CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

208609Orig1s000

CHEMISTRY REVIEW(S)

CHEMISTRY REVIEW

Recommendation:
NDA: Complete Response

NDA 208609

Drug Name/Dosage Form	**Ephedrine Sulfate USP**
Strength	**50 mg/mL**
Route of Administration	Injection
Rx/OTC Dispensed	Rx
Applicant	**Akorn Inc**
US agent, if applicable	

SUBMISSION(S) REVIEWED	DOCUMENT DATE	DISCIPLINE(S) AFFECTED

Quality Review Team

DISCIPLINE	REVIEWER	BRANCH/DIVISION
Drug Substance	**Jeffrey Medwid**	**OPQ/ONDP/DNDPAPI/BII**
Drug Product	**Arthur Shaw**	**OPQ/ONDP/DNDPII/BIV**
Process	**Peter Krommenhoek**	**OPQ/OPF/DPAIII/BVIII**
Microbiology	**Denise Miller**	**OPQ/OPF/DMA/BII**
Facility	**Rose Xu/Rebecca Dombrowski**	**OPQ/OPF/DIA/BII**
Biopharmaceutics	**Angella Lu/Albert Chen**	**OPQ/ONDP/DB/BII**
Regulatory Business Process Manager	Steve Kinsley	OPQ/OPRO/RBPMI/BI
Application Technical Lead	**Julia Pinto**	**OPQ/ONDP/DNDPII/BIV**
Laboratory (OTR)		
ORA Lead	**Paul Perdue**	ORA/OGROP/ORA/OO/OMPTO/ DMPTPO/M
Environmental Assessment (EA)		

Table of Contents

Quality Review Data Sheet

1. **RELATED/SUPPORTING DOCUMENTS:**

A. DMFs:

DMF #	TYPE	HOLDER	ITEM REFERENCED	STATUS	DATE REVIEW COMPLETED	COMMENTS
(b) (4)	II		(b) (4)	Adequate	11/12/2015	
	III			Not reviewed	N/A	Sufficient information in Application

B. Other Documents: N/A

2. **CONSULTS: None**

APPEARS THIS WAY ON ORIGINAL

Executive Summary

I. Recommendations

A. Recommendation and Conclusion on Approvability

Ephedrine Sulfate Injection, USP is a (b) (4) sterilized aqueous solution consisting of ephedrine sulfate as the drug substance. The drug substance is under DMF (b) (4) and supplied by (b) (4). The DMF is adequate to support its use in the drug product. A retest period of (b) (4) months is granted.

(b) (4) Adequate microbiology data is provided to support the manufacturing process and storage of the product in glass ampules. Satisfactory stability data is provided to support an expiry of 36 months for the drug product, when stored at 25C.

Office of Compliance has issued a 483 to the Akorn manufacturing site (FEI 1450114). All other facilities involved in the testing and release of the drug substance and drug product are recommended as adequate. Therefore an approvable recommendation for this application is pending satisfactory resolution of the deficiencies identified in the 483.

B. Recommendation on Phase 4 (Post-Marketing) Commitments, Agreements, and/or Risk Management Steps, if Approvable

II. Summary of Quality Assessments

A. Drug Substance [USAN Name] Quality Summary

Ephedrine Sulfate, USP drug substance is supplied by (b) (4). The manufacture and control of the drug substance is referenced to DMF (b) (4) and reviewed by Jeff Medwid, Ph.D. The drug substance is adequately supported for use in the preparation of the drug product and has a retest period of (b) (4) months.

B. Drug Product [Ephedrine Sulfate] Quality Summary

Ephedrine Sulfate Injection, USP drug product is a clear, colorless solution in water (b) (4) and no other excipients. (b) (4) The product is designed to meet Ephedrine Sulfate Injection USP monograph requirements. The drug product must be diluted with saline or 5% dextrose prior to administration. The product cannot be administered as a bolus injection. The granted expiry is 36 months when stored at 25C.

