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Cat's Claw Tablets

DEFINITION

Cat's Claw Tablets contain Powdered Cat's Claw Extract. Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of Powdered Extract, calculated as pentacyclic oxindole alkaloids.

IDENTIFICATION

The *Sample solution* chromatogram exhibits peaks for speciophylline, uncarine F, mitraphylline, isomitraphylline, pteropodine, and isopteropodine at retention times that correspond to those in *Standard solution A*, as obtained in the test for *Content of Pentacyclic Oxindole Alkaloids and Limit of Tetracyclic Oxindole Alkaloids*. The content of tetracyclic oxindole alkaloids, calculated as the sum of rhynchophylline and isorhynchophylline, is NMT 25% of the labeled amount of pentacyclic oxindole alkaloids.

STRENGTH

• **CONTENT OF PENTACYCLIC OXINDOLE ALKALOIDS AND LIMIT OF TETRACYCLIC OXINDOLE ALKALOIDS**

- Solution A:** Prepare a 10 mM pH 7.0 phosphate buffer by mixing 1 N sodium hydroxide, 1 M monobasic potassium phosphate, and water (3:5:492), and adjust to a pH of 7.0 ± 0.1 by adding more of either solution.
- Solution B:** Acetonitrile
- Solution C:** Methanol and glacial acetic acid (99:1)
- Mobile phase:** See the gradient table below.

Time (min)	Solution A (%)	Solution B (%)	Solution C (%)
0	65	35	0
17	65	35	0
25	50	50	0
30	50	50	0
31	0	0	100
36	0	0	100
39	65	35	0
49	65	35	0

- Standard solution A:** Dissolve an accurately weighed quantity of USP Powdered Cat's Claw Extract RS in methanol, shake for 1 min, and dilute with methanol to obtain a solution having a known concentration of about 0.5 mg/mL of the labeled amount of total oxindole alkaloids. Pass through a filter of 0.45-µm or finer pore size.
- Standard solution B:** 0.1 mg/mL of [USP Isopteropodine RS](#) in methanol. Pass through a nylon filter of 0.45-µm or finer pore size.
- Sample solution:** Accurately weigh not fewer than 20 Tablets and pulverize. Transfer an accurately weighed quantity of the powder, equivalent to 20 mg of the labeled amount of pentacyclic oxindole alkaloids, to a 50-mL centrifuge tube. Sonicate with 10 mL of methanol for 10 min. Centrifuge and transfer this solution to a 50-mL volumetric flask. Repeat the above extraction three more times, combining the extracts in the 50-mL volumetric flask, and dilute with methanol to volume. Transfer 3 mL of the solution to a test tube containing 300 mg of polyamide powder, and shake for 1 min. Pass through a nylon filter of 0.45-µm or finer pore size, and discard the first part of the filtrate.

- Chromatographic system**
(See [Chromatography \(621\), System Suitability.](#))
- Mode:** LC
- Detector:** UV 245 nm
- Column:** 4.6-mm × 10-cm; endcapped 3-µm packing L1
- Flow rate:** 0.75 mL/min
- Injection size:** 10 µL

System suitability**Samples:** *Standard solution A* and *Standard solution B***Suitability requirements****Chromatogram similarity:** The chromatogram obtained using *Standard solution A* is similar to the Reference Chromatogram provided with the USP Powdered Cat's Claw Extract RS being used.**Tailing factor:** NMT 2.0 for the isopteropodine peak, *Standard solution B***Relative standard deviation:** NMT 2.0% from the isopteropodine peak in repeated injections, *Standard solution B***Analysis****Samples:** *Standard solution A*, *Standard solution B*, and *Sample solution*

Measure the areas of the analyte peaks. Identify the retention times of the peaks corresponding to speciophylline, uncarine F, mitraphylline, isomitraphylline, pteropodine, isopteropodine, rhynchophylline, and isorhynchophylline by comparison of the chromatogram of *Standard solution A* with the Reference Chromatogram provided with the lot of the USP Powdered Cat's Claw Extract RS being used.

Calculate the content, in mg, of speciophylline, uncarine F, mitraphylline, isomitraphylline, pteropodine, and isopteropodine, as isopteropodine, in the portion of Tablets taken:

$$\text{Result} = (r_U/r_S) \times C_S \times V$$

r_U = peak response for each relevant alkaloid from the *Sample solution*

r_S = peak response for isopteropodine from *Standard solution B*

C_S = concentration of [USP Isopteropodine RS](#) in *Standard solution B* (mg/mL)

V = final dilution volume of the *Sample solution* (mL)

Calculate the content, in mg, of total pentacyclic oxindole alkaloids (C_T) in the portion of Tablets taken by adding the individual contents of speciophylline, uncarine F, mitraphylline, isomitraphylline, pteropodine, and isopteropodine.

Calculate the percentage of Powdered Cat's Claw Extract with respect to the label claim:

$$\text{Result} = C_T \times (A_{WT}/W) \times (100/L_E) \times (100/L)$$

C_T = content of total pentacyclic oxindole alkaloids in the portion of Tablets taken (mg)

A_{WT} = average weight of Tablets (mg/Tablet)

W = weight of the portion of Tablets taken (mg)

L_E = content of total pentacyclic oxindole alkaloids, mg, in 100 mg of the Extract used to prepare the Tablets

L = amount of Extract per Tablet according to label claim (mg/Tablet)

Calculate the percentage of tetracyclic oxindole alkaloids with respect to the content of pentacyclic oxindole alkaloids in the portion of Tablets taken:

$$\text{Result} = (r_T/r_P) \times 100$$

r_T = sum of peak responses for rhynchophylline and isorhynchophylline in the chromatogram of the *Sample solution*

r_P = sum of peak responses for speciophylline, uncarine F, mitraphylline, isomitraphylline, pteropodine and isopteropodine in the chromatogram of the *Sample solution*

Acceptance criteria: 90.0%–110.0% of the labeled amount of Powdered Extract calculated as pentacyclic oxindole alkaloids; and NMT 25% of tetracyclic oxindole alkaloids with respect to the labeled amount of pentacyclic oxindole alkaloids is found.

PERFORMANCE TESTS

- [DISINTEGRATION AND DISSOLUTION OF DIETARY SUPPLEMENTS \(2040\)](#): Meets the requirements for *Disintegration*
- [WEIGHT VARIATION OF DIETARY SUPPLEMENTS \(2091\)](#): Meets the requirements

CONTAMINANTS

- [MICROBIAL ENUMERATION TESTS \(2021\)](#): The total aerobic microbial count does not exceed 10^4 cfu/g. The total combined molds and yeasts count does not exceed 10^3 cfu/g.
- [ABSENCE OF SPECIFIED MICROORGANISMS \(2022\)](#): Meets the requirements of the tests for absence of *Salmonella* species and *Escherichia coli*.

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight, light-resistant containers, and store at room temperature.
- **LABELING:** The label states the Latin binomial and, following the official name, the article from which Tablets were prepared. The label also indicates the quantity of Powdered Extract per Tablet, in mg. Label Tablets to indicate the content, in mg, of pentacyclic oxindole alkaloids per Tablet.