



Your reliable healthcare partner

USV Custom Peptide Synthesis and Speciality Chemicals Division



USV Corporate Office & Research Center, Mumbai



- **Chemical Process Research Laboratory**
- **Peptide & Nucleotide Laboratory**
- **Drug Delivery Research Laboratory**
- **Biologics Research Laboratory**
- **Analytical Research Laboratory**
- **Corporate Quality Assurance**
- **Supply Chain Department**

Qualification	No. of Scientists	Experience
Post Doc / P.h.D.	>20	10 years-24 years
Post Graduates	>240	03 years-32 years



USV Manufacturing Sites

API/ Peptides/ Specialty Chemicals

1. **Bangalore - Specialty Chemicals**
2. **Ambernath - API and intermediates**
3. **Chiplun - API and Peptides**
4. **Nerul - Biotech products**

Formulation

5. **Daman - Solid Dosage form & Steriles**
6. **Baddi Unit I - Solid orals**
7. **Baddi Unit II - Solid orals**
8. **Vadodara - Solid dosage forms**

Regulatory approvals:

- USFDA/ MHRA/ WHO & other global regulatory bodies - Daman, Chiplun, Baddi Unit II, and Nerul
- ISO certified - Bangalore (ISO 9001:2015), Daman (ISO 14001:2015), Chiplun (ISO 14001:2015)
- WHO GMP certificate - Ambernath



CPS & SCD : Area of Expertise

Custom Peptide Synthesis (CPS)

- Synthesis of conventional, complex, and modified peptides
- Quantities ranging from milligram to multi-kilogram
- Manufactured under both GMP and non-GMP environment

Specialty Chemicals Division (SCD)

- Synthesis of modified amino acids, amino alcohols, resins, and specialty chemicals
- Manufactured at laboratory scale and commercial scale

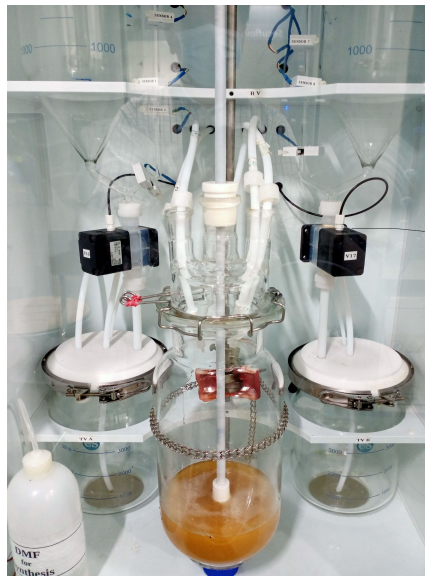


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Peptide & Nucleotide Laboratory, Mumbai



Corridor



**Peptide synthesizer
100 mL - 10 L in Lab**



Prep HPLC 1200 mL

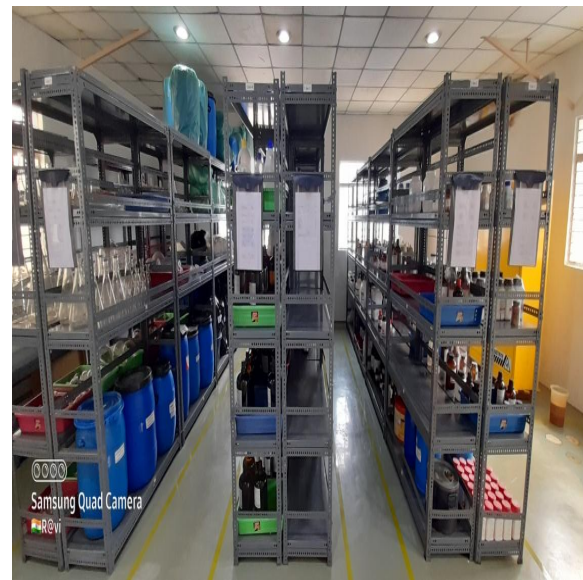


LC-MS



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Specialty Chemicals Division, Bangalore : Production Facility





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Custom Peptides Synthesis Process : Lab Scale

CS-Bio Peptide Synthesizer



CS-Bio Peptide Synthesizer



YMC Semi preparative system (60- 1.2 L/ min)



GENSER 20 L Rotaevaporator



CEM Liberty Microwave based Peptide synthesizer

VERTIS Tray Lyophilizer 10 L





Peptide Process Development & Manufacturing Capabilities

Solid Phase Peptide Synthesis

- Protection strategy: **Fmoc and t-Boc methodologies**
- Mainly Fmoc-based chemistry in automated synthesisers
- Developed Process **>99 mer amino acids, multiple SS bonds, amyloid peptides**

Solution Phase Peptide Synthesis

- For **shorter peptide sequences**
- Cost-effective process at multi gram to kilogram scale
- **QBD based process development**
- **Orthogonal chromatography** process development for **high purity peptides**
- Expert in **Lyophilization cycle development**

Scale-up and cGMP process validation

- Gram to kg level process validation under cGMP condition
- Stability testing as per ICH guidelines
- **> 2000 Peptides manufactured** under USV Peptides ranging from few milligram to multi kilogram in last 10 years under both non-GMP and GMP conditions