C. Summary of Drug Product Intended Use

Proprietary Name of the Drug Product	Ephedrine Sulfate Injection, USP
Non Proprietary Name of the Drug Product	Ephedrine Sulfate Injection, USP
Non Proprietary Name of the Drug Substance	Ephedrine Sulfate
Proposed Indication(s) including Intended Patient Population	(b) (4)
Duration of Treatment	
Maximum Daily Dose	
Alternative Methods of Administration	

D. Biopharmaceutics Considerations: NA

1. BCS Classification:
   - Drug Substance:
   - Drug Product:

2. Biowaivers/Biostudies
   - Biowaiver Requests
   - PK studies
   - IVIVC

E. Novel Approaches: NA

F. Any Special Product Quality Labeling Recommendations : NA

G. Life Cycle Knowledge Information : NA

OVERALL ASSESSMENT AND SIGNATURES: EXECUTIVE SUMMARY

This NDA is recommended as a complete response and approvable pending satisfactory resolution to the issues identified in the inspection of the Akorn drug product manufacturing facility.

Application Technical Lead Signature:

Julia C. Pinto, Ph.D.
Branch Chief(Acting)
ONDP/Division II/Branch IV

Julia C. Pinto -S

Digitally signed by Julia C. Pinto -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Julia C. Pinto -S, 0.9.2342.19200300.100.1.1=1300366849
Date: 2016.07.13 11:48:37 -04'00'

ASSESSMENT OF THE BIOPHARMACUETICS

A separate Review by Tien Mien Chen, Ph.D. and Tapash Ghosh, Ph.D has been entered into Panorama separately.
A biowaiver was requested and has been granted. See below, taken from the Biopharmaceutics Review dated June 9, 2016.

Reviewer's Assessment: Tien Mien Chen, Ph.D

The biowaiver request for submitting the evidence of in vivo bioavailability studies for Ephedrine Sulfate Injection, USP 50 mg/mL, is granted. Therefore, from the Biopharmaceutics perspective, NDA 208609 for Ephedrine Sulfate Injection, USP 50 mg/mL, is recommended for approval.

ASSESSMENT OF MICROBIOLOGY

27. Are the tests and proposed acceptance criteria for microbial burden adequate for assuring the microbial quality of the drug product?

Applicant's Response:

Reviewer's Assessment: P DRUG PRODUCT

P.1 Description of the Composition of the Drug Product

- Description of drug product – Clear, colorless solution of ephedrine in water (b) (4).
- Drug product composition –

Ingredient	Content per mL
Ephedrine Sulfate	50 mg
Water for Injection	Q.S. to 100%

- Description of container closure system – (b) (4) (b) (4) Glass (b) (4) ampule.

P.2 Pharmaceutical Development

P.2.5 Microbiological Attributes

- Container-Closure Integrity – there was no procedure provided for container closure integrity though both a manual and an automatic procedure are mentioned in the batch record. (SOP FL136 for the manual method and SOP WI113 for the automatic method).

Information request:
The process for determining the integrity of the closure for the ampules was not provided.

Leak testing was included in the batch records by either a manual or automatic methods. Provide a summary for these two procedures and the corresponding acceptance criteria.

Response: The sponsor provided that they use a 100% automated inspection method for determining the integrity of the closure for ampoules for each lot manufactured. The method uses a Nikka-Densok Pinhole Inspection machine. The manual method is a dye ingress method used only on sample units. Information on both methods was provided.

(b) (4)

The dye ingress method uses a vacuum/pressure hold system with the ampoules submerged in a dye solution. The submerged ampoules are subjected to a 15 to 25 Hg vacuum for no more than 5 minutes and then returned to atmospheric pressure. Integrity is determined by a visual inspection for the lack of dye ingress into the ampoule. The SOP for setting up the equipment was provided; this SOP covered running the test and assessing the ampoules for dye ingress was covered. The dye solution was only called "Leak Test Solution" and there were no details provided about what the solution was though a separate SOP was referenced for cleaning of the leak test vessel and changing of the dye solution (SOP FL119). Though the information provided for the manual method lack sufficient detail, the information provided on the automatic method is acceptable; therefore, there were no deficiencies cited for the manual method.

Review of Response: The information provided was acceptable and supports the integrity of the ampoules.

- Preservative Effectiveness - NA
- Justification for not having a microbial limit specification for a non-sterile drug product - NA

ADEQUATE

REVIEWER COMMENT – The information provided is acceptable.

P.3 Manufacture
P.3.1 Manufacturers
Akorn Inc.

