



LOGOS PHARMA

Village Maissa Tibba, Tehsil Nalagarh, District Solan (H.P.) INDIA-174 101

QUALITY CONTROL DEPARTMENT FINISHED PRODUCT CERTIFICATE OF ANALYSIS

Name of Product	Tofadol – 5 Tablet		
Generic Name of Product	Tofacitinib Tablets		
Composition of Product	Each film coated tablet contains: Tofacitinib citrate eq. to Tofacitinib 5 mg Excipients: q. s. Colour : Titanium dioxide IP		
Manufactured By	LOGOS PHARMA	Mfg. Lic. No.	MNB/09/809&MB/09/810
Batch No.	LGL06/229/05	AR No.	NAL/2223/QCP/QIM/02147
Mfg. Date	JUN-2022	Exp. Date	MAY-2024
Batch Size	38800 Tabs	Mkt. By	BSA Pharma
Date of Received	06/07/2022	Date of Released	07/07/2022

Sr. No.	Test	Specification	Observation
1.	Description	White coloured round shaped slightly biconvex film coated tablet plain on both side.	White coloured round shaped slightly biconvex film coated tablet plain on both side.
2.	Identification By HPLC	In the assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution.	In the assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution.
3.	Weight of 20 Tablet	3.400 gm \pm 7.5 %	3.3929 gm
4.	Avg. weight	170.0 mg \pm 7.5 %	169.65 mg
5.	Uniformity of weight	Avg. Wt \pm 7.5 %	Min. -0.74 % Max. +0.68 %
6.	Diameter	8.0 \pm 0.2 mm	Min. 8.09 mm Max. 8.14 mm
7.	Thickness	3.2 \pm 0.2 mm	Min. 3.24 mm Max. 3.31 mm
8.	Hardness	NLT 3.0 kg/cm ²	8.99 kg/cm ²
9.	Disintegration time	NMT 30 Minutes at 37 ⁰ \pm 2°C	01 min 12 sec
10.	Dissolution	NLT 75%	101.83 %
11.	Uniformity of Content	85 % to 115 % of Assay	Complies
12.	Assay Each film coated tablet contains: Tofacitinib citrate eq. to Tofacitinib 5 mg	LIMIT NLT 4.5 mg and NMT 5.5 mg of Tofacitinib (i.e. 90.0 % to 110.0 % of labeled amount)	RESULT 5.147 mg/ Tab (102.93 %)

Remark: In the opinion of the under signed the sample complies/~~does not comply~~ for the above mentioned tests as per IP/IH standard.

PARTICULARS	PREPARED BY	CHECKED BY	APPROVED BY
NAME	NEHA	Dileep Kumar	For LOGOS PHARMA
DESIGNATION	Sr. Officer	Sr. Officer	Manager
SIGN/DATE	New 07/07/2022	07/07/2022	Quality Control Manager 07/07/2022