

CARRIER OBJECTIVE

Dedicated and highly motivated M.Pharm graduate with a specialization in Regulatory Affairs seeking a challenging role in Regulatory Affairs to contribute my knowledge, strong analytical skills, and passion for ensuring compliance with pharmaceutical regulations.

KEY EXPERTISE

Around one year and three months of experience in Regulatory affairs department. Preparation of dossier, Solving and preparation of queries related documents etc. according to International pharmaceutical standards.

EDUCATIONAL QUALIFICATION

M. Pharmacy (Regulatory Affairs) (2022-2024)	Parul Institute of Pharmacy & Research (PIPR), Parul University	8.00 (SGPA)
B. Pharmacy (2018-2022)	B. Pharmacy College, Rampura, Kakanpur (GTU)	8.20 CGPA
12 th Science (HSC) (2018)	Aarav School, Kalol	60.70%
10 th (SSC) (2016)	R & B Sarvajanic High School, Derolgam	74%

EXPERIENCE SUMMARY

Regulatory Affairs Officer	PHILRX PHARMA INC. / AMB HK Enterprises INC, Vadodara (March 2024 to May 2025)
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SKILLS SUMMARY

Technical	Good exposure to medicine & R.A related works
	Good knowledge about CTD & ACTD guidelines
	Dossier Preparation
	Basic knowledge of pharmacopeia IP, BP, USP
Tools	Basic knowledge of M.S. word, M.S. excel and Computer.

WORK SUMMARY (ROLES & RESPONSIBILITIES)

- Preparation of dossier for international pharmaceutical market like Philippines in given timeline.
- Solving and preparation of queries related documents which are arising during submission of dossier in Philippines market.
- Preparation of dossiers related documents & raw data.
- Good knowledge about CTD & ACTD guidelines and submission of dossier.
- Preparation of documents like Summary of Product Characteristics as per guideline given by regulatory bodies.
- Preparation of Certificate of Pharmaceutical Products.
- Preparation & review of Finished Product Protocol & COA.
- Preparation and review of Stability Protocol and Stability.
- Preparation and review of raw and packing material Specification as per pharmacopeia.
- Preparation and review of raw material documents.
- Preparation of Artwork and Product Information.

Swati Patel

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CORPORATE STRENGTH

- Always try to improve my self
- Positive attitude
- Hard working
- Problem solving skill
- Honesty and Punctuality

PERSONAL DETAILS

- Date of Birth: 12 June 2001
- Gender: Female
- Nationality: Indian
- Marital Status: Married
- Languages Known: English, Hindi, Gujarati
- Current Address: Hyderabad

DECLARATION

I hereby declare that the above-mentioned information is true and to the best of my knowledge.

Swati Patel