



Australian Government

Department of Health
Therapeutic Goods Administration

Therapeutic Goods Order 93 (Standard for Medicinal Cannabis)
Compliance checklist for sponsors

Submit to TGA

<input type="checkbox"/>	A signed TG093 Declaration form.
<input type="checkbox"/>	Cover letter authorising the TGA to use the declaration for any notification or application received for that product through Special Access Scheme, Clinical Trials or Authorised Prescriber.

Ensure the following are met (may be requested by TGA at any time)

<input type="checkbox"/>	Identification of cannabis plant: 1. Macroscopic examination 2. Microscopic examination 3. Chromatographic procedures
<input type="checkbox"/>	Certificate of Analysis and specifications for raw material. (Signed and dated)
<input type="checkbox"/>	Certificate of Analysis and specification for the final product. (Signed and dated)
<input type="checkbox"/>	Assay tests for active ingredients.
<input type="checkbox"/>	Stability data on final product. Shelf life of the product to be established in accordance with the principles outlined in the relevant International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) quality guidelines adopted by the TGA.
<input type="checkbox"/>	Compliance with other applicable therapeutic goods order. Therapeutic Goods Order 98 Microbiological standards for medicines 2018 i.e. For non-aqueous preparations for oral use: 1. Total aerobic microbial count (TAMC) (Not more than 10^3) 2. Total yeast and mold count (TYMC) (Not more than 10^2) 3. <i>Escherichia coli</i> absent in 1g or 1mL Therapeutic Goods Order 78 Standard for tablets and capsules etc. .

Schedule 1 Tests	Test method
<input type="checkbox"/> Aflatoxin B1 (Not more than 2µg/kg)	Ph Eur 2.8.18
<input type="checkbox"/> Aflatoxin B1 ,B2 , G1 and G2 (not more than 4µg/kg)	Ph Eur 2.8.18
<input type="checkbox"/> Foreign matter (Not more than 2%)	Ph Eur 2.8.2
<input type="checkbox"/> Heavy metals: 1. Arsenic (Not more than 3ppm) 2. Cadmium (Not more than 0.5ppm) 3. Lead (Not more than 5ppm) 4. Mercury (Not more than 0.5ppm)	Ph Eur 2.4.27
<input type="checkbox"/> Ochratoxin A (Not more than 20 µg/kg)	Ph Eur 2.8.22
<input type="checkbox"/> Pesticides (Not more than the limits specified in Ph Eur 2.8.13)	Ph Eur 2.8.13
<input type="checkbox"/> Total ash (Not more than 20%)	Ph Eur 2.4.16