



CHINESE PEPTIDE

Peptide Partners. Concept to Commercial.

Generic APIs

Generic Peptides
Drug Master Files (DMFs)

Generic APIs

Example APIs with DMFs

Part 1 of 2

API NAME	SPECIFIC INDICATION	EARLY R&D	LATE R&D	PROCESS VALIDATION	SUBMITTED / TO BE SUBMITTED	APPROVED / DMF AVAILABLE	ORIGINATOR	
Leuprolide Acetate	Prostate & Breast Cancer	[Progress bar]				MFDS: 20200625-210-J-661 NMPA: Y20190007496 (A) TFDA: DMF64 (4138)		
	Endometriosis	[Progress bar]						
Triptorelin Acetate	Uterine Leiomyomata	[Progress bar]						
	Precocious Puberty	[Progress bar]				NMPA: Y20170001090 (A) NMPA: Approved in 2019(A) MFDS: TBD		
	Prostate and Breast Cancers,	[Progress bar]						
Terlipressin Acetate	Endometriosis	[Progress bar]				ASMF: The Netherlands (03883) ASMF: Germany (4388) EDQM: R0-CEP 2020-111 in 2022 NMPA: Y20200000281 (A)		
	Uterine Fibroids,	[Progress bar]						
Terlipressin Acetate	Assisted Reproduction	[Progress bar]						
	Bleeding esophageal varices	[Progress bar]				US FDA: 034884 ASMF: 2022/03	NMPA: Y20190001147 (A)	
	septic shock	[Progress bar]						
Cetrorelix Acetate	hepatorenal syndrome	[Progress bar]				NMPA: Y20170001378		
	In Vitro Fertilization (IVF)	[Progress bar]						
Exenatide Acetate	Diabetes (type II)	[Progress bar]				NMPA: Y20200001405		
		[Progress bar]						
Triptorelin Pamoate	Endometriosis	[Progress bar]				NMPA: Y20210000906		
	Uterine fibroids	[Progress bar]						
	Premature puberty	[Progress bar]						
	Prostate cancer	[Progress bar]						
	ART	[Progress bar]						
	Irritable Bowel Syndrome	[Progress bar]						












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API NAME	SPECIFIC INDICATION	EARLY R&D	LATE R&D	PROCESS VALIDATION	SUBMITTED / TO BE SUBMITTED	APPROVED / DMF AVAILABLE	ORIGINATOR
Teduglutide Sodium	<ul style="list-style-type: none"> Short Bowel Syndrome 	[Progress bar: Early R&D to Process Validation]					 
Goserelin Acetate	<ul style="list-style-type: none"> Suppress production of the sex hormones 	[Progress bar: Early R&D to Process Validation]			NMPA: 2023 / Q2		
Buserelin Acetate	<ul style="list-style-type: none"> Prostate and Breast Cancer Endometriosis Uterine Leiomyomata Precocious Puberty Assisted Reproduction. 	[Progress bar: Early R&D to Process Validation]					
Plecanatide	<ul style="list-style-type: none"> Chronic Idiopathic Constipation (CIC) 	[Progress bar: Early R&D to Process Validation]					 
Semaglutide	<ul style="list-style-type: none"> Diabetes (type II) 	[Progress bar: Early R&D to Process Validation]					
Degarelix Acetate	<ul style="list-style-type: none"> Advanced Prostate Cancer 	[Progress bar: Early R&D to Late R&D]					
Ganirelix Acetate	<ul style="list-style-type: none"> To inhibit premature LH surges during controlled ovarian hyperstimulation 	[Progress bar: Early R&D to Late R&D]					
Lanreotide	<ul style="list-style-type: none"> Acromegaly GER, NETs, and Carcinoid 	[Progress bar: Early R&D to Late R&D]					



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