

Samples & WS	Specifications	Costa Rica	El Salvador	Guatemala	Honduras	Nicaragua	Panama	República Dominicana	Ecuador
		For Ministry of Health					1 active ingredient		
Standard of API **		na*	na*	1 g	na*	na*	1 g	1 g	1 g
Working standard of related substances/impurities/ internal standard **		na*	na*	500mg	na*	na*	1 g	na	na
Minimum shelf life of working standard at submission		na*	na*	6 months	na*	na*	12 months	12 months	12 months
Minimum shelf life of samples at submission		na*	na*	6 months	na*	12 months	12 months	12 months	6 months
<i>Tablets, Chewable Tablets, Dispersible tablets, Capsules</i>		na*	na*	120	na*	2 pack	240	180	10 units/packs
<i>Granules</i>	(Sachets)(bottles) <150g	na*	na*	20	na*	2 pack	60	30	10 units/packs
<i>Granules</i>	(Sachets) (bottles) ≥ 150g	na*	na*	40	na*	2 pack	60	50	10 units/packs
<i>Sterile powders, Liofilized powders for injection</i>	≥3 ml	na*	na*	40	na*	2 pack	80	120	10 units/packs
	5 ml a 10 ml	na*	na*		na*	2 pack			
	20 to 45 mL	na*	na*		na*	2 pack			
	50 to 100 mL	na*	na*		na*	2 pack			
	100 to 200 mL	na*	na*		na*	2 pack			
	200 to 490 mL	na*	na*		na*	2 pack			
	500 mL and more	na*	na*		na*	2 pack			
<i>Oral liquids Elixirs Emulsions,</i>		na*	na*	26	na*	2 pack	25	78	10 units/packs
<i>oral liquids unit dose</i>		na*	na*	26	na*	2 pack	25	78	10 units/packs
<i>Topic liquids</i>		na*	na*	26	na*	2 pack	25	120	10 units/packs
<i>Sterile solutions for</i>	≥3 ml	na*	na*	100	na*	2 pack	65	222	10 units/packs
	5 ml a 10 ml	na*	na*	60	na*	2 pack	65	162	10 units/packs
	20 to 45 mL	na*	na*	20	na*	2 pack	65	222	10 units/packs

<i>Sterile solutions for injection</i>	50 to 100 mL	na*	na*	20	na*	2 pack	65	80	10 units/packs
	100 to 200 mL	na*	na*	14	na*	2 pack	65	40	10 units/packs
	200 to 490 mL	na*	na*	14	na*	2 pack	65	40	10 units/packs
	500 mL and more	na*	na*	14	na*	2 pack	65	40	10 units/packs
<i>Eyedrops/ Ophthalmic ointments</i>	with AB	na*	na*	80	na*	2 pack	35	95	10 units/packs
	without AB	na*	na*	60	na*	2 pack	35	115	10 units/packs
<i>Eardrops</i>		na*	na*	60	na*	2 pack	25	115	10 units/packs
<i>Creams Gels and Ointments</i>	with AB	na*	na*	40	na*	2 pack	25	70	10 units/packs
	without AB	na*	na*	30	na*	2 pack	25	70	10 units/packs
<i>Aerosols, metered-dose inhalers, dry powder inhalers</i>	with AB	na*	na*	30	na*	2 pack	40	70	10 units/packs
	without AB	na*	na*	20	na*	2 pack	40	70	10 units/packs
<i>Transdermal delivery systems and implants</i>		na*	na*	30	na*	2 pack	35	90	10 units/packs
<i>Biological/ Bitotech Products</i>		na*	na*	According to dosage form	na*	According to dosage form	According to dosage form	According to dosage form	Ask before submission

na = not applicable

AB = Antibiotic

* Working standards for Salvador, Nicaragua and Costa Rica are required once the product is imported or commercialized for the first time, since local authority must release that batch.

** Although amount of working standard is asked in 1 g, we recommend to submit not less than enough for repeating a whole analysis by 3 times.