most of the clearances can be applied through <https://invest.mp.gov.in/> few others can be applied online through the mentioned Departmental portal as mentioned in the document.

*\*Clearances mean certificates, allotments, consents, approvals, permissions, registrations, enrolments, licences and the like, as the case maybe.*

*\* Active Pharmaceutical Ingredients (API)*

## Common Clearances

02

Madhya Pradesh

Sr. No	Clearances Name	Location of the Proposed Industry	Issuing Authority	Link to Governing Legislation	Governing Act/Rules	Timeline	Link to Apply
1	Land Allotment	MP Industrial Area	Madhya Pradesh Industrial Development Corporation (MPIDC)	<a href="#">Land Allotment Rules.pdf (mp.gov.in)</a>	Land Allotment Rules	29 Days	<a href="https://invest.mp.gov.in/services/">https://invest.mp.gov.in/services/</a>
2	Building Plan Approval	MP Industrial Area	MPIDC	<a href="#">MP State Industrial land and Building Management Rules, 2015</a>	MP State Industrial land and Building Management Rules, 2015	10 Days	<a href="https://invest.mp.gov.in/services/">https://invest.mp.gov.in/services/</a>
		Planning Area- Other than MP Industrial Area	Concerned Local Body	<a href="#">Bhumi Vikas Niyam 2012</a>	Bhumi Vikas Niyam 2012	45 Days	<a href="https://164.100.196.30/Content/html/abpas6.4.2/Homepage.html#/">https://164.100.196.30/Content/html/abpas6.4.2/Homepage.html#/</a>
		Non Planning Area-Other than MP Industrial Area	Panchayat & Rural Development Department	<a href="#">Madhya Pradesh Panchayat Raj &amp; Gram Swaraj Adhiniyam, 1993</a>	Under Section 55 of Madhya Pradesh Panchayat Raj & Gram Swaraj Adhiniyam, 1993	45 Days	<a href="https://prd.mp.gov.in/Public/OnlineServices/BuildingConstruction/ApplicationForBuildingConstructionPermission.aspx">https://prd.mp.gov.in/Public/OnlineServices/BuildingConstruction/ApplicationForBuildingConstructionPermission.aspx</a>
3	Change of Land Use	Planning Area- Other than MP Industrial Area	Directorate of Town and Country Planning	<a href="#">Madhya Pradesh Nagar Tatha Gram Nivesh Adhiniyam, 1973</a>	Section 23-a (1-a) of Madhya Pradesh Nagar Tatha Gram Nivesh Adhiniyam, 1973	Not Defined	<a href="https://geoportal.mp.gov.in/geoportal/Project_TnCP.aspx">https://geoportal.mp.gov.in/geoportal/Project_TnCP.aspx</a>
		Non-Planning Area- Other than MP Industrial Area (Diversion)	Commissioner of Land Records (CLR)	<a href="#">Madhya Pradesh Revenue Code,1959</a>	Madhya Pradesh Revenue Code,1959	15 Days	<a href="https://mpbhulekh.gov.in">Madhya Pradesh (mpbhulekh.gov.in)</a>

