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Oxymorphone Hydrochloride Tablets, 5 mg and 10 mg

ANDA 202321

## 3.2.P.4.4 Justification of Specifications

## 3.2.P.4.4 JUSTIFICATION OF SPECIFICATION(S)

The table below outlines the drug product manufacturer's release specifications for the FD&C Blue No. 2 Aluminum Lake used in the production of Oxymorphone Hydrochloride Tablets, 5 mg. A justification has been provided for each specification.

Provided in this section are Certificates of Analysis from the raw material manufacturer, Sensient, and the drug product manufacturer, DSM (CofA Initial Testing and CofA Repass Testing). In addition, an FDA Additive Certificate is included in this section.

Table 3.2.P.4.4-1 Specifications for FD&amp;C Blue No. 2 Aluminum Lake

Test	Specification	Justification
Physical Examination	A medium blue powder. When a portion of the powder is shaken in water, insoluble solids with a colorless or blue supernatant are observed.	Conforms to 21 CFR 70 through 82
Identification (IR)	The infrared absorption spectrum of a 1 percent dispersion of the sample in potassium bromide exhibits maxima at the same wavelength as, and with similar relative intensity to, that of a previously passed lot, similarly obtained.	

Oxymorphone Hydrochloride Tablets, 5 mg and 10 mg

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## 3.2.P.4.4 Justification of Specifications

06/06/2007

BIN A 29806  
MAT 022040  
TW 6-8-07SENSIENT™QA Lab Supervisor  
DSM Pharmaceuticals  
Intersections US13/NC 11 and  
HWY US 264  
Greenville NC 27835-1887Sensient Colors Inc.  
Sensient Pharmaceutical Technologies  
107 Wade Avenue  
South Plainfield, New Jersey 07080 U.S.A  
800-853-7804COLOR ADDITIVE CERTIFICATE  
FD&C BLUE NO. 2 ALUM LAKE 12-14%

MANUFACTURED BY ST. LOUIS MO

CUSTOMER P.O. 4500049018  
CUSTOMER CODE 022040  
FDA LOT NO. AN9181  
PACK WEIGHT 20.000000 KG  
QUANTITY 40.00 KGORDER NUMBER 0779872  
RESOURCE NUMBER 099021020  
MANUFACTURE DATE 01/29/2007  
FDA PURE DYE % 13%

We hereby guarantee that the batch of color listed above is a FDA certified colorant. The use of this color is subject to the terms, conditions, and restrictions set forth in the Federal, Food, Drug, and Cosmetic Act and the regulations listed within.  
The following page is a copy of FDA'S analytical report.

Mark Goldschmidt  
Quality Manager

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Oxymorphone Hydrochloride Tablets, 5 mg and 10 mg

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## 3.2.P.4.4 Justification of Specifications

LOT NO: AN9181 FD&amp;C BLUE No. 2 ALUMINUM LAKE

Sensient Colors Inc.

Batch No.: 769CI

Weight: 4,629.66 LBS

FEB-07-2007

DETERMINATION	METHOD	FOUND	UNIT	DATE
TARTRATE BUFFER TITRATION	1	13	%	FEB-07-2007
SPECTROPHOTOMETRIC	25	12.7	%	JAN-31-2007
WATER INSOLUBLE MATTER-HCL	27	0.02	%	FEB-01-2007
MERCURY	7	PT	ppm	FEB-01-2007
LEAD	8	PT	ppm	FEB-01-2007
ARSENIC	9	PT	ppm	FEB-01-2007

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CALLUP DUPLICATE - NOT OFFICIAL COPY  
Food and Drug Administration Analytical Results

74 20071916 FORM FDA 3000 OMB NO. 0910-0216 (10/31/2001) 8720

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Oxymorphone Hydrochloride Tablets, 5 mg and 10 mg  
3.2.P.4.4 Justification of Specifications

ANDA 202321

DSM

Certificate of  
Analysis

## FD&amp;C Blue No. 2 Lake

Batch Number:	A29806	Item Number:	022040
Job Name:	A29806-PA-07-100924	Expiration Date:	1/28/2010
Job Type:	PA		
Job Status:	Authorized		
Date Dispositioned:	7/9/2007	Vendor Lot Number:	AN9181
Date of Manufacture:	1/29/2007		
Nbr of Containers:	2	PO Number:	4500049018

QA Signature: \_\_\_\_\_

Date: \_\_\_\_\_

2-18-2010

Test	Results	Specifications	Comments
Physical Examination	Conforms	A medium blue powder with a mild odor. When a portion of the powder is shaken in water, insoluble solids with a colorless or blue supernatant are observed.	No Comments
Identification (IR)	Conforms	The infrared absorption spectrum of a 1 percent dispersion of the sample in potassium bromide exhibits maxima at the same wavelength as, and with similar relative intensity to, that of a previously passed lot, similarly obtained.	No Comments

\* = Result Entered from non-DSM COA

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Oxymorphone Hydrochloride Tablets, 5 mg and 10 mg  
3.2.P.4.4 Justification of Specifications

ANDA 202321

DSM

Certificate of  
Analysis

## FD&amp;C Blue No. 2 Lake

Batch Number:	A29806	Item Number:	022040
Job Name:	A29806-RP-09-115139	Expiration Date:	1/28/2010
Job Type:	RP		
Job Status:	Authorized		
Date Dispositioned:	6/17/2009	Vendor Lot Number:	AN9181
Date of Manufacture:	1/29/2007		
		PO Number:	4500049018
Receipt Date:	6/8/2007		

QA Signature:

Date:

2-18-2010

Test	Results	Specifications	Comments
Physical Examination	Conforms	A medium blue powder. When a portion of the powder is shaken in water, insoluble solids with a colorless or blue supernatant are observed.	No Comments

## Specification



Sensient Colors Inc.  
2526 Baldwin Street  
St. Louis, MO 63106-1903  
Tel 314 658-7443 Fax 314 658-7314  
www.sensient-tech.com

NO. 09902 FD&C BLUE #2 ALUM LAKE 12-14% FDA/EC

<u>DESCRIPTION:</u>	A bright blue, water insoluble pigment made by absorbing FD&C Blue #2 dye on a substrate of Alumina.
<u>CAS NO:</u>	16521-38-3
<u>EC NUMBER:</u>	E132 Indigotine, Indigo Carmine
<u>PURE DYE:</u>	12 - 14%
<u>IDENTIFICATION:</u>	Compares favorably to accepted standard.
<u>PACKAGING:</u>	<p>Standard packaging for this product is one, five and twenty kilogram units packaged in corrugated cartons with plastic liners. A 200-pound minimum order is required for all custom products. Custom packaging is available upon request.</p> <p>The four additional trailing digits to our current five digit product numbers are used primarily to identify package size and type.</p>
<u>STORAGE:</u>	Product should be stored in a closed container at 50°F to 120°F. Product may pick up moisture from humid storage conditions if the container is not tightly sealed, which could cause agglomerations to form.
<u>SHELF LIFE:</u>	Product is best used within six years from date of manufacture when stored under recommended storage conditions.
<u>KOSHER STATUS:</u>	This product is Kosher certified.
<u>STATUS:</u>	<p>This product is approved by the FDA and meets the specifications outlined in the Code of Federal Regulations, Title 21, Parts 70 to 82.</p> <p>This product is manufactured to comply with the EC Directive 95/45/EC and 94/36/EC. This product complies with FAO/WHO specifications 52/1 and 52/2.</p>

CSL/SABM/DP  
R 03/08