Application General

eBS Logo

Product Name:	By-Health Xin Luo Su Tablets
Product Code:	Other products
Client Name:	Pentavite Pty Ltd
Sponsor Name:	Pentavite Pty Ltd
Is this Application in response to a Section 30:	No
Can this product be used as a code stock:	No
This application is to:	create a new ARTG Entry
Submission Cost:	$983.00
Payment Exemption No:	
Application Status:	Completed
Application Type:	New (A new AUST L will be generated)
Validation Report:	19/11/2024 7:59:29 AM

Information Messages

Successful validation of this application is not to be considered as an indication that a medicine is compliant with the legislative requirements. The listed medicines validation system is a tool to assist sponsors in listing a medicine on the ARTG. Sponsors are expected to be aware of, and comply with, all relevant regulatory requirements for their listed medicine.

s47

s47 has conditions -The licence does not authorise testing for sterility or endotoxin assays.

s47 - has conditions -This licence authorises the physical and chemical testing of medicinal products at level 3, T-Block and metals analysis of medicinal products at N-Block.

s47 has conditions -None

s47 - has conditions -The manufacture of Registered liniments excludes therapeutic products to which any part of the Poisons Standard applies, except for the active ingredients: camphor, turpentine oil and methyl salicylate. The manufacture of gels and creams is restricted to antibacterial hand hygiene products (hand sanitiser) only. This licence does not authorise the manufacture of medicines listed for export that include substances at a level only permitted in medicines contained within Schedules 2, 3, 4 & 8 of the Poisons Standard, except liniments containing the active ingredients: camphor, turpentine oil and/or methyl salicylate.

When for oral use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the label: - (SODIUM) ‘The recommended daily dose of this medicine contains [state quantity and units] of sodium’ (or words to that effect). (Ingredient(s) concerned: 'Croscarmellose sodium')

Pass with condition: For use as an excipient only as a colour and only in medicines limited to oral and topical routes of administration. (Ingredient(s) concerned: 'titanium dioxide')

Gluten is a mandatory component of Maltodextrin where the ingredient is derived from gluten containing grains such

as wheat, barley, rye and oats and must be declared in the application when the route of administration is other than Topical and Mucosal. Medicines containing gluten require the label statement GLUTEN 'Contains [insert name of ingredient]'. s47 (contains: Maltodextrin))

The ingredient 'lactose' must be derived from bovine milk in order to be eligible for self-assessment and must comply with the European Pharmocopoeial monograph for the minimisation of TSE risk (Ingredient(s) concerned: 'lactose')

PRODUCT DETAILS

Dosage Form:	Tablet, film coated
Route of Administration:	Oral
Maximum daily dose:	1

FORMULATION DETAILS

ACTIVE INGREDIENTS:

STANDARD

PROPRIETARY INGREDIENTS

Ingredient: s47

Active Ingredient: Lycopersicon esculentum fruit Juice powder (from s47) 7.5 mg

EXCIPIENT INGREDIENTS:

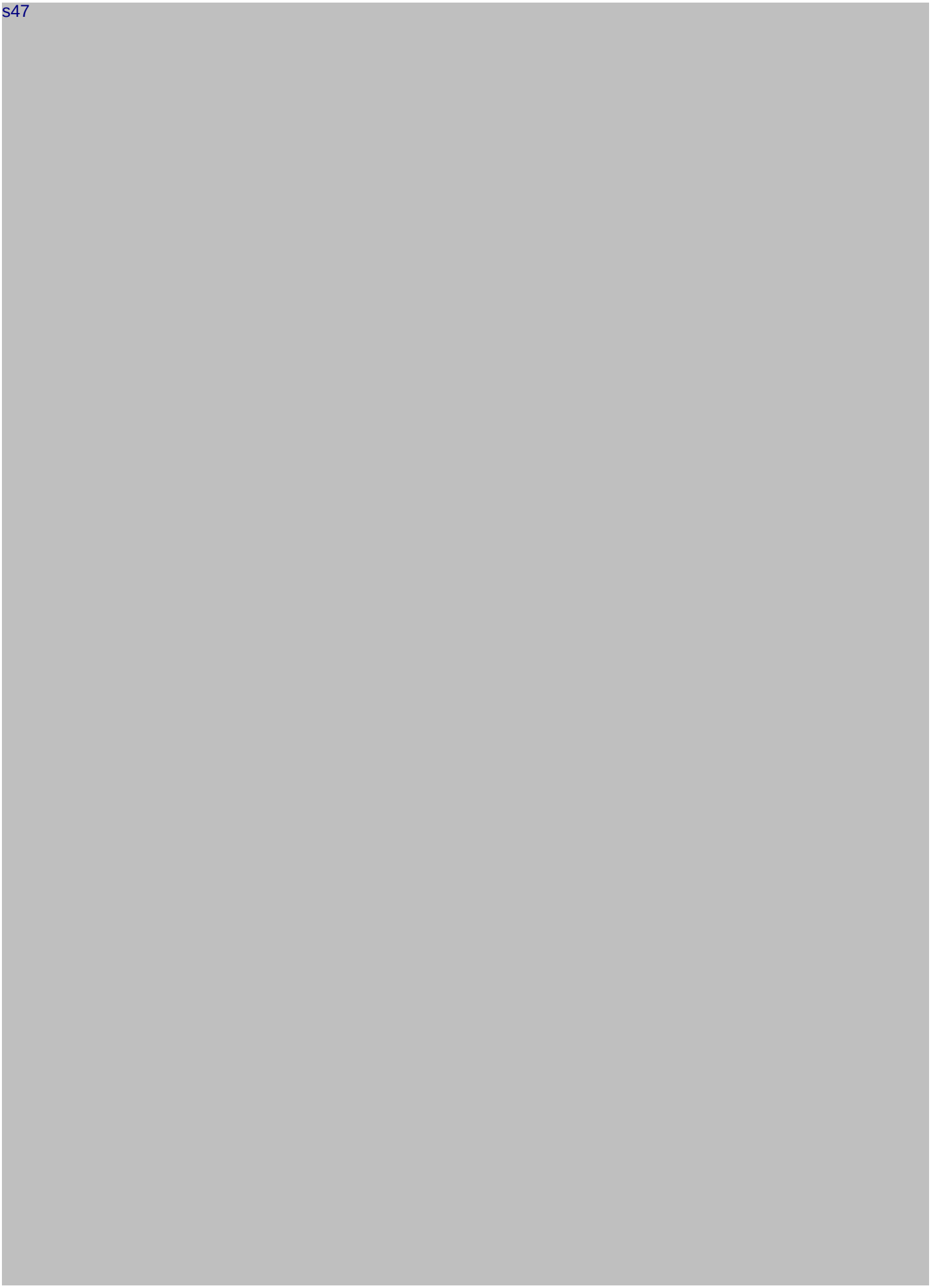
STANDARD

Ingredient:	microcrystalline cellulose
Ingredient:	croscarmellose sodium
Ingredient:	hypromellose
Ingredient:	polyvinyl alcohol
Ingredient:	purified talc
Ingredient:	triacetin
Ingredient:	brilliant scarlet 4R aluminium lake
Ingredient:	allura red AC aluminium lake
Ingredient:	indigo carmine aluminium lake
Ingredient:	silicon dioxide
Ingredient:	magnesium stearate
Ingredient:	titanium dioxide
Ingredient:	s47

s47

MANUFACTURER DETAILS

s47



[redacted]

INDICATIONS & WARNINGS

Warning:	(LACT) Contains lactose (or words to that effect).
Subsection 26B(1) Notification:	For the purpose of subsection 26B(1) you are notifying the Secretary that a certificate under subsection 26B(1) is not required for this application.