Sr. No	Clearances Name	Location of the Proposed Industry	Issuing Authority	Link to Governing Legislation	Governing Act/Rules	Timeline	Link to Apply
4	Property Registration	All Property in the State	Inspectorate General of Registration and Superintendent of Stamps(IGRS)	<a href="#">Indian Stamp Act,1899 (Madhya Pradesh Amendment),2016 -download (mpigr.gov.in)</a> <a href="#">The Registration Act, 1908-download (mpigr.gov.in)</a>	The Registration Act, 1908 Indian Stamp Act, 1899 (Madhya Pradesh Amendment), 2016	01 Day	<a href="#">User Registration (mpigr.gov.in)</a>
5	Mutation	Planning Area-Other than MP Industrial Area	Concerned Local Body	<a href="#">Madhya Pradesh Revenue Code,1959</a>	Madhya Pradesh Revenue Code,1959	Not Defined	<a href="http://www.mpenagarpalika.gov.in">www.mpenagarpalika.gov.in</a>
		Non-Planning Area-Other than MP Industrial Area	Principle Revenue Commissioner	<a href="#">Madhya Pradesh Revenue Code,1959</a>	Madhya Pradesh Revenue Code,1959	45 Days	<a href="http://mpbhulekh.gov.in">Madhya Pradesh (mpbhulekh.gov.in)</a>
6	Tree Felling NoC	Planning Area-Other than MP Industrial Area	Concerned Urban Local Body	<a href="#">The Madhya Pradesh Municipalities Act, 1961</a> <a href="#">Madhya Pradesh Municipal Corporation Act 1956</a>	The Madhya Pradesh Municipalities Act, 1961 Madhya Pradesh Municipal Corporation Act 1956	30 Days	<a href="https://mpenagarpalika.gov.in:8000/sap/bc/webdynpro/sap/zcrm_tree_cut#">https://mpenagarpalika.gov.in:8000/sap/bc/webdynpro/sap/zcrm_tree_cut#</a>
7	Tree Transit	Planning Area-Other than MP Industrial Area	Concerned Urban Local Body	<a href="#">The Madhya Pradesh Municipalities Act, 1961</a> <a href="#">Madhya Pradesh Municipal Corporation Act 1956</a>	The Madhya Pradesh Municipalities Act, 1961 Madhya Pradesh Municipal Corporation Act 1956	30 Days	<a href="https://mpenagarpalika.gov.in:8000/sap/bc/webdynpro/sap/zmp_tree_transit1#">https://mpenagarpalika.gov.in:8000/sap/bc/webdynpro/sap/zmp_tree_transit1#</a>

Sr. No	Clearances Name	Location of the Proposed Industry	Issuing Authority	Link to Governing Legislation	Governing Act/Rules	Timeline	Link to Apply
8	Fire NoC	Planning Area Including MP Industrial Area	Concerned Local Body	<a href="https://govtpressmp.nic.in/pdf/extra/2020-09-28-Ex-355.pdf">https://govtpressmp.nic.in/pdf/extra/2020-09-28-Ex-355.pdf</a>	MP-Bhumi-Vikas-Adhiniyam-2012	30 Days	<a href="https://mpenagarpalika.gov.in:8000/sap/bc/webdynpro/sap/zcrm_firenoc_application?sap-client=500&amp;sap-language=EN#">https://mpenagarpalika.gov.in:8000/sap/bc/webdynpro/sap/zcrm_firenoc_application?sap-client=500&amp;sap-language=EN#</a>
		Non Planning Area-Other than MP Industrial Area	Concerned District Administration	<a href="https://govtpressmp.nic.in/pdf/extra/2020-09-28-Ex-355.pdf">https://govtpressmp.nic.in/pdf/extra/2020-09-28-Ex-355.pdf</a>	MP-Bhumi-Vikas-Adhiniyam-2012	30 Days	
9	Factory Plan/ Layout approval	Any Area in the State	Labour Department	<a href="https://cglabour.nic.in/ShramAvuktNew/FactoryRule.pdf">https://cglabour.nic.in/ShramAvuktNew/FactoryRule.pdf</a>	Under Section 6 & 7 of the Factories Act, 1948 read with Rules 3 (a) of MP Factories Rules, 1962	07 Days	<a href="http://www.labour.mp.gov.in">http://www.labour.mp.gov.in</a>
10	New Service Connection (NSC) Application-Temporary	Discom- East Zone	Concerned Discom Authority	<a href="https://cercind.gov.in/Act-with-amendment.pdf">https://cercind.gov.in/Act-with-amendment.pdf</a>	Electricity Act, 2003, Section 42 & 43	07 Days	<a href="https://smartbijlee.mpez.co.in/">https://smartbijlee.mpez.co.in/</a>
		Discom- West Zone	Concerned Discom Authority	<a href="https://cercind.gov.in/Act-with-amendment.pdf">https://cercind.gov.in/Act-with-amendment.pdf</a>	Electricity Act, 2003, Section 42 & 43	07 Days	<a href="https://mpwzservices.mpw.in.co.in/mpeb_english/home">https://mpwzservices.mpw.in.co.in/mpeb_english/home</a>
		Discom-Central Zone	Concerned Discom Authority	<a href="https://cercind.gov.in/Act-with-amendment.pdf">https://cercind.gov.in/Act-with-amendment.pdf</a>	Electricity Act, 2003, Section 42 & 43	07 Days	<a href="https://portal.mpcz.in/web/eodb/#1593498795598-95be74f4-298e">https://portal.mpcz.in/web/eodb/#1593498795598-95be74f4-298e</a>
11	Right of Way/Road Cutting Permission	Planning Area-Other than MP Industrial Area	Concerned Local Body	<u>The Madhya Pradesh Municipalities Act, 1961</u> <u>Madhya Pradesh Municipal Corporation Act 1956</u>	The Madhya Pradesh Municipalities Act, 1961 Madhya Pradesh Municipal Corporation Act 1956	30 Days	<a href="https://www.mpenagarpalika.gov.in:8001/sap/bc/webdynpro/sap/zrc_application?sap-client=500&amp;sap-language=EN#">https://www.mpenagarpalika.gov.in:8001/sap/bc/webdynpro/sap/zrc_application?sap-client=500&amp;sap-language=EN#</a>



