

Specification

Technical Data Sheet

CAS 61177-45-5	STORAGE -15 to -20 °C	MOLECULAR WEIGHT 237.25
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PRODUCT

Potassium clavulanate (ckdb)

Product number	90035823
CAS number	61177-45-5
Molecular formula	C ₈ H ₈ NO ₅ ·K
Molecular weight	237.25 g/mol

PARAMETER	SPECIFICATION
Appearance	White to Off-white crystalline powder (hygroscopic)
Assay	Liquid chromatography: 96.5 - 102.0% (as potassium clavulanate, anhydrous)
Grade	EP grade
Identification	Conforms to reference
pH	5.5 - 8.0 (Sol. S)
Aliphatic amines	≤ 0.2%
Impurities	Impurity A) ≤ 0.2% , Impurity B) ≤ 0.2% , Impurity C) ≤ 0.2%
Polymeric impurities and other impurities	≤ 0.40 (Absorbing at 278nm)
Related Substances	Impurity E) ≤ 1.0% , Impurity G) ≤ 1.0%
Residual Solvents: Acetone	≤ 5000ppm
Residual Solvents: Isopropanol	≤ 5000ppm
Residual Solvents: Methanol	≤ 1000ppm
Solubility	Freely soluble in water, slightly soluble in ethanol (96%), very slightly soluble in acetone.
Specific optical rotation	+53 to +63° (as anhydrous substance)

PARAMETER	SPECIFICATION
Total Impurities	$\leq 2.0\%$
2-ethylhexanoic acid	$\leq 0.8\%$
Any Unidentified Impurity	$\leq 0.1\%$
Identification (IR)	Comparable to reference spectrum (EP 2.2.24)
Water (KF)	$\leq 0.5\%$

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.

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