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RESEARCH**

APPLICATION NUMBER:

211158Orig1s000

CLINICAL MICROBIOLOGY/VIROLOGY
REVIEW(S)

**Division of Anti-Infective Products
Clinical Microbiology Review**

NDA-211158

SDN 11

Name of the Product: TIGECYCLINE

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Clinical Microbiology Review

Date Review Completed: 07/17/2018

NDA, 505(b)(2): 211158

Date Company Submitted: 09/29/2017

Date received by CDER: 10/02/2017

Date Assigned: 10/02/2017

Date Completed: 07/17/2018

Reviewer: **Jalal Sheikh, Ph.D.**

NAME OF THE APPLICANT: Amneal Pharmaceuticals LLC, Hauppauge, NY, USA

DRUG PRODUCT NAMES: Tigecycline for injection, 50 mg/vial

DRUG CATEGORY: Antibacterial

PROPOSED DOSAGE FORM AND STRENGTH: For Injection: 50 mg, lyophilized powder for reconstitution in a single-dose 5 mL vial.

ROUTE OF ADMINISTRATION AND DURATION OF TREATMENT:

- Initial dose of 100 mg, followed by 50 mg every 12 hours administered intravenously over approximately 30 to 60 minutes.
- Severe hepatic impairment (Child Pugh C): Initial dose of 100 mg followed by 25 mg every 12 hours.

DISPENSED: Prescription product (Rx)

PROPOSED INDICATION: Tigecycline, USP is a tetracycline class antibacterial indicated in patients 18 years of age and older for the treatment of:

- Complicated Skin and Skin Structure Infections caused by susceptible isolates of *Escherichia coli*, *Enterococcus faecalis* (vancomycin-susceptible isolates), *Staphylococcus aureus* (methicillin-susceptible and -resistant isolates), *Streptococcus agalactiae*, *Streptococcus anginosus* grp. (includes *S. anginosus*, *S. intermedius*, and *S. constellatus*), *Streptococcus pyogenes*, *Enterobacter cloacae*, *Klebsiella pneumoniae*, and *Bacteroides fragilis*.
- Complicated Intra- Abdominal Infections caused by susceptible isolates of *Citrobacter freundii*, *Enterobacter cloacae*, *Escherichia coli*, *Klebsiella oxytoca*, *Klebsiella pneumoniae*, *Enterococcus faecalis* (vancomycin-susceptible isolates), *Staphylococcus aureus* (methicillin-susceptible and -resistant isolates), *Streptococcus anginosus* grp. (includes *S. anginosus*, *S. intermedius*, and *S. constellatus*), *Bacteroides fragilis*, *Bacteroides thetaiotaomicron*, *Bacteroides uniformis*, *Bacteroides vulgatus*, *Clostridium perfringens*, and *Peptostreptococcus micros*. and

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- Community Acquired Bacterial Pneumonia caused by susceptible isolates of *Streptococcus pneumoniae* (penicillin-susceptible isolates), including cases with concurrent bacteremia, *Haemophilus influenzae*, and *Legionella pneumophila*.

RELATED DOCUMENTS:

IND-128826

NDA-21821

TYPE OF SUBMISSION:

New Drug Application, 505(b)(2)

PURPOSE OF SUBMISSION: Original Application

REMARKS: Amneal's Tigecycline for Injection, 50 mg/vial is qualitatively different from reference listed drug (RLD), Tygacil for injection 50 mg/vial (Tigecycline, NDA 21281). The table below provides details on the formulation comparison:

RLD, Tygacil for Injection, 50 mg / vial (NDA 21821)	Amneal's Tigecycline for Injection USP, 50 mg/vial	Function
Tigecycline	Tigecycline	Active ingredient
Lactose Monohydrate	--	(b) (4)
--	Arginine	
Hydrochloric Acid / Sodium Hydroxide (Quantity sufficient for adjustment of pH)	Hydrochloric Acid / Sodium Hydroxide (Quantity sufficient for adjustment of pH)	Adjustment of pH

SUMMARY AND RECOMMENDATIONS:

No new clinical microbiology data was submitted to this application for review.

However, in a previous communication to the Applicant, this reviewer recommended that the Microbiology section of the Package Insert should be updated in accordance to the 21st Century Cures Act. The Applicant complied and subsequently submitted an amended label. Therefore, from a clinical microbiology perspective, the application is acceptable.

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SIGNATURES:

Jalal Sheikh, Ph.D.
Clinical Microbiology Reviewer
CDER/OAP/DAIP
July 18, 2018

Concurrence:

Avery Goodwin, Ph.D.
Acting Clin Micro Team Lead
July 18, 2018

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

JALAL U SHEIKH
07/18/2018

AVERY C GOODWIN
07/18/2018