Peptide Manufacturing Equipments

Sr. no.	Equipment	Capacity
1	Peptide synthesizer	10 L, 50 L
2	Glass assembly	10 L, 50 L
3	Rotavap	20 L, 50 L
4	Glass lined reactor	70 L
5	Automated reactor	20 L
6	Cold cabinet	200 L, 350 L
7	Semi HPLC system	1.2 L
8	Reverse osmosis	25 L, 100 L
9	Semi automatic filtration system	5 L
10	Glass assembly	50 L
11	Ion exchange system	100 mL/min
12	DAC column	150, 200, 450 mm
13	Lyophilizer (CIP, SIP)	25 L, 50 L
14	Buffer tank	0.25, 0.7, 1, 2 KL



Analytical Equipments

- HPLC (UV, ELSD, PDA detectors)
- Gas Chromatograph (with headspace sampler)
- LCMS
- Ion Chromatography
- FTIR
- XRPD
- NMR Spectrometer
- Particle Size Analyser
- Melting range apparatus
- Amino acid Analyser
- Osmometer
- UV Spectrophotometer
- pH meter
- Dissolution Apparatus

- HPTLC
- CHNS-O Analyzer
- DSC
- TGA
- Atomic Absorption Spectrophotometer
- Autotitrator & KF Titrator
- UPLC
- Refractometer
- Polarimeter
- Sonicator
- Conductivity meter
- Homogeniser
- Photostability chamber
- Analytical balance

- Micro evaporator
- Buchi Evaporator
- Mettler Microbalance
- Muffle furnace
- LOD Oven
- Millipore - Water purified system
- Hardness Tester
- Cold cabinets
- Centrifuge Machine
- BOD OVEN
- Orbital Shaker
- Coulometer
- Microtronics Data logger
- Ultrasonic Bath



Peptide Modifications

- **N-terminal acetylation/deamidation**
- **C-terminal amidation**
- **Site specific peptide modifications**
- **Biotinylated peptides**
- **Conjugation to KLH, BSA**

- **Fluorescent tagged peptides**
- **Incorporation of unusual amino acids**
- **Cyclic and phosphorylated peptides**
- **Peptide libraries**
- **Chloromethyl Ketone peptides**
- **Phosphopeptides**



GMP Peptides

Plant Capabilities

- Synthesis of peptide using solid and solution phase
- Peptidomimetics
- Conjugation of Peptide
- Pegylation of Peptide
- HPLC purification of peptide with purity >99% of multi-kg quantities

- Characterisation of peptide by Mass, LC-MS, purity by HPLC, quantification by AAA, ion determination by Ion Chromatography
- Synthesis, Isolation and Characterisation of impurities

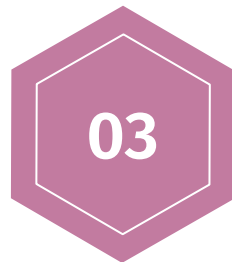
Dedicated peptide facility for GMP grade peptide at Chiplun, Maharashtra



