Therapeutic Trypanocide for Animal African Trypanosomosis (AAT)

GALVmed
Protecting Livestock – Improving Human Lives

Target Product Profile (TPP)

A safe and effective therapeutic product for ruminants and other livestock infected with common Trypanosome species (especially *T. congolense* and *T. vivax* including isolates resistant to diminazene and isometamidium)

Attribute	Ideal TPP (Wants)	Minimum TPP (Needs)
1 **Active Ingredient**	Novel agent with new mechanism of action. No cross- or side-resistance to existing product actives.	Novel agent. Side-resistance to existing veterinary products acceptable if overcome by greater intrinsic potency or speed of action.
2 **Indication for use**	Treatment of *T. congolense, T. vivax, T. brucei* and *T. evansi* infections, including strains resistant to existing trypanocides.	Treatment of *T. congolense* and *T. vivax* infections, including strains resistant to existing trypanocides.
3 **Target species**	Cattle, sheep, goat & other ruminants, camels, horses, donkeys, pigs.	Cattle
4 **Route of administration**	Injectable (i.m. and s.c.) plus oral option for sheep.	Injectable (preferably i.m. or s.c.) or Pour-on or Oral.
5 **Formulation**	Injectable: Pre-formulated solution. Oral: Solid bolus or suspension/solution drench.	Injectable: Pre-formulated solution or suspension or sterile powder in vial for reconstitution. If injectable not possible then consider either pre-formulated pour-on or oral (solid bolus or liquid).
6 **Regimen**	Single administration.	Two administrations (provided the interval between the two administrations is short).
7 **Recommended time of treatment**	At first diagnosis of disease (clinical signs or parasitaemia).	At first diagnosis of disease (clinical signs or parasitaemia).
8 **Expected efficacy**	Absence of parasitaemia and improvement of clinical signs, e.g. anaemia. [For Regulatory Studies: Absence of clinically significant parasitaemia, e.g. buffy coat method for duration of regimen period, and normal haematocrit/PCV].	Absence of parasitaemia and improvement of clinical signs, e.g. anaemia. [For Regulatory Studies: Absence of clinically significant parasitaemia, e.g. buffy coat method for duration of regimen period, and normal haematocrit/PCV].

Therapeutic Trypanocide for Animal African Trypanosomosis (AAT)

Attribute	Ideal TPP (Wants)	Minimum TPP (Needs)
9 Target animal safety	No clinically significant adverse drug reactions. Minimal administration site reactions. Safe for use in breeding animals (male and female) – demonstrated in target species.	No serious adverse drug reactions. Acceptable reactions at administration site. Safe for use in breeding animals (male and female) – demonstrated in laboratory animal studies.
10 Withdrawal period	Milk zero. Meat <14 days.	Milk <7 days. Meat ≤28 days.
11 Special requirements for animals	Compatible for concomitant use with common treatments e.g. ectoparasiticides, antimicrobials, anthelmintics & vaccines.	None stated.
12 Special requirements for persons	No special precautions required beyond good practice.	Routine personal protective equipment. No major hazard on accidental self-injection or pour-on.
13 Special requirements for environmental protection	No special precautions.	Minimal soil/water residues. Minimal restrictions on disposal of packaging.
14 Package size	1, 5, 10 and 50 doses packages.	1 and 10* doses. **Product price dependent*
15 Price to user	<US$2/dose (300kg animal).	Higher prices than US$2/dose are a major challenge unless justified by value-added properties and include syringes, etc.
16 Storage requirements	Ambient temperature ≤40°C/75% RH.	Ambient temperature ≤30°C/75% RH * **FAO/WHO Guideline*
17 Shelf-life as packaged	≥3 years*	≥ 18 months* * *At world zone IVb for regulatory purposes*
18 Shelf-life after first opening	≥7 days & <28 days	≥24 hours for single-dose ≥7 days for multidose vial