Synthimed LABS

Synthimed Labs Private Limited
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Certificate of Analysis

Product	:	Fexofenadine Hydrochloride (Pharmaceutical Allopathic Raw Material of Pharmaceutical Grade Fexofenadine HCl USP)	Mfg. Date	:	July-2025
Lot Number	:	7270225078	Expiry Date	:	June-2030
Analytical Report Number	:	FP/L/113625	No. of Containers	:	02
Ref. Spec. Number	:	S/ANS/FP/022	Quantity	:	50.0kg

S.No.	Parameters	Limits	Results
1	Description	White or almost white powder.	Almost white powder
2	Solubility	Slightly soluble in water, freely soluble in methanol, very slightly soluble in acetone	Slightly soluble in water, freely soluble in methanol, very slightly soluble in acetone
3	Identification		
	By IR	IR absorption spectrum of test substance to be concordant with that of standard spectrum.	IR absorption spectrum of test substance is concordant with that of standard spectrum.
	By HPLC	Retention time of Fexofenadine peak in test preparation should correspond with that of Fexofenadine peak in standard preparation.	Retention time of Fexofenadine peak in test preparation is correspond with that of Fexofenadine peak in standard preparation
	Chemical	White precipitate should be formed	Complies
4	Water	Not more than 0.5% w/w	0.18 % w/w
5	Residue on ignition	Not more than 0.1% w/w	0.02 %w/w
6	Content of Chloride (Potentiometrically)(On anhydrous basis)	6.45 to 6.75 %w/w	6.61 %w/w
7	Limit of Fexofenadine related compound B (By HPLC)		
	Fexofenadine related compound- B	Not more than 0.20%	≤ 0.04 %
8	Related Compounds (By HPLC)		
	Fexofenadine related compound-A	Not more than 0.20%	≤ 0.05 %
	Decarboxylated degradent	Not more than 0.15%	≤ 0.05 %
	Any other unknown impurity	Not more than 0.10%	≤ 0.02 %
	Total impurities	Not more than 0.50%	All impurities below LOQ Level
9	Assay (By HPLC)(On anhydrous basis)	98.0 to 102.0 % w/w	100.4 % w/w
10	Residual solvents (By GC-Head space)		
	Methanol	Not more than 3000 ppm	≤ 34 ppm
	Ethanol	Not more than 5000 ppm	≤ 15 ppm
	Isopropyl alcohol	Not more than 5000 ppm	926 ppm
	Ethyl acetate	Not more than 5000 ppm	723 ppm
	Isopropyl acetate	Not more than 5000 ppm	60 ppm

Non Negotiable

Non Negotiable

Remarks: - (1) The above results comply as per USP specification.
(2) Sales Order No.:- 50810
(3) B/C.NO.:- 0598TF2536538530 DT.02.01.2026

21/01/26
Prepared by
(Quality Control)

21/01/26
QA RELEASE

21/01/26
Approved by
(Quality Control)