Sr. No	Clearances Name	Location of the Proposed Industry	Issuing Authority	Link to Governing Legislation	Governing Act/Rules	Timeline	Link to Apply
12	Water Connection	MP Industrial Area	MPIDC	-	-	15 Days	<a href="#">Invest MP – Invest Madhya Pradesh</a>
		Planning Area-Other than MP Industrial Area	Concerned Urban Local Body	<a href="#">The Madhya Pradesh Municipalities Act, 1961</a> <a href="#">Madhya Pradesh Municipal Corporation Act 1956</a>	The Madhya Pradesh Municipalities Act, 1961 & Madhya Pradesh Municipal Corporation Act 1956	15 Days	<a href="http://www.mpenagarpalika.gov.in">www.mpenagarpalika.gov.in</a>
		Non Planning Area-Other than MP Industrial Area	Water Resources Department	<a href="http://mpwrdd.gov.in">Chapter00-Short-Title-Rules (mpwrdd.gov.in)</a>	Madhya Pradesh Irrigation Act, 1931 (No. 3, 1931 )	15 Days	-
13	Consent to Establish	Any Area in the State	Concerned Local Body	<a href="https://mppcb.mp.gov.in/PdfView.aspx?h=Acts/Rule&amp;pdf=/proc/Air%20Act.pdf">https://mppcb.mp.gov.in/PdfView.aspx?h=Acts/Rule&amp;pdf=/proc/Air%20Act.pdf</a> <a href="https://mppcb.mp.gov.in/PdfView.aspx?h=Acts/Rule&amp;pdf=/proc/WaterAct-1974.pdf">https://mppcb.mp.gov.in/PdfView.aspx?h=Acts/Rule&amp;pdf=/proc/WaterAct-1974.pdf</a>	The Air (Prevention And Control Of Pollution) Act, 1981 Water (Prevention and Control of Pollution) Act 1974	30 Days	<a href="https://xgn.mp.nic.in/">https://xgn.mp.nic.in/</a>

Sr. No	Clearances Name	Location of the Proposed Industry	Issuing Authority	Link to Governing Legislation	Governing Act/Rules	Timeline	Link to Apply
01	Consent to Operate	Any Area in the State	M P Pollution Control Board	<a href="https://mppcb.mp.gov.in/PdfView.aspx?h=Acts/Rule&amp;pdf=/proc/Air%20Act.pdf">https://mppcb.mp.gov.in/PdfView.aspx?h=Acts/Rule&amp;pdf=/proc/Air%20Act.pdf</a> <a href="https://mppcb.mp.gov.in/PdfView.aspx?h=Acts/Rule&amp;pdf=/proc/WaterAct-1974.pdf">https://mppcb.mp.gov.in/PdfView.aspx?h=Acts/Rule&amp;pdf=/proc/WaterAct-1974.pdf</a>	<p>The Air (Prevention And Control Of Pollution) Act, 1981</p> <p>Water (Prevention and Control of Pollution) Act 1974</p>	30 Days	<a href="http://xgn.mp.nic.in">http://xgn.mp.nic.in</a>
02	Application for Drawing Approval Under Electrical Installation HV/EHV/ Diesel Generator/ Non-Conventional	Concerned Discom Area	Chief Electrical Inspector	<a href="https://energy.mp.gov.in/sites/default/files/documents/85602015.pdf">https://energy.mp.gov.in/sites/default/files/documents/85602015.pdf</a>	Electrical Inspector (Regulation 43)	07 Days	<a href="https://esd.mponline.gov.in/portal/services/home.aspx">https://esd.mponline.gov.in/portal/services/home.aspx</a>
03	Application for Inspection and Approval of HV/EHV/Diesel Generator/Non-conventional Installation by Electrical Inspector	Concerned Discom Area				07 Days	<a href="https://esd.mponline.gov.in/portal/services/home.aspx">https://esd.mponline.gov.in/portal/services/home.aspx</a>

