

NEW DEVELOPMENT AT GLSYNTECH – APIs and their Key Intermediates

We are pleased to share several new developments at *GLSyntech* for selected active pharmaceutical ingredients (APIs), along with their key intermediates.

GLSyntech does not plan for any cGMP manufacturing for APIs in-house. Instead, we prefer to work with cGMP partners by supplying those key intermediates with cost competitiveness, superior product quality, and supply stability. APIs on the market will face strong generic competition when their patent protection is either expired or will soon be expired. Continuing to improve their product qualities and manufacturing process costs becomes critical to maintain and/or increase their market shares. The latest developments at **GLSyntech** have been driven by implementing green chemistry, improving manufacturing process economics, and enhancing product quality and process patentability.

Here is the summary of those developments.

ΑΡΙ				Its Key Intermediates			
Chemical Structure	API Name	CAS Number		Chemical Structure	Chemical Name	CAS Number	Current Development Status
	Levetiracetam/Keppra®	[102767-28-2]		HO	(S)-alpha-ethyl-2-oxo-1-pyrrolidine acetic acid	[102849-49-0]	Commercial
					(RS)-alpha-ethyl-2-oxo-1-pyrrolidine acetic acid	[67118-31-4]	Commercial
				ну соон	2-N-(Carboxypropyl)aminobutyric acid	NA	Commercial
CCAN STATISTIC	Linagliptin/Tradjenta®	[668270-12-0]		NH2 NH2 2HCI	R-3-piperidine-amine dihydrochloride	[334618-23-4]	Commercial

The process of making Levetiracetam is very efficient with a good potential of achieving a one-pot manufacturing process. It is green chemistry enacted with high overall yield, leading to advantageous production costs and competitive prices at the market. With the success of Levetiracetam's commercial process several key intermediates for Brivaracetam/Briviact[®], CAS# 357336-20-0, and Lacosamide/Vimpat[®], CAS# 175481-36-4, are under active development now.

The commercial manufacturing process for R-3-piperidine-amine dihydrochloride is based on an enzymatic method. That process shows its superiority in production output/cost, product quality, and no heavy metal used, compared to its chemical processes.

Please let us know if you are interested in further discussions, product sampling, and any other inquiries. Please feel free to email us at <u>sales@glsyntech.com</u>, or call us at +1 215 367 5129.

Issued in May 2023