Status: Currently Official on 13-Feb-2025
Official Date: Official as of 01-Dec-2024
Document Type: USP Monographs
DocId: GUID-A55A9E11-616C-4151-A0BA-F6A1E55CA4A7_3_en-US
DOI: https://doi.org/10.31003/USPNF_M3470_03_01
DOI Ref: 39k96

Delete the following:

▲Amitraz Concentrate for Dip

DEFINITION

Amitraz Concentrate for Dip contains amitraz in a suitable vehicle. It may contain a suitable stabilizing agent. It contains NLT 90.0% and NMT 120.0% of the labeled amount of amitraz ($C_{19}H_{23}N_3$).

IDENTIFICATION

• **A. Thin-Layer Chromatography**

Standard solution: 5 mg/mL of USP Amitraz RS in toluene

Sample solution: Nominally 5 mg/mL of amitraz from Concentrate for Dip diluted with toluene

Chromatographic system

(See *Chromatography ⟨621⟩, Thin-Layer Chromatography*.)

Mode: TLC

Adsorbent: 0.25-mm layer of chromatographic silica gel mixture

Application volume: 2 µL

Developing solvent system: Cyclohexane, ethyl acetate, and triethylamine (5:3:2)

Spray reagent: 0.5% solution of *N*-(1-naphthyl)ethylenediamine dihydrochloride in methanol

Analysis

Samples: *Standard solution* and *Sample solution*

Stand the plate to a depth of 3.5 cm in a solution prepared by dissolving 35 g of acetamide in 100 mL of methanol, adding 100 mL of triethylamine, and diluting to 250 mL with methanol. Allow the wet plate to stand in a current of cold air for 30 s. Immediately apply the *Samples* separately to the plate, at a level about 1 cm below the top of the impregnated zone. Promptly develop the plate until the solvent front has moved three-fourths of the length of the plate. Remove the plate from the developing chamber and allow to air-dry. Examine the plate under short-wavelength UV light.

Acceptance criteria: The R_F value of the principal spot of the *Sample solution* corresponds to that of the *Standard solution*.

• **B.** The retention time of the amitraz peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY

• **Procedure**

Internal standard solution: 0.7% v/v solution of squalane in methyl acetate

Standard solution: 5.0 mg/mL of USP Amitraz RS in *Internal standard solution*

Sample solution: Nominally equivalent to 5.0 mg/mL of amitraz from Concentrate for Dip in *Internal standard solution*

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: GC

Detector: Flame ionization

Column: 0.53-mm × 15-m fused silica; coated with a 1.5-µm layer of liquid phase G9

Temperatures

Column: 220°

Inlet: 230°

Detector: 300°

Carrier gas: Helium

Flow rate: 12 mL/min

Injection volume: 1 µL

System suitability

Sample: *Standard solution*

[Note—The elution order is amitraz, followed by squalane.]

Suitability requirements

Resolution: NLT 3.0 between amitraz and squalane

Relative standard deviation: NMT 2.0% from the peak area ratio of amitraz to squalane

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of amitraz ($C_{19}H_{23}N_3$) in the portion of Concentrate for Dip taken:

$$\text{Result} = (R_U/R_S) \times (C_S/C_U) \times 100$$

R_U = peak response ratio of amitraz and squalane from the *Sample solution*

R_S = peak response ratio of amitraz and squalane from the *Standard solution*

C_S = concentration of USP Amitraz RS in the *Standard solution* (mg/mL)

C_U = nominal concentration of amitraz in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–120.0%

SPECIFIC TESTS

• **Water Determination, *Method I*⟨921⟩:** NMT 0.15%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed containers.

• **Labeling:** Label it to indicate that it is for veterinary use only and that it is to be diluted before use. The label also states the name and quantity of diluent to be used, the directions for dilution, and the conditions for storage of the constituted Concentrate for Dip.

• **USP Reference Standards ⟨11⟩**

USP Amitraz RS▲ (USP 1-Dec-2024)

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
AMITRAZ CONCENTRATE FOR DIP	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. 49(3)

Current DocID: GUID-A55A9E11-616C-4151-A0BA-F6A1E55CA4A7_3_en-US

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