Sr. No	Clearances Name	Location of the Proposed Industry	Issuing Authority	Link to Governing Legislation	Governing Act/Rules	Timeline	Link to Apply
04	New Service Connection (NSC) Application-Permanent	Discom- East Zone	Concerned Discom Authority	<a href="https://cercind.gov.in/Act-with-amendment.pdf">https://cercind.gov.in/Act-with-amendment.pdf</a>	Electricity Act, 2003, Section 42 & 43	07 Days	<a href="https://smartbijlee.mpez.co.in/">https://smartbijlee.mpez.co.in/</a>
		Discom- West Zone	Concerned Discom Authority	<a href="https://cercind.gov.in/Act-with-amendment.pdf">https://cercind.gov.in/Act-with-amendment.pdf</a>	Electricity Act, 2003, Section 42 & 43	07 Days	<a href="https://mpwzservices.mpw.in.co.in/mpeb_english/home">https://mpwzservices.mpw.in.co.in/mpeb_english/home</a>
		Discom-Central Zone	Concerned Discom Authority	<a href="https://cercind.gov.in/Act-with-amendment.pdf">https://cercind.gov.in/Act-with-amendment.pdf</a>	Electricity Act, 2003, Section 42 & 43	07 Days	<a href="https://portal.mpcz.in/web/eodb/#1593498795598-95be74f4-298e">https://portal.mpcz.in/web/eodb/#1593498795598-95be74f4-298e</a>
05	Professional Tax Registration	Any Area in the State	Commercial Tax Department	<a href="https://mptax.mp.gov.in/mpvatweb/download/Act/pdf/PTActRules.pdf">https://mptax.mp.gov.in/mpvatweb/download/Act/pdf/PTActRules.pdf</a>	Under section 8 of Madhya Pradesh Profession Tax Act, 1995	01 Day	<a href="https://mptax.mp.gov.in">https://mptax.mp.gov.in</a>
06	GST Registration	Any Area in the State	Commercial Tax Department	<a href="https://gstcouncil.gov.in/sites/default/files/consti-amend-Act.pdf">https://gstcouncil.gov.in/sites/default/files/consti-amend-Act.pdf</a>	The Constitution (One Hundred and First Amendment) Act 2017	01 Day	<a href="https://reg.gst.gov.in/registration/">https://reg.gst.gov.in/registration/</a>
07	Shop & Establishment	Any Area in the State	Labour Department	<a href="https://www.code.mp.gov.in/WriteReadData/Pdf/Act_1958_0025_Pdf_F119_English.pdf">https://www.code.mp.gov.in/WriteReadData/Pdf/Act_1958_0025_Pdf_F119_English.pdf</a>	Madhya Pradesh Shops & Establishments Act 1958	01 Day	<a href="https://labour.mponline.gov.in/Portal/Services/Shram/default.aspx">https://labour.mponline.gov.in/Portal/Services/Shram/default.aspx</a>
08	Factory License	Any Area in the State	Labour Department	<a href="https://labour.gov.in/sites/default/files/factories_act_1948.pdf">https://labour.gov.in/sites/default/files/factories_act_1948.pdf</a>	Factories Act, 1948	07 Days	<a href="https://labour.mponline.gov.in/Portal/Services/Shram/default.aspx">https://labour.mponline.gov.in/Portal/Services/Shram/default.aspx</a>
09	Licenses to Contractors under Contract Labour (Regulation and Abolition) Act, 1970	Any Area in the State	Labour Department	<a href="https://clc.gov.in">Contract Labour (Regulation &amp; Abolition) Act, 1970   Chief Labour Commissioner (clc.gov.in)</a>	Contract Labour Act, 1970	03 Days	<a href="https://registration.shramsavidha.gov.in/user/login">https://registration.shramsavidha.gov.in/user/login</a>





