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The study of the identification of Astragalus extract

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Plant extract is a kind of product that takes plants as raw materials, according to the needs of the final product, through the physical and chemical extraction and separation process, directional acquisition and concentration one or more active ingredients in plants, without changing the structure of the active ingredients. Therefore, in terms of its material composition basis, in addition to whether the content of the index components reaches the standard, we should also pay attention to whether other active ingredients in the original plants are retained, this is an important aspect to judge the quality of a plant extract product, even the authenticity.

Taking "astragalus extract" as an example, the indicator component concerned by customers are often Astragaloside IV or Cycloastragenol, which leads to the manufacturers only concerned about the content enrichment of the indicator component, while ignoring the retention of other components in the products. In fact, other saponins (Astragaloside I, II, III,

etc.), polysaccharides and flavonoids (Calycosin, Calycosin 7-*O*-b-D-Glucopyranoside, Formononetin, Ononin etc.) are still the active ingredients closely related to the end use of the product.

How to judge the quality and authenticity of astragalus extract? "Astragalus extract" (USP43-NF38 published in 2020) in the United States Pharmacopoeia provides us with a simple and effective method. High performance thin layer chromatography (HPTLC) was used to describe the chromatographic behavior of the components in Astragalus membranaceus extract with Astragaloside IV(A), Daidzin and Daidzein(B), Astragalus Root Dry Extract(C) RS. The description is as follows:

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Suitability requirements

Chromatographic pattern: Under long-wave UV light (365 nm), following derivatization, *Standard solution A* exhibits an orange band in the middle of the lower third of the plate due to astragaloside IV, with a retardation factor (R_F) of approximately 0.15. In *Standard solution B*, daidzin and daidzein form bluish-grey bands with R_F of approximately 0.34 and 0.76, respectively; the proximal band is sharper, while the distal is somewhat diffuse. In *Standard solution C*, four orange bands are seen in the lower third of the plate, corresponding to astragalosides IV, III, II, and I with R_F of approximately 0.15, 0.18, 0.24, and 0.34, respectively. The R_F of the astragaloside I band approximates that of daidzin in *Standard solution B*. The upper two-thirds of the plate typically display a number of bluish, greenish, and pinkish bands, one of which corresponds to that of daidzein in *Standard solution B*.

Analysis

Samples: *Standard solution A*, *Standard solution B*, *Standard solution C*, and *Sample solution*

Apply the *Samples* as bands and dry in air. Develop in a saturated chamber. Air-dry, treat with *Derivatization reagent*, heat for 5 min at 105°, and examine under long-wave UV light (365 nm).

Acceptance criteria

Acceptance criteria: Under long-wave UV light (365 nm), the *Sample solution* exhibits bands corresponding in color and R_F to similar bands from *Standard solution C*, at the R_F values listed in *Chromatographic pattern*. [NOTE—The extract of *Hedysarum polybotros*, a common adulterant, does not show orange bands corresponding to astragalosides I and II.]

According to this method, we studied the extract of Astragalus membranaceus of our company.

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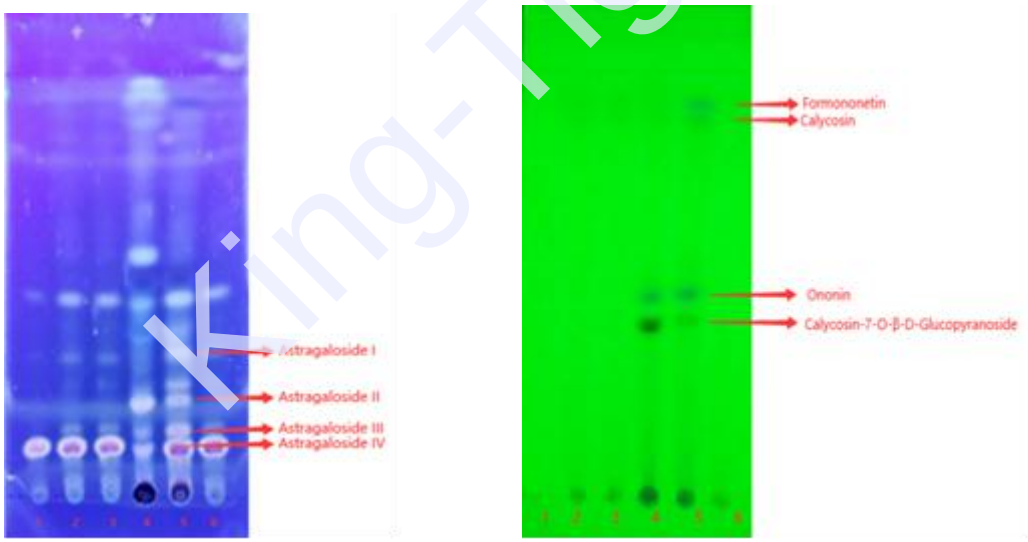
Figure 1: Astragalus standard extract (USP)



