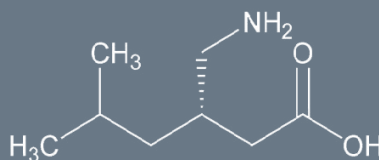


# Pregabalin

## Quality Solutions

Category: Psychiatric



Authorized Distributor

USP can support your development and manufacturing activities on Pregabalin-based medicines with these existing and upcoming standards.

## Official and Proposed Documentary Standards and Associated Physical Materials

MONOGRAPH 1

<b>PREGABALIN</b> Official as of 01-Nov-2020	
USP Mandelic Acid RS	<a href="#">USP-1375058</a>
USP Pregabalin RS	<a href="#">USP-1559618</a>
USP Pregabalin Related Compound A RS	<a href="#">USP-1559629</a>
USP Pregabalin Related Compound C RS	<a href="#">USP-1559647</a>
<b>PHARMACEUTICAL ANALYTICAL IMPURITY(IES)*</b>	
USP rac-5,6-Dehydropregabalin PAI   <b>New</b>	<a href="#">USP-1A02350</a>
USP rac-4,5-Dehydropregabalin PAI   <b>New</b>	<a href="#">USP-1A02330</a>
USP Lactosyl Pregabalin Pyrrolidone PAI   <b>New</b>	<a href="#">USP-1A02340</a>
USP Diisobutyl Diazecinedione PAI   <b>New</b>	<a href="#">USP-1A02400</a>
Isobutylglutarmonoamide   <b>New</b>	<a href="#">USP-1A01840</a>
Isobutylglutarmonoamide (R-isomer)   <b>New</b>	<a href="#">USP-1A01830</a>
rac-Pregabalin Imide Dimer Amide   <b>New</b>	<a href="#">USP-1A02380</a>

\* Documents in PF Online are not official and not suitable to demonstrate compliance. They may never become official.

\* Pharmaceutical Analytical Impurities (PAI products) are released using a process developed by USP's subject matter experts. The release process is based on internal policies, standard operating procedures, and requirements as defined by USP's Quality Management System. USP is an ISO 9001:2015 certified facility. PAI products are different from official USP Reference Standards. PAI products are not required for compendial compliance.

01-Aug-2023. For publications related to **Pregabalin** in PF online after this date, please visit the integrated [USP-NF/PF online](#).

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