

## Fexofenadine HCI USP44

Batch no

202405001

Mf date

May 10 2024

Expiry

May 09 2026

Molecular Structure

Molecular Formula

C<sub>32</sub>H<sub>39</sub>NO<sub>4</sub> HC I

Molecular Weight

538.12

CAS Registry Number

138452-21-8

May 24 2024

<u>Tests</u>	Specifications	Results
Appearance	White to off-white powder or crystalline powder; bitter taste, odorless	White powder
Identification	HPLC, IR, reaction of chloride	Positive
Residue on ignition	≤ 0.1%	0. 07%
Heavy metals	≤ 0.002%	Conforms
Impurity B	≤ 0.2%	ND
Water	≤ 2.0%	0. 22%
Related substance	Impurity A ≤ 0.2%	0. 05%
	Decarboxylated degradant ≤ 0.15%	ND
·	Single impurity ≤ 0.1%	0. 02%
×	Total impurities ≤ 0.5%	0. 08%
Content of chloride	6. 45 ~ 6. 75%	6. 7%
Residual solvents	Ethanol ≤ 0.5%	0. 022%
	Ethyl acetate ≤ 0.5%	0. 08%
Assay (oab)	98.0 $^{\sim}$ 102.0% of $C_{32}H_{39}NO_4$ HC1	99.3%
Packaging and storage	Preserve in well-closed, light-resista	

Packaging and storage	Preserve in well-closed, light-resistant containers, and store at controlled room temperature
Conclusion	Material complies with USP44