1: Astragaloside IV RS
2,3,6: Common Astragalus Extract
4: USP Astragalus Root Dry Extract RS
5: King-tiger Astragalus Extract

1: Astragaloside IV RS
2,3,6: Common Astragalus Extract
4: USP Astragalus Root Dry Extract RS
5: King-tiger Astragalus Extract

Figure 2: HPTLC Picture

According to this method, our products have passed the identification of the third-party international laboratory.

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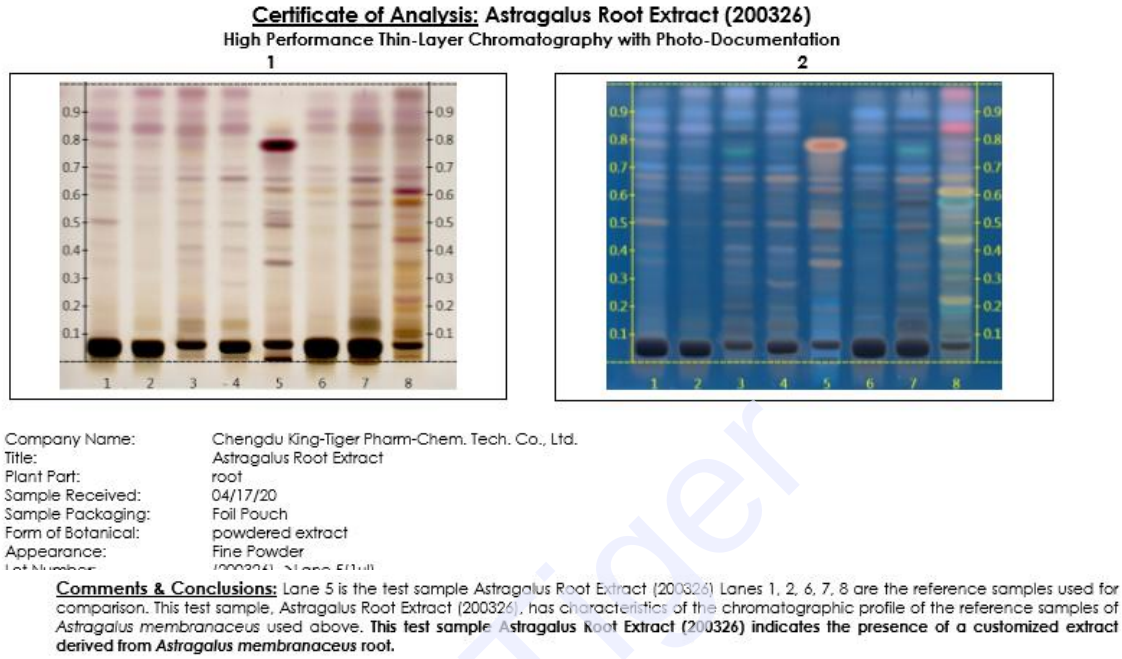

Certificate of Analysis: Astragalus Root Extract (200326)
High Performance Thin-Layer Chromatography with Photo-Documentation

Company Name:	Chengdu King-Tiger Pharm-Chem. Tech. Co., Ltd.
Title:	Astragalus Root Extract
Plant Part:	root
Sample Received:	04/17/20
Sample Packaging:	Foil Pouch
Form of Botanical:	powdered extract
Appearance:	Fine Powder

Comments & Conclusions: Lane 5 is the test sample Astragalus Root Extract (200326) Lanes 1, 2, 6, 7, 8 are the reference samples used for comparison. This test sample, Astragalus Root Extract (200326), has characteristics of the chromatographic profile of the reference samples of *Astragalus membranaceus* used above. **This test sample Astragalus Root Extract (200326) indicates the presence of a customized extract derived from *Astragalus membranaceus* root.**

Figure 3: Third party identification **report**

To sum up, the self-study results and third-party reports show that our company Astragalus extract products fully meet the requirements of USP, and are consistent with USP standard extract of Astragalus membranaceus. In addition to the Astragaloside IV or Cycloastragenol, the active ingredients of Astragalus membranaceus are retained to the maximum extent.

Chengdu King-tiger® Astragalus membranaceus extract, no excipients added, promise the whole Astragalus components, safer and more effective.

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Source

1. ASTRAGALUS ROOT DRY EXTRACT. USP43-NF38.