Sr. No	Clearances Name	Location of the Proposed Industry	Issuing Authority	Link to Governing Legislation	Governing Act/Rules	Timeline	Link to Apply
10	Registration of Principal Employer	Any Area in the State	Labour Department	<a href="https://clc.gov.in/clc/Acts-Rules/contract-labour-regulation-abolition-act-1970">https://clc.gov.in/clc/Acts-Rules/contract-labour-regulation-abolition-act-1970</a>	Contract Labour (Regulation and Abolition) Act, 1970	03 Days	<a href="http://www.labour.mp.gov.in">www.labour.mp.gov.in</a>
11	Registration of Principal Employer employing Inter State Migrant Workers	Any Area in the State	Labour Department	<a href="https://clc.gov.in/clc/acts-rules/contract-labour-regulation-abolition-act-1970">https://clc.gov.in/clc/acts-rules/contract-labour-regulation-abolition-act-1970</a>	Inter-State Migrant Workers Act, 1979, Contract Labour (Regulation and Abolition) Act, 1970	03 Days	<a href="http://www.labour.mp.gov.in">www.labour.mp.gov.in</a>
12	Application for Trade License	Any Area in the State	Concerned Local Body	<u>Madhya Pradesh Municipal Corporation Act 1956</u>	Madhya Pradesh Municipal Corporation Act 1956	30 Days	
13	Registration under Boiler Act 1923	Any Area in the State	Directorate of Boiler	<a href="https://db.mp.gov.in/Uploaded%20Document/THE%20BOILERS%20ACT%201923.pdf">https://db.mp.gov.in/Uploaded%20Document/THE%20BOILERS%20ACT%201923.pdf</a>	Boiler Act 1923	30 Days	<a href="http://invest.mp.gov.in">http://invest.mp.gov.in</a>
14	Authorization for Hazardous waste	Any Area in the State	Madhya Pradesh -Pollution Control Board	<a href="http://cpcb.nic.in">cpcb.nic.in</a>	Hazardous Wastes (Management, Handling & Transboundary Movement) Rules, 2016	30 Days	<u>Pollution Control Board :: (mp.nic.in)</u>
15	Authorization for Bio-Medical waste	Any Area in the State	Madhya Pradesh -Pollution Control Board	<u>The Bio-Medical Wastes Management Rules, 2016</u>	Bio-Medical Waste Management Rules, 2016	45 Days	<a href="http://xgn.mp.nic.in/">http://xgn.mp.nic.in/</a>

## Sector Specific Clearances





03

Madhya Pradesh


# 3.1 Clearance Applicable for API and Formulation Sub Sector (1/3)

Value Chain	Clearance	Issuing Authority	Governing Legislation	Link to Apply	Stage
Research and Development/ Manufacturing and Wholesale distribution / Retail Distribution and Sales	Registration Certificate for the imported bulk drug and finished product in India 	Drug Controller General – Central Drugs Standard Control Organization, Government of India	<u><a href="#">THE DRUGS AND COSMETICS ACT (1940) AND RULES (1945)</a></u>	Required for import of all drugs into India. Apply on: <u><a href="#">CDSCO online portal</a></u>	Post-Operation of Manufacturing or Research and /or sales facility
	Import License for Bulk Drugs and Finished Product into India (Schedule-X) 	Drug Controller General – Central Drugs Standard Control Organization, Government of India	<u><a href="#">THE DRUGS AND COSMETICS ACT (1940) AND RULES (1945)</a></u>	Required for import of all drugs into India under Schedule–X in Act/Rules. Apply on: <u><a href="#">CDSCO online portal</a></u>	
	Import License for Bulk Drugs and Finished Product into India (Other than Schedule-X) 	Drug Controller General – Central Drugs Standard Control Organization, Government of India	<u><a href="#">THE DRUGS AND COSMETICS ACT (1940) AND RULES (1945)</a></u>	Required for import of products into India for all drugs except those under Schedule–X in Act/Rules Apply on: <u><a href="#">CDSCO online portal</a></u>	
	License for Manufacturing synthetic narcotic drugs 	The Narcotics Commissioner, Central Bureau of Narcotics, Government of India	<u><a href="#">Narcotic Drugs and Psychotropic Substances Act &amp; Rules, 1985 and subsequent amendments</a></u>	All License applications are available online on <u><a href="#">Central Bureau of Narcotics - Unified Portal</a></u>	Pre – Operation of Manufacturing and/or Research Unit

