



Commercial API List

(MFG Facility Approval: Health Canada, EDQM, EUGMP, FAMHP, WHO-INDIA)

Sr. No.	API Name	Grade	Approval status CEP / DMF	Remark
1	Buprenorphine	Ph. Eur. / USP	R1-CEP 2015-387 - Rev 00	---
2	Buprenorphine HCl	Ph. Eur. / USP	R1-CEP 2017-228 - Rev 00	---
3	Fentanyl	Ph. Eur. / USP	R1-CEP 2016-018 - Rev 00	---
4	Fentanyl citrate	Ph. Eur. / USP	R1-CEP 2016-023 - Rev 00	---
6	Naltrexone HCl	Ph. Eur. / USP	R1-CEP 2016-053 - Rev 00	---
7	Methadone HCl	Ph. Eur. / USP	R0-CEP 2017-277 - Rev 02	---
8	Bisoprolol Fumarate	Ph. Eur. / USP	R0-CEP 2020-095- Rev 00	---
7	Naloxone HCl dihydrate	Ph. Eur. / USP	Under evaluation/CEP 2022-086-P01	Expected by December 2023
8	Apomorphine HCl hemihydrate	Ph. Eur. / USP	Under evaluation/CEP 2021-135-P01	Expected by December 2023
9	Nalbuphine HCl	Non-pharmacopoeial	---	eCTD Available
10	Eflornithine HCl (Monohydrate)	Non-pharmacopoeial	EMA approved EU/ASMF/00137	---
			Submitted to USFDA (Active) 031780	IMPD dossier
11	Nalmefene HCl	Non-pharmacopoeial	Submitted to USFDA (Active) 034367	IMPD dossier in US eCTD available for EC

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12	Promedol HCl	Non-pharmacopoeial (Russian pharmacopoeia)	---	Registered in Russia & Kazakhstan DMF in CTD available
13	n-Butyl cyanoacrylate	Non-pharmacopoeial	---	Dossier available CE certification as Tissue adhesive available
14	Naltrexone	Non-pharmacopoeial	---	DMF in CTD format available

APIs – Developed / Under Development

Sr. No.	API Name	Grade	Approval status CEP / DMF
1	Nalbuphine	Non-pharmacopoeial	---
2	Carbamazepine	Ph. Eur.	---
3	Sodium Oxybate	Non-pharmacopoeial	---
4	Dinalbuphine Sebacate	Non-pharmacopoeial	---
5	Naltrexone decanoate	Non-pharmacopoeial	---

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6	Clonazepam	Ph. Eur.	---
7	Diazepam	Ph. Eur.	---
8	Midazolam	Ph. Eur.	---
9	Remifentanil Hydrochloride	Ph. Eur.	---
10	Sufentanil	Ph. Eur.	---
11	Sufentanil Citrate	Ph. Eur.	---
12	Oxycodone Hydrochloride	Ph. Eur.	---
13	Dihydrocodeine hydrogen Tartrate	Ph. Eur.	---
14	Hydromorphone Hydrochloride	Ph. Eur.	---
15	Hydrocodone Hydrogen Tartrate	Ph. Eur.	---
16	Oxymorphone Hydrochloride	USP	---
17	Pregabalin	Ph. Eur.	---
18	Methyl Naltrexone Bromide	Ph. Eur.	---
19	Tramadol Hydrochloride	Ph. Eur.	---

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