

Specification

Technical Data Sheet

CAS 1260141-27-2	STORAGE 2 to 8 &deg;C	MOLECULAR WEIGHT 461.46
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PRODUCT**Vonoprazan fumarate**

Product number	90032177
CAS number	1260141-27-2
Molecular formula	C17H16FN3O2S·C4H4O4
Molecular weight	461.46 g/mol

PARAMETER	SPECIFICATION
Appearance	White or off-white crystal or crystalline powder
Assay	98.0-102.0% (DRIED BASIS)
Acetonitrile	≤0.041%
Fumaric acid	23.9-26.5%
Heavy metals	≤20ppm
Loss on Drying	≤0.40%
Melting Point	193°C-197°C
Acetic acid	≤0.5%
Benzene	≤0.0002%
Dichloromethane	≤0.06%
Ethanol	≤0.5%
Ethyl acetate	≤0.5%
Fluoride (F-)	3.7%-4.3%
HPLC	The retention time of the major peak of the sample solution corresponds to that of the standard solution as obtained in the assay.

PARAMETER	SPECIFICATION
Infrared Absorption	The infrared absorption spectrum of the sample shall be consistent with that of the reference substance
Methanol	≤0.3%
Methylamine	≤0.1%
N,N-diisopropylethylamine	≤0.1%
Organic impurities	Single impurity: ≤0.15%. Total impurities: ≤1.0%
Pyridine	≤0.02%
Residue on Ignition	≤0.1%
Solubility	Slightly soluble in methanol or water and practically insoluble in isopropanol or acetonitrile
N,N-dimethylacetamide	≤0.109%
Tetrahydrofuran	≤0.072%

SPECIFICATION STATEMENT	The values stated above represent the standard specification for this product, issued under Molekula Ltd 's quality management system. Batch-specific results are provided on the Certificate of Analysis.
STORAGE	Store as indicated on the product label, away from light, moisture and incompatible materials.

Molekula Ltd would like to thank you for your support of our products and service.
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