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(b) (4)

[redacted]

P.5 Control of Drug Product
P.5.1 Specifications
P.5.2 Analytical Procedures

- Endotoxin –
  - Method: USP <85> Gel Clot
  - Endotoxins Specification: < (b) (4) EU/mg;
    USP Monograph limit: < (b) (4) EU/mg

Lysate sensitivity: (b) (4) EU/mL
Drug potency: 50 mg/mL
Calculated MVD: (b) (4)
Validation of the test shows no inhibition or enhancement using a dilution of 1:1000. A dilution of 1:1000 will be used for routine testing.

Finished lot # 011031 contains (b) (4) EU/mg
Finished lot # 111111 contains EU/mg
Finished lot # 111421 contains EU/mg
(Section3.2.R bmr011031 (page 206), bmr 111111(page 161), and bmr111421(page 155).

(b) (4)

Calculated endotoxin dose at the proposed endotoxins specification and maximum dose:
(b) (4) EU/mg x 50 mg = (b) (4) EU/dose
(b) (4) ÷ 70 kg average weight of adult = (b) (4) EU/kg/hr

The endotoxin dose at the proposed endotoxins specification and maximum dose as calculated by this reviewer is within the USP <85> recommendation of 5EU/kg/hr.

Comments: The release testing is supported by enhance/inhibition (method suitability) testing of the product. The proposed specification is acceptable for the proposed maximum dose.

- Sterility –
  - Method – USP <71> Membrane filtration
  - Specification - Sterile
  - Method suitability – followed USP <71> for membrane filtration using a 300 mL rinse per filter. The filter membrane type was the Steritest canister for ampoules (cat # TZHALA210); the rinse fluids used were not identified in the report.

Comments: The release testing is supported by bacteriostasis/fungistasis (method suitability) testing of the product.

- Microbial Limits - NA

ADEQUATE

REVIEWER COMMENT –

P.7 Container Closure System - NA

P.8 Stability

P.8.1 Stability Summary and Conclusion

MAINTENANCE OF MICROBIOLOGICAL CONTROL AND QUALITY: STABILITY CONSIDERATIONS

Expiration of 36 months is proposed.

Long term: 25 ± 2°C/40 ± 5 % RH

Sterility and endotoxin tested at 0 and 36 months.

Accelerated: 40 ± 2°C/75 ± 5 %RH

No microbial quality testing time points.

Reviewer Note: Normally sterility testing is performed at initial, at expiration and annually in between. As this is a glass ampule with no container/closure interface, the testing at initial and expiration is acceptable. There are no quality microbiology concerns with this testing schedule.

P.8.2 Post-Approval Stability Protocol and Stability Commitment

Akorn will place the first three commercial production batches of Ephedrin Sulfate Injection USP, 50 mg/mL on stability under the long term storage conditions. Thereafter, a minimum of one batch annually will be added to the stability program.

- Container Closure Integrity (CCI) – CCI is tested by sterility testing at initial and at expiration.
- Endotoxin – Endotoxin is tested at initial and at expiration for the long term storage conditions. The acceptance criterion is the same as the release specification.
- Microbial Limits - NA

P.8.3 Stability Data

Stability data for 17 lots were provided. Three lots were designated as the registration lots with extended hold and light exposure studies. These were Lots 011031, 111111, and 111421.

Lot 011031: data up to 24 months was provided. Endotoxin and sterility were performed and met the acceptance criteria.

Lot 111111: Data up to 18 months was provided. Sterility was performed at 12 months and met the acceptance criteria. Endotoxin was not performed at this time point.

Lot 111421: Data up to 18 months was provided. Sterility was performed at 12 months and met the acceptance criteria. Endotoxin was not performed at this time point.

ADEQUATE

REVIEWER COMMENT – The information provided is adequate.

A APPENDICES

A.2 Adventitious Agents Safety Evaluation - NA

A.2.1 Materials of Biological Origin - NA

A.2.2 Testing at Appropriate Stages of Production - NA

A.2.3 Viral Testing of Unprocessed Bulk - NA

A.2.4 Viral Clearance Studies - NA

R REGIONAL INFORMATION

R.1 Executed Batch Record

Executed lot #(s): 011031, 111111, and 111421

The batch records confirm that validated [redacted] (b) (4) process and component [redacted] (b) (4) processes were used for the manufacture of the exhibit batch.

