

POTENCY OF INJECTABLE DIGITALIS PREPARATIONS

DIGITALIS as a useful cardiac tonic has been known in medicine for well over a century. In the form of a fresh infusion of its leaves and an alcoholic tincture which are both official in the British Pharmacopœia, Digitalis has been most frequently used by the oral route. In many cases of cardiac failure, however, absorption from the gastro-intestinal tract is very largely impaired. The need for an injectable Digitalis preparation, therefore, has always been felt.

"Unofficial" preparations available for this purpose are many, the commonest one being called "Digitalin". Nativelle¹ first introduced pure crystalline Digitalin in 1869. This was later proved to be identical with 'Digitoxin' (C₄₁H₆₄O₁₃). 'German' Digitalin is, however, not pure Digitoxin but probably a mixture of glycosides obtained from Digitalis seeds consisting largely of Digitonin, Digitoxin and other glycosides. 'French' Digitalin, also known as 'Homolle's Digitalin', is also reported to be

a mixture of Digitanin, Digitoxin, and other glycosides. Each of these preparations and lately an American product claimed to be 'German Digitalin', have been used by manufacturers in India for the preparation of injectable products. There is also a feeling in the minds of the physicians that purified glycosides of Digitalis available in this form are less liable to deterioration, which is generally believed to occur with liquid preparation of Digitalis, such as the 'tincture' and the 'infusion'.

As part of our testing service on behalf of the Defence Department and the Director-General, Indian Medical Service, a study of the comparative potency of twelve imported samples of Digitalin was taken up in this Laboratory. The general characters, solubility, potency figures of these samples are given in the accompanying table. The bio-assay method followed was on guinea-pigs as previously recommended from this Laboratory (Bose and Mukerji, 1942).² The method briefly consisted of anæsthetizing the animal with intraperitoneal (1.8 gm./kg. weight) urethane, transfus-

Potency of samples in terms of Digitalis pulverta B.P.*

Sample	Character	Solubility	Strength of solution in alcohol 10%	Mean lethal Dose c.c. kgm.	Potency Unit/gramme of powder	Potency claimed Unit/gramme of powder	Percentage of potency in terms of claimed potency
A	Slightly yellowish amorphous powder.	Sparingly soluble in water; soluble in alcohol; solution is clear.	1 in 1,000	23.82	47.39	80	59.2
B	Whitish amorphous powder with small lumps.	Very slightly soluble in water; soluble in alcohol; solution is clear.	1 in 1,000	14.95	75.51	80	94.4
C	Colourless, clear liquid of an agreeable aromatic odour with a bitter taste.	Freely miscible with water and alcohol.	1 in 8	14.25	0.63 (units/c.c.)	1.25 (units/c.c.)	50.4
D	White tablets.	Readily soluble in water and alcohol; solution is clear.	1 in 1,000	13.50	83.62	80 (approx.)	104.5
E	White tablets.	Do.	1 in 1,000	28.60	39.47	80 (approx.)	49.3
F	Greenish hard mass.	Soluble in water and alcohol; solution is almost clear. (Slight haze.)	1 in 1,000	10.89	103.67	80	130.0
G	White tablets.	Readily soluble in water and alcohol; solution is clear.	1 in 1,000	19.00	59.38	80 (approx.)	74.2
H	Do.	Do.	1 in 1,000	12.77	88.40	80	110.5
I	Do.	Do.	1 in 1,000	11.67	96.70	80	120.0
J	Do.	Do.	1 in 1,000	12.07	93.50	80	116.8
K	Do.	Do.	1 in 1,000	17.13	65.89	80 (approx.)	82.4
L	Do.	Do.	1 in 1,000	27.40	41.20	80 (approx.)	51.5

* The unitage has been calculated from the average lethal dose, 9.07 c.c. (1.129 units) kg. weight of guinea-pig, obtained by the authors with the standard digitalis tincture (1 in 80). B. P. C. Standard = 80 I.U. per gramme.