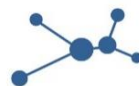


PRODUCT SPECIFICATIONS



ValueMED
PHARMA S.R.L.
Italian Healthcare Research

Product name: GYNEPINK RELIEF

Classification in the country of origin: CE Medical Device class I*

Manufacturer: ValueMED Pharma S.r.l.

Dosage form: 5 vaginal douches 100 ml each

Packaging particulars: clear LDPE botte with vaginal dispenser plus leaflet in a cardboard box

**as per requirements and provisions of Directive 93/42/EEC and subsequent modifications and integrations*

TEST DONE	METHOD	SPECIFICATIONS	REFERENCE
Appearance	Visual and organoleptic inspection	clear liquid	-
Flavour		n.a.	-
Odour		clove flower buds	-
Colour		transparent	-
MICROBIAL EXAMINATION			
TAMC	PH. EUR	$< 2 \times 10^2$ CFU/g	PH. EUR
TYMC	PH. EUR	$< 2 \times 10^1$ CFU/g	PH. EUR
Pseudomonas aeruginosa	PH. EUR	absence in 1 g	PH. EUR
Staphylococcus aureus	PH. EUR	absence in 1 g	PH. EUR
Candida albicans	PH. EUR	absence in 1 g	PH. EUR

CHEMICAL ANALYSIS			
Pb	n.a.	prohibited	Reg. 1223/2009 and subs. amends.
Cd	n.a.	prohibited	as above
Hg	n.a.	prohibited	as above
OTHER INFORMATIONS			
GMOs (in accordance with REG EC 1829/2003 and 1830/2003)		The product does not contain any GMOs or GMOs derivate raw materials	-
BSE/TSE (in accordance with EMEA guidelines)		No risk of BSE/TSE	-
RADIATION (in accordance with DIR 1999/2/EC and DIR 1999/EC)		Not irradiated	-
PSYCHOTROPICS		absent	-
NARCOTICS		absent	-
NANOTECHNOLOGIES USE IN PRODUCTION		absent	-
DOPING SUBSTANCES		absent	-
ALLERGENS (in accordance with DIR 2003/89/EC)		Allergen free	-

BIOLOGICAL ANALYSIS			
SPECIES IDENTIFICATION:			
BOVINE	DNA sequencing	absent	-
PIG	DNA sequencing	absent	-
EQUINE	DNA sequencing	absent	-
OVINE/CAPRINE	DNA sequencing	absent	-
CHICKEN	DNA sequencing	absent	-
TURKEY	DNA sequencing	absent	-
DUCK	DNA sequencing	absent	-
GOOSE	DNA sequencing	absent	-



Republic of San Marino,
03/04/2019
Quality Assurance Dept.
Rossini Alice