2. REVIEW OF COMMON TECHNICAL DOCUMENT-QUALITY (CTD-Q)
MODULE 1

A. PACKAGE INSERT

Storage temperature: 20-25°C
Route of administration: IV
Container: Single dose; [redacted] (b) (4)

ADEQUATE

REVIEWER COMMENT – There are no microbiology concerns for the label as proposed

2.3.P.7 Container/Closure System

28. Is the proposed container/closure system for the drug product validated to function as a barrier to microbial ingress? What is the container/closure design space and change control program in terms of validation?

Applicant's Response:

Reviewer's Assessment:See Question 29.

A APPENDICES

A.2 Adventitious Agents Safety Evaluation

29. Are any materials used for the manufacture of the drug substance or drug product of biological origin or derived from biological sources? If the drug product contains material sourced from animals, what documentation is provided to assure a low risk of virus or prion contamination (causative agent of TSE)?

Applicant's Response:

Reviewer's Assessment:See Question 29.

30. If any of the materials used for the manufacture of the drug substance or drug product are of biological origin or derived from biological sources, what drug substance/drug product processing steps assure microbiological (viral) safety of the component(s) and how are the viral inactivation/clearance capacity of these processes validated?

Applicant's Response:

Reviewer's Assessment:See Question 29.

OVERALL ASSESSMENT AND SIGNATURES: MICROBIOLOGY

Reviewer's Assessment and Signature:
Recommendation is to approve from a quality microbiology perspective.

Denise A. Miller
Sr. Microbiology Reviewer
OPQ/OPF/DMA/Branch II

Secondary Review Comments and Concurrence:
I concur with the Microbiology assessment and approval recommendation.
Neal J. Sweeney, Ph.D. 15June2016
Microbiology Quality Assessment Lead (Acting)
OPQ/OPF/DMA/Branch II

ASSESSMENT OF ENVIRONMENTAL ANALYSIS

Applicant's Response: The Applicant has provided the following statement regarding the environmental assessment.

As required by 21 CFR §25.15(d) Akorn Inc. (Akorn) states that to the applicant's knowledge, no extraordinary circumstances as specified under 21 CFR 25.21 exist that would preclude a categorical exclusion.

Based on all currently available information, Akorn estimates the highest quantity of the active moiety expected to be produced for direct use in any of the next five years is less than 1ppb.

Reviewer's Assessment:

Adequate

OVERALL ASSESSMENT AND SIGNATURES: ENVIRONMENTAL

Reviewer's Assessment and Signature:

Julia C. Pinto, Ph.D.

Review of Common Technical Document-Quality (Ctd-Q) Module 1

Labeling & Package Insert

1. Package Insert

(a) "Highlights"

Item	Information Provided in NDA	Reviewer's Assessment
Product title, Drug name (201.57(a)(2))		
Proprietary name and established name Dosage form, route of administration	*EPHEDRINE SULFATE INJECTION, USP 50 mg/mL*	**ACCEPTABLE** Note that the applicant has not proposed a Proprietary name
Controlled drug substance symbol (if applicable)	N/A	
Dosage Forms and Strengths (201.57(a)(8))		
A concise summary of dosage forms and strengths	• *EPHEDRINE SULFATE INJECTION, USP 50 mg/mL, (equivalent to (b) (4) mg ephedrine base) is injected intravenously as a bolus. Dilute before administration* • *Bolus intravenous injection 5 to 10 mg as needed, not to exceed 50 mg.*	**ACCEPTABLE** Note that the applicant has added installed regarding dilution.

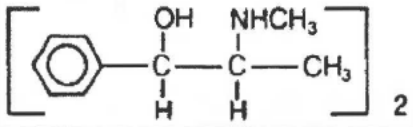
Conclusion: ACCEPTABLE

(b) "Full Prescribing Information" Section # 3: Dosage Forms and Strengths

Item	Information Provided in NDA	Reviewer's Assessment
Available dosage forms Strengths: in metric system	*EPHEDRINE SULFATE INJECTION, USP 50 mg/mL, is supplied as 1 mL ampules of 50 mg/mL ephedrine sulfate in water, equivalent to (b) (4) mg ephedrine base*	**ACCEPTABLE**
A description of the identifying characteristics of the dosage forms, when applicable.	N/A	N/A

