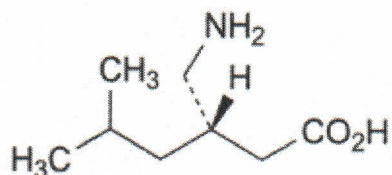


Pregabalin EP

Batch no D5389-24-009
Mf date Sep 17 2024
Retest Aug 2029
Batch size 182.08 kg

Molecular Structure



Molecular Formula $C_8H_{17}NO_2$

Molecular Weight 159.23

CAS Registry Number 148553-50-8

Jun 24 2025

Tests	Specifications	Results
Appearance	White or almost white powder	White powder
Identification	IR, Enantiomeric purity test	Positive
Water	$\leq 0.5\%$	$< 0.1\%$
Sulfated ash	$\leq 0.1\%$	$< 0.1\%$
Enantiomeric purity (HPLC)	Impurity B $\leq 0.15\%$	$< RL$ (RL:0.05%)
Related substances (HPLC)	Each unidentified impurity $\leq 0.10\%$ eluting before pregabalin	$< RL$ (RL:0.05%)
	Impurity A $\leq 0.15\%$	$< RL$ (RL:0.05%)
	Each unidentified impurity $\leq 0.10\%$ eluting after pregabalin	$< RL$ (RL:0.05%)
	Total impurities $\leq 0.5\%$	$< RL$ (RL:0.05%)
Residual solvents	Ethanol ≤ 5000 ppm	$< LOD$ (LOD: 3.6 ppm)
	Chloroform ≤ 60 ppm	$< LOD$ (LOD: 3.5 ppm)
	Isopropanol ≤ 5000 ppm	833 ppm
Assay (oab) HPLC	98.0 ~ 102.0% of $C_8H_{17}NO_2$	99.8%

Packaging & storage	Preserve in well-closed, light-resistant containers
Conclusion	Material complies with EP

Pregabalin (PGB/S-PGB): (S)-3-(Aminomethyl)-5-methylhexanoic acid
 Impurity A: (S)-4-Isobutyl-2-pyrrolidinone (Abbr: Lactam)
 Impurity B: (R)-3-(Aminomethyl)-5-methylhexanoic acid (Abbr: R-PGB)