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CIRON DRUGS & PHARMACEUTICALS PVT. LTD.
C -1101/1102, Lotus Corporate Park, Graham Firth
Steel Compound, Jay Coach Junction, Western
Express Highway, Goregaon (East),
Mumbai – 400063.

STP No.:
C1/FP/QA/STP/E/SA/0183/047/H/O
O/01/06

Reference Specification No.:
C1/FP/QA/SPEC/E/SA/0183/047/H/
OO/01/06

FINISHED PRODUCT STANDARD TESTING PROCEDURE

Pharmacopoeia Reference: In-house

Finished Product Name: Haloperidol Decanoate Injection 50 mg
per ml

Effective Date: 19/09/2024

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SR. NO.	ANALYTICAL TEST PROCEDURES	METHOD NO
1.	Description: Take 5ml of sample in test tube and observe its colour on white background.	C1/FP/QA/STP/E/SA/018 3/047/H/OO/01/06-01
2.	Identification:	C1/FP/QA/STP/E/SA/018 3/047/H/OO/01/06-02
2A.	Chemical test: Reagents and Chemicals: 1. Sucrose 2. Hydrochloric acid conc. Procedure: Shake a volume containing 5 mg of Haloperidol Decanoate (0.1 ml of injection) with 1 ml of a 1% w/v solution of sucrose in hydrochloric acid and allow to stand for 5 minutes.	C1/FP/QA/STP/E/SA/018 3/047/H/OO/01/06-02A
2B.	Thin Layer Chromatography: Reagents and Chemicals: 1. Chloroform 2. Ethanol (96%): Dilute 96 ml of absolute ethanol to 100 ml with distilled water. Procedure: Carry out in subdued light the method for thin-layer chromatography, using a plate 200 mm × 200 mm in size and silica gel GF254 as the coating substance. For the development use chloroform as the mobile phase. Apply to the bottom of the plate 10 µl volume of the injection containing 25 µg of Haloperidol Decanoate. Apply to the	C1/FP/QA/STP/D/SA/018 3/047/H/OO/01/04-02B

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bottom of the plate, 10 µl of a 2.0% w/v solution of Haloperidol
decanoate EPCRS/WS in ethanol (96%). Develop over a path of 12
cm.

Visualization:

After removal of the plate, allow it to dry in air and examine under
ultraviolet light (254 nm).

3.

Extractable volume:

Single-Dose Containers:

Select 1 container if the volume of the container is 10 mL or more, 3
containers if the nominal volume is more than 3 mL and less than 10
mL, or 5 containers if the nominal volume is 3 mL or less. Take up
individually the total contents of each container selected into a dry
syringe of a capacity not exceeding three times the volume to be
measured and fitted with a 21-gauge needle not less than 2.5 cm (1
inch) in length.

Expel any air bubbles from the syringe and needle, and then
discharge the contents of the syringe, without emptying the needle,
into a standardized, dry cylinder (graduated to contain rather than to
deliver the designated volumes) of such size that the volume to be
measured occupies at least 40% of its graduated volume.

Alternatively, the volume of the contents in mL may be calculated as
the mass, in g, divided by the density. The volume is not less than
the nominal volume in the case of containers examined individually.

Multi-Dose Containers:

For Injections in multiple-dose containers labeled to yield a specific
number of doses of a stated volume, select 1 container, and proceed
as directed for single-dose containers, using the same number of

C1/FP/QA/STP/E/SA/018
3/047/H/OO/01/06-03

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	separate syringe assemblies as the number of doses specified. The volume is such that each syringe delivers not less than the stated dose.	
4.	Leakage Test: Collect approximately 10 ampoules and shake. In a desiccator add 100 ml of 1% methylene blue solution & put ampoules in it & close the desiccator. Connect the vacuum pipe line to the desiccator and maintain vacuum for 10 minutes. After completion of vacuum, open the desiccator and wipe the outer surface of ampoules. Check the colour of the solution of the ampoules, whether it contains blue colour. If the solution contains blue colour it confirms leakage of ampoules.	C1/FP/QA/STP/E/SA/0183/047/H/OO/01/06-04
5.	Particulate Matter: 1) Start the instrument (LAF) 15 minutes before the activity. 2) Filter the water for injection through 0.2 µm membrane filter. Collect the filtered WFI water in a vacuum flask previously cleaned with Nitric acid. Rinse the vacuum flask with filtered WFI water and drain. After that collect the filtered water in it. 3) All glassware to be used for particulate contamination test shall be rinsed with Filtered WFI water. 4) Switch on the instrument. 5) Set the upper and lower position of sensor probe using SET buttons. Set the position depending upon the type of container used for sampling. 6) Use LOAD button to lift the sensor arm or to send it to the bottom level. 7) Rinse the syringe with Filtered WFI water using syringe CLEAN button before starting the particle counting.	C1/FP/QA/STP/E/SA/0183/047/H/OO/01/06-05

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8) To test the sample as per USP, EP or JP, click on the name of required Pharmacopoeia.
9) Rinse the beaker with sample to be tested and fill the required volume of sample in beaker. Put the beaker under sensor probe, move the sensor arm up to the bottom level.
10) Select the Pharmacopoeia menu as mention above and select the test for Small volume injectables and large volume injectables. Enter the details like number of containers, Container volume and Dilution factor and click on Start. Instrument will automatically count the particles and display the result.
11) Wash the syringe with particle free water after completion of use. Keep the sensor arm dipped in Filtered WFI water and switch off the instrument.

