



RENOWED LIFE SCIENCES
PLOT NO-10,11 SEC-6B, I.I.E, SIDCUL HARIDWAR-249403

CERTIFICATE OF ANALYSIS

FINISH PRODUCT

(See Rule 150 E (F) Under The drug & Cosmetic Act 1940 & Rules There under)

Product Name	TOFASE 5 Tab	Ref. No.	TRS/0924/DT409037 F
Generic Name	Tofacitinib Tablets-IP 5 mg		
Batch No.	DT409037	AR. No.	FP-1405/24
Batch Size	1.0 Lac Tabs	Mfg. Date	09/2024
Sample Date	23/09/2024	Exp. Date	08/2026
Analysis Date	23/09/2024	Release Date	03/10/2024

Sr.No	Test	Specification	Result
1.	Description	White coloured round biconvex, film coated tablet plain on both side	White coloured round biconvex, film coated tablet plain on both side
2.	Identification	Should be comply in assay	Complies
3.	Average weight	115 mg $\pm$ 7.5 %	111.08 mg
4.	Uniformity of weight	$\pm$ 7.5 % of average weight	-1.44% to +1.47%
5.	Dissolution:	(Q) NLT- 80%	90.28% to 101.72%
6.	Related Substances Any Peak corresponding to DCT Any other secondary peak Sum of all secondary peak	NMT-0.5%w/w NMT-0.5%w/w NMT-2.0% w/w	Not Detected 0.19% 0.19%
7.	Assay: Each film coated tablet contains: Tofacitinib citrate IP eq. to Tofacitinib 5mg	 4.5 mg to 5.5 mg 90.0% to 110.0%	 4.91 mg 98.20%

Conclusion: The above sample ~~complies~~/does not complies as per IP/BP/USP/IH specification.

Analyzed By/Date	Checked By/Date	Approved By/Date
 03/10/24	 03/10/24	 03/10/24