Conclusion: ACCEPTABLE

#11: Description

Item	Information Provided in NDA	Reviewer's Assessment
Proprietary name and established name	*EPHEDRINE SULFATE INJECTION, USP 50 mg/mL*	**ACCEPTABLE**
Dosage form and route of administration		
Active moiety expression of strength with equivalence statement for salt (if applicable)	*Each mL contains ephedrine sulfate 50 mg (equivalent to (b) (4) mg ephedrine base) in water for injection.*	**ACCEPTABLE**
Inactive ingredient information	No excipients. *The pH is adjusted with sodium hydroxide and/or glacial acetic acid, if necessary*	**ACCEPTABLE**
Statement of being sterile (if applicable)	*"...a clear, colorless, sterile solution..."*	**ACCEPTABLE**
Pharmacological/ therapeutic class	*alpha-and beta-adrenergic agonist and a norepinephrine-releasing agent*	**ACCEPTABLE**
Chemical name, structural formula, molecular weight	*(1R,2S)-(-)-2-methylamine-1-phenylpropan-1-ol sulfate* *428.5 g/mol*  2	**ACCEPTABLE**
Other important chemical or physical properties (such as pKa, solubility, or pH)	*freely soluble in water and ethanol, very slightly soluble in chloroform, and practically insoluble in ether.*	**ACCEPTABLE**

Conclusion: ACCEPTABLE

#16: How Supplied/Storage and Handling

Item	Information Provided in NDA	Reviewer's Assessment
Strength of dosage form	*50 mg/mL*	**ACCEPTABLE**
Available units (e.g., bottles of 100 tablets)	*1 mL ampules in packs of 10*	**ACCEPTABLE**
Identification of dosage forms,	N/A	**ACCEPTABLE**
Special handling (e.g., protect from light, do not freeze)	*Protect from light.*	Studies show no effect of freeze-thaw. **ACCEPTABLE**
Storage conditions	*Store at 20□C to 25□C (68□F to 77□F) [see USP Controlled Room Temperature]*	**ACCEPTABLE**

Manufacturer/distributor name listed at the end of PI, following Section #17

Item	Information Provided in NDA	Reviewer's Assessment
Manufacturer/distributor name	*Mfd. by: Akorn, Inc*	Included on Ampule label not on PI. **ACCEPTABLE**

Conclusion: ACCEPTABLE

2. Container and Carton Labeling

1) Immediate Container Label

(b) (4)

