

# A Review on Force Degradation Studies for Drug Substances

**Mr. Sandeep R. Purkar, Mr. Nirbhay Sumatilal Sancheti, Ms. Harshada Vasant Pund,  
Mr. Kalash Sanjay Tatiya**

Gokhale Education Society's, Sir Dr. M.S. Gosavi College of Pharmaceutical Education and Research, Nashik

**Abstract:** *The objective of the review article is to give detailed description and guidance of the forced degradation studies as per regulatory guidelines. Forced degradation or alternatively referred as stress testing and it demonstrates specificity when developing stability indicating methods, especially when little is known about potential degradation products. Forced degradation study provides information about the degradation pathways and degradation products of the drug substance that could form during storage, transportation. Force degradation study also helps in the elucidation of the structure of the degradation products. Forced degradation study provide the chemical behaviour and chemical nature of the molecule which ultimately helps in the development of formulation during manufacturing and packaging specification, thus this review article provides knowledge of the current trends in performance of forced degradation study and establishing the analytical methods that helpful for development of stability indicating method.*

**Keywords:** Drug

## REFERENCES

- [1]. ICH Q1A (R2) Stability Products [https://www.ema.europa.eu/en/documents/scientific-guideline/ich-q-1-r2-stability-testing-new-drug-substances-products-step-5\\_en.pdf](https://www.ema.europa.eu/en/documents/scientific-guideline/ich-q-1-r2-stability-testing-new-drug-substances-products-step-5_en.pdf)
- [2]. ICH Q2 (R1) Validation of Analytical Procedures [https://www.ema.europa.eu/en/documents/scientific-guideline/ich-q-2-r1-validation-analytical-procedures-text-methodology-step-5\\_en.pdf](https://www.ema.europa.eu/en/documents/scientific-guideline/ich-q-2-r1-validation-analytical-procedures-text-methodology-step-5_en.pdf)
- [3]. ICH Q3A (R2) Impurities in New Drug Substances [https://www.ema.europa.eu/en/documents/scientific-guideline/ich-q-3-r2-impurities-new-drug-substances-step-5\\_en.pdf](https://www.ema.europa.eu/en/documents/scientific-guideline/ich-q-3-r2-impurities-new-drug-substances-step-5_en.pdf)
- [4]. ICH Q3B (R2) Impurities in New Drug Products [https://www.ema.europa.eu/en/documents/scientific-guideline/ich-q-3-b-r2-impurities-new-drug-products-step-5\\_en.pdf](https://www.ema.europa.eu/en/documents/scientific-guideline/ich-q-3-b-r2-impurities-new-drug-products-step-5_en.pdf)
- [5]. ICH Q6A Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products (Chemical Substances) [https://www.ema.europa.eu/en/documents/scientific-guideline/ich-q-6-test-procedures-acceptance-criteria-new-drug-substances-new-drug-products-chemical\\_en.pdf](https://www.ema.europa.eu/en/documents/scientific-guideline/ich-q-6-test-procedures-acceptance-criteria-new-drug-substances-new-drug-products-chemical_en.pdf)
- [6]. USP General Chapter <1225>: Validation of Compendial Procedures
- [7]. Empower PDA Software Manual — Getting Started guide
- [8]. Snyder, L., Kirkland, J., and Glajch, J. Practical HPLC Method Development. Wiley, 1997.
- [9]. Beginners Guide to Liquid Chromatography (Waters Series), 1st Edition. Waters Corporation, 2014.
- [10]. Ahuja, S., and Rasmussen, H. HPLC Method Development for Pharmaceuticals. Academic Press, 2007.
- [11]. Kats, R. "Forced Degradation Studies: Regulatory Considerations and Implementation." BioPharm International, Jul. 01, 2005.
- [12]. Reynolds D., et al. "Available Guidance and Best Practices for Conducting Forced Degradation Studies." Pharmaceutical Technology, Feb. 1, 2002.