

01.11.2017

Certificate of analysis
BELLADONNA LEAF
 Belladonnae folium (Atropa belladonna L.)

Batch number: UHA - 01/0907
 Batch size: 2 440 kg
 Expiry date: 07.09.2019
 According to: 04/2010:0221 EP

No	Qualify parameter	Acceptance criteria	Result
1.	Appearance	The leaves are green or brownish-green, slightly darker on the upper surface, often crumpled and rolled and partly matted together in the drug. The leaf is petiolate and the lamina is acute and decurrent. The margin is entire. The flowering stems are flattened and bear at each node a pair of leaves unequal in size, in the axils of which occur singly the flowers or occasionally fruits. The flowers have a gamosepalous calyx and campanulate corolla. The drug may contain fruits, as globular berries, green or brownishblack and surrounded by the persistent calyx with widely spread lobes. Slightly nauseous odour	Passed
2.	Identification:	A. Macroscopic description B. TLC C. A deep violet colour develops D. TLC	Passed
3.	Foreign matter (2.8.2)	maximum 3 per cent of stems with a diameter greater than 5 mm.	2.0 per cent, Passed
4.	Total ash (2.4.16)	maximum 16.0 per cent.	14.2 per cent, Passed
5.	Ash insoluble in hydrochloric acid (2.8.1)	maximum 4.0 per cent.	3.5 per cent, Passed
6.	Loss on dryins (2.2.32.)	maximum 7.0 per cent.	6.8 per cent, Passed
7.	ASSAY:	minimum 0.30 per cent of total alkaloids, expressed as hyoscyamine (C ₁₇ H ₂₃ NO ₃ ; Mr 289.4) (dried drug).	0.68 per cent, Passed
8.	Healy metals (2.4.27): - cadmium (Cd) - lead (Pb) - mercury (Hg)	maximum 1.0 ppm; maximum 5.0 ppm; maximum 0.1 ppm.	Passed 0.004 ppm 0.1 ppm 0.01 ppm
9.	Aflatoxins (2.8.18): - aflatoxin B ₁ - sum of aflatoxin (B ₁ , B ₂ , G ₁ , G ₂)	maximum 2 µg/kg maximum 4 µg/kg	Passed 0.9 µg/kg 0.9 µg/kg
10.	Pesticide residues (2.8.13)	The limits indicated in table 2.8.13.-1 or be checked precisely according to (GACP).	Passed
11.	Radionuclides: - cesium-137 (¹³⁷ Cs) - strontium-90 (⁹⁰ Sr)	maximum 500 Bk/kg maximum 200 Bk/kg	Passed 54.0 ± 21.6 Bk/kg 17.3 ± 6.9 Bk/kg

Conclusion: The raw material meets the requirements of the 04/2010:0221 EP.

Director

Roman Milkhailich