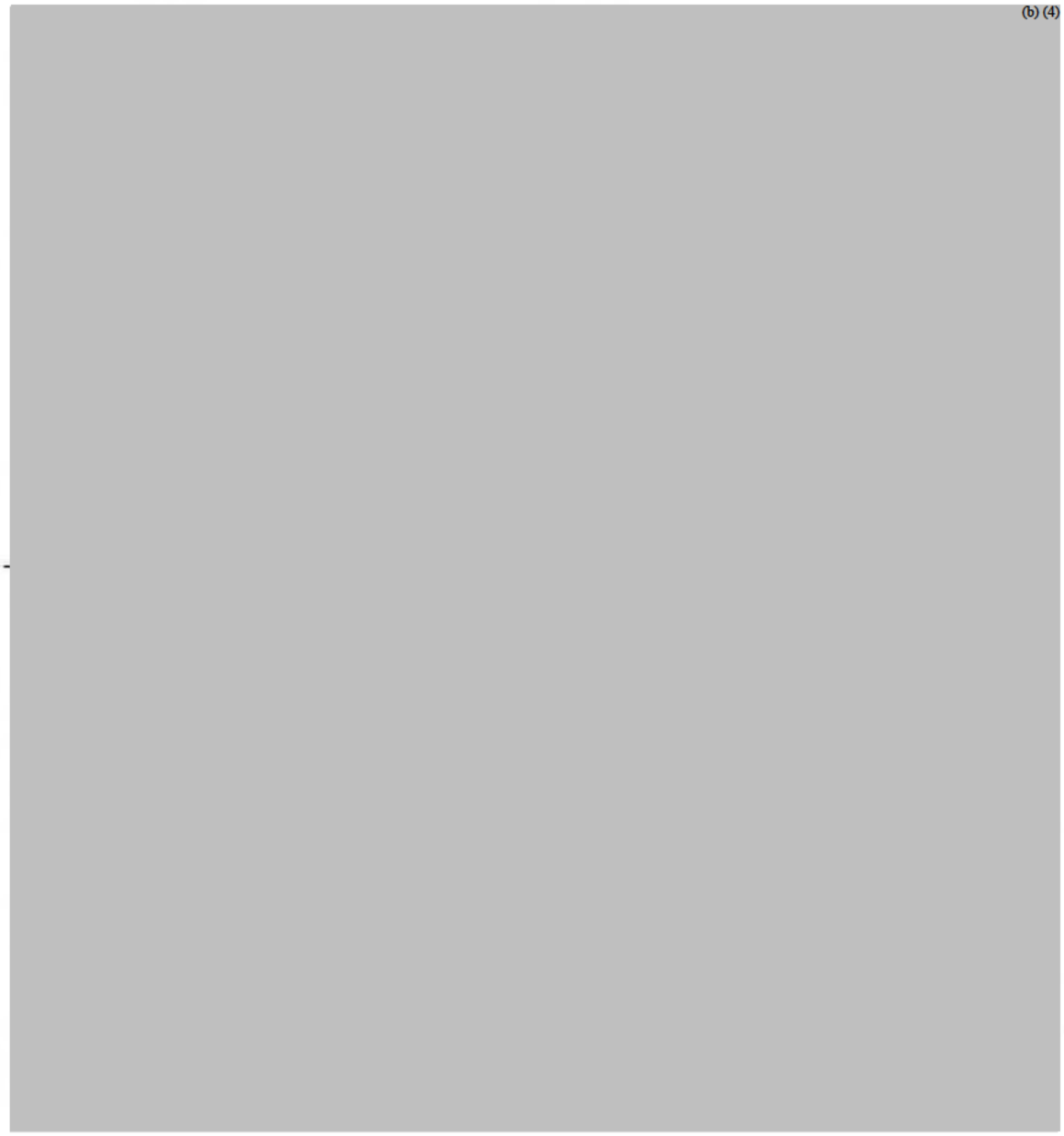
Reviewer's Assessment: **ACCEPTABLE**

Item	Comments on the Information Provided in NDA	Conclusions
Proprietary name, established name	No comment	**ACCEPTABLE**
Strength	No comment	**ACCEPTABLE**
Route of administration	No comment	**ACCEPTABLE**
Net contents	No comment	**ACCEPTABLE**
Name of all inactive ingredients	Not provided There are no inactive ingredients.	**ACCEPTABLE**
Lot number	No comment	**ACCEPTABLE**
Expiration date	No comment	**ACCEPTABLE**
"Rx only"	No comment	**ACCEPTABLE**
Storage	No comment	**ACCEPTABLE**
NDC number	No comment	**ACCEPTABLE**
Bar Code	No comment	**ACCEPTABLE**
Name of manufacturer/distributor	No comment	**ACCEPTABLE**
Others	N/A	

Conclusion: ACCEPTABLE

2) Carton Labeling

(b) (4)



Item	Comments on the Information Provided in NDA	Conclusions
Proprietary name, established name	No comment	ACCEPTABLE
Strength	No comment	ACCEPTABLE
Net contents	No comment	ACCEPTABLE
Lot number	No comment	ACCEPTABLE
Expiration date	No comment	ACCEPTABLE
Name of all inactive ingredients	Water for Injection	ACCEPTABLE
Sterility Information	Not provided	
"Rx only"	No comment	ACCEPTABLE
Storage Conditions	No comment	ACCEPTABLE
NDC number	No comment	ACCEPTABLE
Bar Code	No comment	ACCEPTABLE
Name of manufacturer/distributor	No comment	ACCEPTABLE
"See package insert for dosage information"	No comment	ACCEPTABLE
"Keep out of reach of children"	N/A	ACCEPTABLE
Route of Administration	No comment	ACCEPTABLE

Conclusion: ACCEPTABLE

OVERALL ASSESSMENT AND SIGNATURES: LABELING

Reviewer's Assessment and Signature: ACCEPTABLE

Arthur Shaw, Ph.D.