6.	Bacterial Endotoxins Test: Procedure as per the current SOP (C1QC/077) for bacterial endotoxins.	C1/FP/QA/STP/E/SA/018 3/047/H/OO/01/06-06						
7.	Sterility: Procedure as per the current SOP (C1QC/135) for Sterility test.	C1/FP/QA/STP/E/SA/018 3/047/H/OO/01/06-07						
8.	Related substances (By HPLC): Reagents & Chemicals: 1. Tetra Butyl Ammonium Hydrogen Sulphate 2. Water 3. Acetonitrile Chromatographic parameters: <table border="1"> <tr> <td>Instrument used</td><td>:</td><td>HPLC</td></tr> <tr> <td>Method</td><td>:</td><td>Isocratic</td></tr> </table>	Instrument used	:	HPLC	Method	:	Isocratic	C1/FP/QA/STP/E/SA/018 3/047/H/OO/01/06-08
Instrument used	:	HPLC						
Method	:	Isocratic						

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Column	:	C18, 250mm x 4.6mm, 5um, Inertsil
Column Temperature	:	Ambient
Detector	:	UV Detector
Detector wavelength	:	230nm
Injection volume	:	10µl
Flow rate	:	1.0ml/min
Diluent	:	Acetonitrile : water (930:70 v/v)

Solution Preparation:

Buffer preparation:

27gm Tetra butyl ammonium hydrogen sulphate in 1000ml of water.
Mix well.

Mobile Phase:

Mix the volume of 420ml of Buffer solution and 580ml of Acetonitrile.
Filter & degas.

Blank Solution: Diluent

Placebo Solution:

Pipette out 1.0ml of placebo injection eq.to 50.0 mg of Haloperidol Decanoate in 50ml volumetric flask, add 35ml of diluent & sonicate for 5min with intermittent shaking and dilute up to the mark with diluent. Filter the solution with GFC filter & inject clear solution. (1.0 mg/ml Haloperidol Decanoate).

Test Solution:

Pipette out 1.0ml of Test injection eq.to 50.0 mg of Haloperidol

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Decanoate in 50ml volumetric flask, add 35ml of diluent & sonicate for 5min with intermittent shaking and dilute up to the mark with diluent. Filter the solution with GFC filter & inject clear solution. (1.0 mg/ml Haloperidol Decanoate).

Standard Solution:

Weigh accurately about 20.0mg of Haloperidol Decanoate WS in 20ml volumetric flask, add 10 ml of diluent to dissolve and dilute up to the mark with diluent. Transfer 5.0ml of above solution into a 50ml of volumetric flask and dilute up to the mark with diluent. Further Dilute 1.0ml to 20 ml with diluent. (0.005mg/ml).

Procedure:

Inject the blank solution one time, placebo solution one time, standard solution six times and test solution one times into the chromatograph. Record the peak responses and evaluate statistically.

Calculation:

Calculate Individual maximum impurity and Total impurities by following formula.

1.% Individual Impurity:

Area of individual impurity

Obtained from Test solution Conc. of reference solution

=----- x ----- x 100

Area of reference solution Conc. of Test solution

2. % Total Impurities:

Area of total impurities

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	obtained from Test solution Conc. of reference solution =----- x ----- x 100 Area of reference solution Conc. of Test solution	
9.	Assay:	C1/FP/QA/STP/E/SA/018 3/047/H/OO/01/06-09
9A.	Haloperidol Decanoate eq. to Haloperidol : (By Titrimetric) Reagents and Chemicals: 1) Anhydrous Acetic Acid (AR Grade) 2) Methyl ethyl ketone (AR Grade) 3) 0.1M Perchloric Acid 4) Naphtholbenzein Solution Method: Solution Preparation: Mixture: Anhydrous Acetic Acid: Methyl Ethyl Ketone (1:7) Naphtholbenzein Solution: 0.2% w/v solution of 1-naphtholbenzein in anhydrous acetic acid 0.1M Perchloric Acid: To 900ml of glacial acetic acid add 8.5ml of perchloric acid, mix, add 30 ml of acetic anhydride, dilute to 1000 ml with glacial acetic acid, mix and allow to stand for 24 Hrs. Standardization of 0.1 M Perchloric Acid: Weigh accurately about 0.35 gm potassium Hydrogen phthalate , previously dried powdered lightly and dried at 120° C for 2 Hrs. &	C1/FP/QA/STP/E/SA/018 3/047/H/OO/01/06-09A

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dissolve it in 50 ml anhydrous glacial acetic acid add 0.1 ml of crystal violet solution and titrate with perchloric acid solution until the violet color changes to emerald green color. Perform the blank determination.