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GMP Facility Infrastructure

cGMP compliant
synthesis area



Lab scale-up and process
scale lyophilizer

Reactors of multiple
sizes

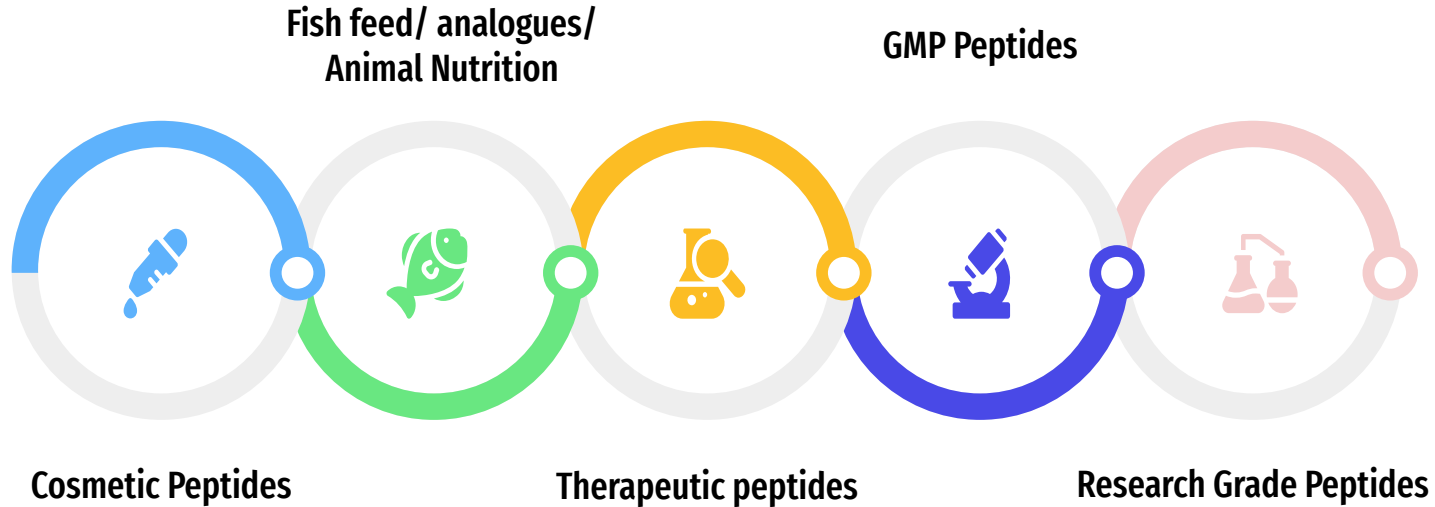
cGMP compliant finish
area

Analytical facility including
Ion Chromatography,
AAA, LC-MS



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Custom Peptides Synthesis (CPS) : Area of Expertise



>2000 Peptides synthesized till date

Milligram to multi Kilograms scale synthesis at non-GMP & GMP level

Delivered: amino acid length di-peptide to 99 AA peptide



CPS Key Segment : Cosmetic Peptides

Heptapeptide

01

1. Heptapeptide-8 (consists of arginine, isoleucine, leucine and phenylalanine)
2. Heptapeptide-7

Hexapeptide

02

1. Palmitoyl Oligopeptide
2. Hexapeptide-10
3. Acetyl Hexapeptide-8
4. Acetyl Hexapeptide-3

Pentapeptide

03

1. Pentapeptide
2. Cyclopeptide-5
3. Palmitoyl Pentapeptide-4

Tetrapeptide

04

1. Tetrapeptide-21
2. Acetyl Tetrapeptide-11
3. Tripeptide-10
4. Acetyl Tetrapeptide-9
5. Caprooyl Tetrapeptide-3



CPS Key Segment : Cosmetic Peptides

Tripeptide

05

1. Trifluoroacetyl Tripeptide-2
2. Copper Tripeptide (GHK-Cu)
3. Diaminopropionoyl Tripeptide-33
4. Hexanoyl Dipeptide-3
5. Palmitoyl Tripeptide-3

Dipeptide

06

1. Carnosine

Mixtures

07

1. Palmitoyl Oligopeptide & Palmitoyl Tetrapeptide-7
2. Palmitoyl Dipeptide-5



Specialty Chemicals : Products & Services

- ❑ Resins for Solid-Phase Peptide Synthesis
- ❑ Resins for Solid-Phase Organic synthesis
- ❑ Resins for Solution-Phase Organic synthesis
- ❑ Polymer-bound reagents & Catalysts
- ❑ Chiral 2-Amino alcohols and its derivatives
- ❑ Chiral pyrrolidines and amines
- ❑ Unusual amino acid and its derivatives
- ❑ Building blocks for diversomer synthesis
- ❑ Custom Synthesis
- ❑ Contract manufacture
- ❑ Contract research



Specialty Chemicals Division : Analytical Facilities

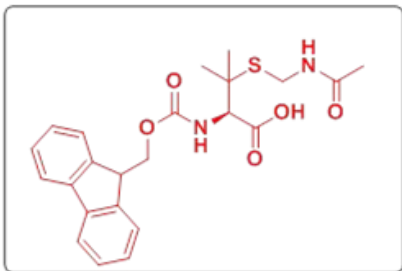
Analytical facilities

- Ultraviolet spectrophotometer
- Infrared spectrophotometer
- Digital polarimeter
- Gas chromatography
- High performance liquid chromatography

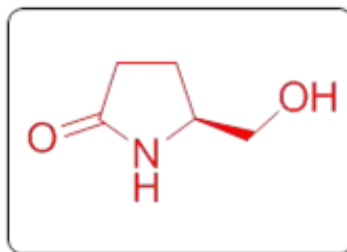
Access to

- NMR
- GC-MS and LC-MS systems
- C,H,N,O,S Elemental analyzer
- Atomic Absorption spectrometer

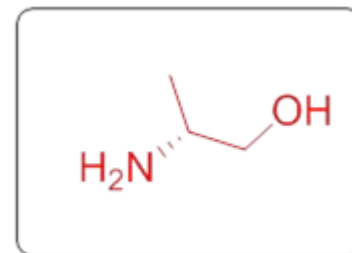
Specialty Chemicals Division : Recent Deliveries



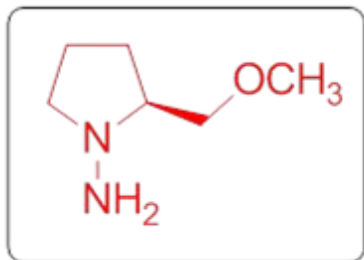
Fmoc-Pen(Acm)-OH
>100 kg



L-Pyroglutaminol
>20 Kg



D-(-)-Alaninol
>10 kg



(S)-(-)-1-Amino-2-(methoxymethyl)pyrrolidine

SAMP: >100 kg compound prepared with required specifications



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For any inquiries or information, please reach out to our experts at

For Custom Peptides

custompeptides@usv.in

For Specialty Chemicals

custom.synthesis@usv.in

Thank you