# 3.1 Clearance Applicable for API and Formulation Sub Sector (2/3)







Value Chain	Clearance	Issuing Authority	Governing Legislation	Link to Apply	Stage
Manufacturing & Wholesale Distribution (M&WD)	License to Manufacture Drug 	Director of Drugs Control – Food Safety and Drug Authority, Government of Madhya Pradesh	<u>THE DRUGS AND COSMETICS ACT (1940) AND RULES (1945)</u>	Required for all drugs except those under Schedule–X in Act/Rules*.  Apply on: <a href="http://Food And Drugs Administration, Madhya Pradesh (mponline.gov.in)">Food And Drugs Administration, Madhya Pradesh (mponline.gov.in)</a>	Pre-Operation of Manufacturing or Research unit
	Wholesaler Drug License 	Director of Drugs Control – Food Safety and Drug Authority, Government of Madhya Pradesh	<u>THE DRUGS AND COSMETICS ACT (1940) AND RULES (1945)</u>	Required for all drugs except those under Schedule–X in Act/Rules  Apply on: <a href="http://Food And Drugs Administration, Madhya Pradesh (mponline.gov.in)">Food And Drugs Administration, Madhya Pradesh (mponline.gov.in)</a>	Pre-Operation of Manufacturing or Research unit
	World Health Organization (WHO) – Good Manufacturing Practice Certificate 	Director of Drugs Control – Food Safety and Drug Authority, Government of Madhya Pradesh	<u>THE DRUGS AND COSMETICS ACT (1940) AND RULES (1945)</u>	The licensee shall comply with the requirements of Good Manufacturing Practices as laid down in Schedule M.  Apply on: <a href="http://Food And Drugs Administration, Madhya Pradesh (mponline.gov.in)">Food And Drugs Administration, Madhya Pradesh (mponline.gov.in)</a>	Post-Operation of Manufacturing Unit
	Good Laboratory Practice (GLP) Certificate 	Director of Drugs Control – Food Safety and Drug Authority, Government of Madhya Pradesh	<u>THE DRUGS AND COSMETICS ACT (1940) AND RULES (1945)</u>	Required for the nonclinical safety testing of items contained in pesticide products, cosmetic, veterinary drugs and industrial chemicals  Apply on: <a href="http://Food And Drugs Administration, Madhya Pradesh (mponline.gov.in)">Food And Drugs Administration, Madhya Pradesh (mponline.gov.in)</a>	Pre-operation of laboratory or R&D/ manufacturing unit

# 3.1 Clearance Applicable for API and Formulation Sub Sector (3/3)

Value Chain	Clearance	Issuing Authority	Governing Legislation	Link to Apply	Stage
Retail Distribution and Sales	Free Sale Certificate for Drugs and Cosmetics 	Director of Drugs Control – Food Safety and Drug Authority, Government of Madhya Pradesh	<u>THE DRUGS AND COSMETICS ACT (1940) AND RULES (1945)</u>	Required for all imports/exports Apply on: <a href="https://fdamp.mponline.gov.in/">https://fdamp.mponline.gov.in/</a> (login to your account)	Post-Operation or Sales Facility