Procedure:

Take 10 ml of injection equivalent to 500 mg of Haloperidol in 50 ml of a mixture of 1 volume of anhydrous acetic acid & 7 volumes of methyl ethyl ketone. Titrate with 0.1M perchloric acid using 0.2 ml of naphtholbenzein solution as indicator. End point is light yellow to green 1 ml of perchloric acid is equivalent to 37.59 mg of Haloperidol.

Calculation:

Corrected Burette Reading in ml = Burette Reading - Blank Reading
% Assay of Haloperidol Decanoate BP eq. to Haloperidol =
Corrected B.R. x Actual Molarity of 0.1M Perchloric Acid x 37.59
x100

Theoretical Molarity of 0.1M Perchloric Acid x eq.mg of Haloperidol
in Vol. taken for Assay

$\text{mg/ml} = \frac{\% \text{ Assay} \times 50\text{mg}}{100}$

9B. Benzyl Alcohol: (By HPLC)

Chemicals & Reagents:

- 1) Orthophosphoric acid (AR Grade)
- 2) Sodium Hydroxide (AR Grade)
- 3) Acetonitrile (Qualigens grade)

C1/FP/QA/STP/E/SA/018
3/047/H/OO/01/06-09B

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4) HPLC water (Purified)

Chromatographic parameters:

Instrument used	:	HPLC
Method	:	Gradient
Column	:	C18, 250mm x 4.6mm, 5µm, Inertsil ODS 3V
Oven Temp.	:	30°C
Detector	:	UV
Detector wavelength	:	254nm
Injection volume	:	50µl
Flow rate	:	1.0ml/min
Diluent.	:	Acetonitrile: Water (90:10 v/v)

**Note: For the standard solution, the run time is only 20 mins.
For the Blank solution and Test solution, the run time is 120
mins.**

Solution Preparation:

Mobile Phase (A):

Buffer preparation pH 2.5:

Pipette out 1ml of orthophosphoric acid solution in 1000ml water, mix
well & adjust pH 2.5 with sodium hydroxide & orthophosphoric acid
solution. Filter & degas.

Mobile Phase (B):

Acetonitrile (100%).

Gradient program is describe below:

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Time	Mobile Phase A	Mobile Phase B
0.01	60	40
10.0	60	40
15.0	60	40
20.0	60	40
30.0	10	90
50.0	10	90
70.0	10	90
80.0	10	90
90.0	60	40
100.0	60	40
110.0	60	40
120.0	60	40

Diluent:

Acetonitrile: Water (90:10 v/v)

Blank solution: Diluent

Standard Solution:

Standard Solution for Benzyl alcohol:

Weigh accurately 30 mg of Benzyl alcohol in 200 ml of volumetric flask, add 150ml of diluent, sonicate to dissolve & dilute up to the mark with diluent. (0.15 mg/ml benzyl alcohol).

Test Solution:

Pipette out 1.0ml of sample eq.to 15mg of Benzyl alcohol in 100ml

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volumetric flask, add 70ml of diluent & sonicate for 5min with
intermittent shaking and dilute up to the mark with diluent. Filter the
solution with 0.45µm syringe filter & inject clear solution. (0.15 mg/ml
benzyl alcohol).

Procedure:

Inject the blank solution one time, standard solution six times & test
solution one time into the chromatograph. Record the peak
responses & evaluate statistically.

System suitability:

RSD of six Assay standard solution NMT-2.0%

Calculation:

Content for Benzyl alcohol in mg/ml =

			Label claim
Test solution area	Final standard conc.	Std Potency	(mg/ml)
----- x -----	x as is basis	x -----	=
mg/ml			
Mean standard	Final test conc.		100
area			

mg/ml
% of Benzyl alcohol = ----- x 100
Label claim in mg/ml

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REVISION HISTORY

Sr. No.	Revision No.	Effective date	Change control no.	Review details
1.	04	10/09/2019	C1QA/DC/15/003 C1QA/DC/16/125	Change in numbering system & Specification format as per new GMP pro software & Revised SOP no: CQA/028-02
2.	05	28/11/2022	C/X/CCF/CQA/22/14 4	Related substances and Assay method updated as per the AMV.
3.	05	11/10/2023	-----	Specification revised as there are no changes.
4.	06	19/09/2024	C/X/CCF/CQA/24/06 4	Sterility added in the place of Leakage Test in the shelf life specification.

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