

Decontamination of Digitalis and its Tablets by Gamma Radiation

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Digitalis and its tablets were irradiated at graded doses of 5-25 kGy to determine minimum decontamination dose and monitored for changes, if any, in physicochemical characteristics. The irradiated samples were tested for stability at different temperature and humidity conditions. Digitalis and its tablets were successfully decontaminated at 15 kGy and found to be stable upto 25 kGy dose of gamma radiation.

LEAVES of digitalis (*Digitalis Purpurea*) and their tablets are reported to carry a high bioburden^{2,2} and pharmacopoeia recommend microbial limits for both^{30,40}. To achieve prescribed microbiological quality, there is a need for their decontamination. Advantages of gamma irradiation, a cold method of sterilisation, over other methods are well known⁵. The feasibility of decontaminating digitalis and its tablets by gamma radiation is reported here.

Digitalis purpurea leaves were procured from local market. The tablets of powdered leaves were prepared using dicalcium phosphate, starch (Loba Chemie) and alcoholic solutions of polyvinyl pyrrolidone (BDH Chemicals, U.K.) as binder. The powdered leaves (#40) and tablets were packed either in neutral glass vials or polythene bags and irradiated by Co-60 gamma radiation at 5, 10, 15, 20 and 25 kGy dose at ISOMED, BARC, Bombay.

Unirradiated (control) and irradiated (25 kGy) samples of digitalis were tested for physicochemical characteristics like extractive values⁶, total cardenolic glycosidal content^{3a}, thin layer chromatography^{3a}, high performance thin layer chromatography and electron spin resonance spectra. Control and irradiated (25 kGy) samples of digitalis tablets were

tested for total cardenolic glycosidal content^{3b}, hardness, friability and disintegration time.

Control and irradiated (graded doses) samples of digitalis and its tablets were tested for total aerobic count and the absence of objectionable microorganisms^{4b}.

Control and irradiated (25 KGy) samples were stored at ambient temperature (28±4)° 37°, 45° and 60° and tested for total cardenolic glycosidal content at weekly intervals. Digitalis with elevated moisture content (10-16% w/w) was subjected to irradiation and post-irradiation stability studies over a period of four weeks were carried out.

The studies on irradiated (25 kGy) digitalis revealed no changes in extractive values, total cardenolic glycosidal content, TLC and HPTLC patterns indicating no change in the extent of polar, medium polar, non polar components as well as active constituents after irradiation. ESR studies revealed that no free radical was generated due to irradiation. Physicochemical testing of irradiated (25 kGy) digitalis tablets revealed no significant change when compared with control (Table 1).

Digitalis and its tablets with an initial bioburden of 10⁶ c.f.u/g and 10⁵ c.f.u/tablet respectively, con-

Table - 1: Effect of Gamma Radiation (25 Kgy) on Physiochemical Characteristics of Digitalis Tablets

Characteristics	Control	Irradiated
Total Cardenolic glycosidal content (% w/w)	0.144	0.148
Hardness (Kg/cm ²)	4.0	5.0
Friability (%)	0.334	0.331
Disintegration time (min.)	12.0	13.0

taining objectionable microorganisms viz., *S. aureus*, *E. coli* and *Salmonella* were satisfactorily decontaminated at 15 kGy dose.

Accelerated stability studies at elevated temperature revealed post-irradiation stability of digitalis and its tablets. Digitalis glycosides are not stable at moisture content of 10% w/w and above, irrespective of irradiation. However, digitalis with 8% w/w moisture content was found to be stable to irradiation upto 25 kGy dose.

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