# 3.2 Clearance Applicable for API and Formulation Narcotics and Psychotropics

Value Chain	Clearance	Issuing Authority	Governing Legislation	Link to Apply	Stage
Research and Development/ Manufacturing and Wholesale distribution	License for Manufacturing synthetic narcotic drugs 	The Narcotics Commissioner, Central Bureau of Narcotics, Government of India	<u><a href="#">Narcotic Drugs and Psychotropic Substances Act &amp; Rules, 1985 and subsequent amendments</a></u>	All License applications are available online on <u><a href="#">Central Bureau of Narcotics - Unified Portal</a></u>	Pre – Operation of Manufacturing and/or Research Unit
	Registration for Import of Poppy Seeds 			Specific information on required documents etc.. can be found on the <u><a href="#">Central Bureau of Narcotics - Department Website</a></u>	
Manufacturing and Wholesale Distribution	Export Authorization for Narcotic Drugs and Psychotropic Substances 			Specific information on required documents etc.. can be found on the <u><a href="#">Central Bureau of Narcotics - Department Website</a></u>	Post Operation of Manufacturing Unit
	Import Certificate for Narcotic Drugs and Psychotropic Substances 				
	No Objection Certificate (NoC) for export of Pre-Cursor Chemicals 				
No Objection Certificate (NoC) for Import of Pre-Cursor Chemicals 	Pre-Operation of Manufacturing and / or Research unit				

# 3.3

# Clearance Applicable for Medical Device Sub Sector (1/2)

Value Chain	Clearance	Issuing Authority	Governing Legislation	Link to Apply	Stage
Research and Development/ Manufacturing and Wholesale distribution	Certificate of Registration for a Notified Body for audit of Class A and Class B Medical Devices	Drug Controller General – Central Drugs Standard Control Organization, Government of India	<u>THE DRUGS AND COSMETICS ACT (1940) AND RULES (1945)</u> & <u>MEDICAL DEVICES RULES, 2017</u>	A notified body accredited by National Accreditation Body (designated by Central Government) may apply in MD 1 to CLA for grant of registration certificate in MD 2 on <a href="#">sugam online portal</a> .	Pre – Operation of Manufacturing and/or research Unit
	Import License for Medical Devices			Requires an application under form MD-14, available on <a href="#">sugam online portal</a> .	Pre – Operation of Manufacturing and/or research Unit
Manufacturing and Wholesale distribution	Test license to import Medical Devices for test, evaluation, clinical investigations, etc.			Requires an application under form MD-17, available on <a href="#">sugam online portal</a> .	Post Operation of Manufacturing and/or sales Unit
	License\ Loan License to Manufacture Medical Devices for sale or for distribution			Requires an application under form MD-7 & MD-8, available on <a href="#">sugam online portal</a> .	
	Permission to import or manufacture medical device which does not have its predicate device			Requires an application under form MD-26, available on <a href="#">sugam online portal</a> , after completion of its clinical investigation	
	Permission to import or manufacture new in vitro diagnostic medical device			Requires an application under form MD-24, available on <a href="#">sugam online portal</a> .	

# 3.3

# Clearance Applicable for Medical Device Sub Sector (2/2)

Value Chain	Clearance	Issuing Authority	Governing Legislation	Link to Apply	Stage
Manufacturing and Wholesale distribution / Retail Distribution and Sales	Permission to conduct clinical investigation of Investigational Medical Device	Drug Controller General – Central Drugs Standard Control Organization, Government of India	<u>THE DRUGS AND COSMETICS ACT (1940) AND RULES (1945)</u> & <u>MEDICAL DEVICES RULES, 2017</u>	Requires an application under form MD-22, available on <a href="#">sugam online portal</a> .	Post Operation of Manufacturing and/or sales Unit
Research and Development/ Manufacturing and Wholesale distribution	Permission to conduct clinical performance evaluation for new in vitro diagnostic medical device			Requires an application under form MD-24, available on <a href="#">sugam online portal</a> .	Pre-Operation of Manufacturing and/or research Unit
	Test license to manufacture for test, evaluation, clinical investigations, etc..			Requires an application under form MD-12, available on <a href="#">sugam online portal</a> .	Pre-Operation of Testing and/or research Units
Manufacturing and Wholesale distribution	Permission to import or manufacture new in vitro diagnostic medical device			Requires an application under form MD-24, available on <a href="#">sugam online portal</a> .	Pre-Operation of Manufacturing Unit
Research and Development	Registration of Medical Device Testing Laboratory			Requires an application under form MD-39, available on <a href="#">sugam online portal</a> .	Pre-establishment of Testing Lab

**For queries, Please reach out to Pharma Sector Expert**

**SPOC Name :**

**Email I.D:**