

SINOWAY Newsletter

June, 2022

☆ Challenges and Opportunities for Second Quarter

▲ **Supply chain problems continue to be main challenge** of Second Quarter for exporters and oversea buyers.

On May 11, the Animal Husbandry and Veterinary Service Bureau of the Ministry of Agriculture and Rural Affairs of the People's Republic of China issued the implementation of Notice of the New GMP for Veterinary Drugs.

It was noticed that veterinary drug companies which have not passed the inspection of new version veterinary drug GMP before June 1, 2022 will not be allowed to produce veterinary drug any more.

There had been more than 1,500 veterinary drug GMP enterprises registered in the national veterinary drug database previously. After June 2, 2022, there were only 627 production enterprises left who have obtained the new version of the veterinary drug GMP certificate.

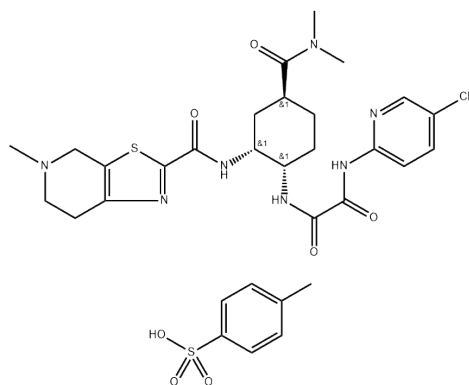
▲ China ceases marking cities with COVID-positive cases in the travel code.

► The Ministry of Industry and Information announced officially that China's travel code will be no longer adding an asterisk(*) to those cities with positive COVID cases, in order to "facilitate the travel of users". This policy may play a positive role in promoting the flow of people and boosting the economic growth in China.

☆ Sinoway Product for June

Product Name: Edoxaban (Tosylate Monohydrate) The patent will be expired in 2023.

CAS No: 1229194-11-9



1. Specifications: Assay 98.0%~102.0%(on anhydrous basis); Single impurity: NMT 0.1%.
Total impurities: NMT 0.5%.

Application: API for Anticoagulant use(only applicable in the non-patent areas)

Highlights:

- * Produced under ICH Q7/GMP regulation
- * Documents: GMP under applying , Written Confirmation, DMF.
- * More competitive price with better quality than India source
- * Intermediates available (avoid patents)

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Chemical name	CAS No.	Quality
tert-Butyl [(1R,2S,5S)-2-amino-5-[(dimethylamino)carbonyl]cyclohexyl]carbamate	365998-36-3 (Avoid patent)	99.00% up by HPLC Single
2-[(5-Chloropyridin-2-yl)amino]-2-oxoacetic acid ethyl ester monohydrochloride	1243308-37-3	impurity: NMT 0.1%.
tert-Butyl [(1R,2S,5S)-2-amino-5-[(dimethylamino)carbonyl]cyclohexyl]carbamate oxalate	1210348-34-7	Total impurities: NMT 0.5%.
5-Methyl-4,5,6,7-tetrahydrothiazolo[5,4-c]pyridine-2-carboxylic acid hydrochloride	720720-96-7	

Any questions or other inquiries, please always be free to contact us. Thank you!