



Introduction

Dear Sir / Madam,

We are manufacturers of APIs – **Famotidine**, **Ranitidine HCl**, **Telmisartan**, Intermediates & fine chemicals.

Estd. In 1989, Orchev Pharma Pvt. Ltd. has an experience of **32 years** and involved in manufacturing of Active Pharma Ingredients, Intermediates and Fine Chemicals. Our pharma products are manufactured in compliance and accordance with GMP, USFDA and ICH Q7 guidelines and having strong customer base in more than **50 countries** world-wide.

Our plant has following regulatory approvals:-

1. USFDA [AUGUST 2018]
2. EU-GMP (AEMPS - SPAIN) [JUNE 2015]
3. WHO-GMP Certificate & Written Confirmation (WC)
4. COS (CEP) from EDQM
5. COFEPRIS, Mexico [MAY 2013]
6. Korean FDA
7. Registration in counties like Russia, IRAN-MOH, UKRAINE-MOH, UZBEKISTAN-MOH etc.
8. ISO 9001 : 2015 issued by TÜV SÜD
9. DMF filed with TPD – CANADA

Famotidine:

Famotidine is our product in focus and we aim to become largest & most reliable manufacturer.

Key benefit of **ORCHEV's Famotidine:**

- Our US customer got approval of their ANDA using our **US-DMF# 036764 (Oct23)**
- We received **CEP 2022-207** from EDQM (Aug23)
- Our **Chinese DMF # Y20220000306** got approval from **NMPA** with IDL Status "A" (Dec23)
- **IL# 028647** & **TDMF** consolidated & approved by **Taiwan FDA (Feb24)**
- KDMF filled **Korean FDA** with initial review complete.
- WHO-GMP, Written Confirmation (WC) & DMF, Risk Assessments, etc. available.
- **Famotidine as per USP/EP/BP/CP/IP/JP** for Tablet, Injection and Solution dosage formulations available.
- With 100 Mt annual capacity & Both Key intermediates of Famotidine manufactured in-house, gives us better control over supply chain, quality, cost and supporting regulatory authorities' requirement of intermediate supplier's audit.

Our product list is as below:

PRODUCT	CATEGORY	STATUS
Active pharma ingredient (Bulk Drugs)		
Ranitidine HCl	Antiulcer	Commercial
Famotidine	Antiulcer	Commercial
Telmisartan	ARBs (Blood pressure)	Commercial
Levetiracetam	Antiepileptic	Available shortly
Intermediates		
N-4-AMINOIMINOMETHYL-THIOMETHY-2-THIZOLYL GUANIDINE DIHYDROCHLORIDE CAS No. 88046-01-9	Famotidine Intermediate	Commercial
N-Sulfamyl-3-Chloro Propionamidine Hydrochloride (IFM) CAS No. 106649-95-0	Famotidine Intermediate	Commercial
N-((4-Chloromethyl)-2-thiozoyl)guanidine hydrochloride (FIT) (CAS 84545-70-0)	Famotidine Intermediate	Commercial

We are known as highly **reliable partner** for Active Pharma Ingredients because of timely delivers, customized PSD supply as per customer's requirement, high quality material, extremely quick support for regulatory documents and commitment towards continuously changing GMP norms.

Also you will find prime quality material and competitive price from ORCHEV.