Secondary Review Comments and Concurrence:

Julia C. Pinto, Ph.D.
Branch Chief(Acting)
ONDP/Division II/Branch IV

I. Attachments

A. Lifecycle Knowledge Management

a) Drug Product

From Initial Risk Identification			Review Assessment		
Attribute/	Factors that	Initial Risk	Risk	Final Risk	Lifecycle

CQA	can impact the CQA	Ranking	Mitigation Approach	Evaluation	Considerations/ Comments
		H, M, or L		Acceptable or Not Acceptable	

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/s/

JONATHAN T DOW
03/15/2017

Recommendation:
NDA: Approval

NDA 208609

Drug Name/Dosage Form	**Ephedrine Sulfate USP**
Strength	**50 mg/mL**
Route of Administration	Injection
Rx/OTC Dispensed	Rx
Applicant	**Akorn Inc**
US agent, if applicable	

SUBMISSION(S) REVIEWED	DOCUMENT DATE	DISCIPLINE(S) AFFECTED

Quality Review Team

DISCIPLINE	REVIEWER	BRANCH/DIVISION
Drug Substance	**Jeffrey Medwid**	**OPQ/ONDP/DNDPAPI/BII**
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Regulatory Business Process Manager	Steve Kinsley	OPQ/OPRO/RBPMI/BI
Application Technical Lead	**Julia Pinto**	**OPQ/ONDP/DNDPII/BIV**
Laboratory (OTR)		
ORA Lead	**Paul Perdue**	ORA/OGROP/ORA/OO/OMPTO/ DMPTPO/M
Environmental Assessment (EA)		

Executive Summary

I. Recommendations

A. Recommendation and Conclusion on Approvability

Ephedrine Sulfate Injection, USP is a (b) (4) sterilized aqueous solution consisting of ephedrine sulfate as the drug substance. The drug substance is under DMF (b) (4) and supplied by (b) (4) The DMF is adequate to support its use in the drug product. A retest period of (b) (4) months is granted.

(b) (4)
(b) (4) Adequate microbiology data is provided to support the manufacturing process and storage of the product in glass ampules. Satisfactory stability data is provided to support an expiry of 36 months for the drug product, when stored at 25C.

In the first review cycle, the Office of Compliance had issued a 483 to the Akorn manufacturing site (FEI (b) (4)). All other facilities involved in the testing and release of the drug substance and drug product were recommended as adequate. In this resubmission all the deficienicies sited have been satisfactorily resolved. The office of compliance has therefore recommended approval for all sites related to the manufacture and testing ephedrine sulfate and ephedrine sulfate injection.

B. Recommendation on Phase 4 (Post-Marketing) Commitments, Agreements, and/or Risk Management Steps, if Approvable

II. Summary of Quality Assessments

A. Drug Substance [USAN Name] Quality Summary

Ephedrine Sulfate, USP drug substance is supplied by (b) (4). The manufacture and control of the drug substance is referenced to DMF (b) (4) and reviewed by Jeff Medwid, Ph.D. The drug substance is adequately supported for use in the preparation of the drug product and has a retest period of (b) (4) months.

B. Drug Product [Ephedrine Sulfate] Quality Summary

Ephedrine Sulfate Injection, USP drug product is a clear, colorless solution in water (b) (4)
(b) (4) and no other excipients. (b) (4)
(b) (4) The product is designed to meet Ephedrine Sulfate Injection USP monograph requirements. The drug product must be diluted with saline or 5% dextrose prior to administration. The product cannot be administered as a bolus injection. The granted expiry is 36 months when stored at 25C.

C. Summary of Drug Product Intended Use

Proprietary Name of the Drug Product	Ephedrine Sulfate Injection, USP
Non Proprietary Name of the Drug Product	Ephedrine Sulfate Injection, USP
Non Proprietary Name of the Drug Substance	Ephedrine Sulfate
Proposed Indication(s) including Intended Patient Population	(b) (4)
Duration of Treatment	
Maximum Daily Dose	
Alternative Methods of Administration	

This NDA is recommended for approval.

Application Technical Lead Signature:

Julia C. Pinto, Ph.D.
Branch Chief(Acting)
ONDP/Division II/Branch IV

Inspection View

Updated Inspection View for OPQ Layout Template

Task Information	Task Name	Com	Assignments	Pln Comp	Act Comp	Task	Actions	Additional
Parent: Manufacturing Facility Inspection (1)								
18	Overall Manufacturing Inspection Recommendation	IQA Second Cycle Review	Ruo (Rose) Xu	6/5/17	2/6/17	Complete	Go to Form	Recommendation: Approve

APPEARS THIS WAY ON ORIGINAL

Julia
Pinto

Digitally signed by Julia Pinto
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