

Certificate of analysis

Product nam **Butylscopolamine**
 Description: *Hyoscine Butylbromide*
 Code: **SBB**
 Batch: **31815005**
 Net Weight: 5.00 Kg

Certificate n. 050208
 Date of manufacture: 04-2015
 Date of reanalysis: 04-2020

Parameters	Results	Units	Method	Specifications
Aspect	Complies	--	Ph.Eur monograph: "Hyoscine Butylbromide", current edition	White or almost white, crystalline powder
Solubility:	Complies	--	Ph.Eur monograph: "Hyoscine Butylbromide", current edition	Freely soluble in water and methylene chloride, sparingly soluble in ethanol
Identification B: melting point	140.0	°C	Ph.Eur monograph: "Hyoscine Butylbromide", current edition	Between 139 °C and 141 °C
Identification C: IR spectrum	Complies	--	Ph.Eur monograph: "Hyoscine Butylbromide", current edition	Complies with reference standard
Identification D:	Complies	--	Ph.Eur monograph: "Hyoscine Butylbromide", current edition	Complies
Identification E:	Complies	--	Ph.Eur monograph: "Hyoscine Butylbromide", current edition	Complies
Identification F: bromides test	Complies	--	Ph.Eur monograph: "Hyoscine Butylbromide", current edition	It gives the reaction of bromides
Appearance of solution	Complies	--	Ph.Eur monograph: "Hyoscine Butylbromide", current edition	The 5% water solutions is clear and colourless
pH	6.1	--	Ph.Eur monograph: "Hyoscine Butylbromide", current edition	Between 5.5 and 6.5
Specific optical rotation	- 19.6	°	Ph.Eur monograph: "Hyoscine Butylbromide", current edition	Between -20.0 and -18.0
Loss on drying	0.4	%	Ph.Eur monograph: "Hyoscine Butylbromide", current edition	Not more than 2.5 %
Related substances HPLC:			Ph.Eur monograph: "Hyoscine Butylbromide", current edition	
Impurity A: Hyoscine	0.05	%		Not more than 0.10 %
Impurity B: Tropic acid	<0.02	%		Not more than 0.20 %
Impurity C: Methylhyoscine	0.07	%		Not more than 0.20 %
Impurity D: Propylhyoscine	<0.02	%		Not more than 0.20 %
Impurity E: N-butylhyoscine	<0.02	%		Not more than 0.20 %
Impurity F: Pseudo-isomer	<0.02	%		Not more than 0.20 %
Impurity G: Apo-N-butylhyoscine	<0.02	%		Not more than 0.20 %
Each individual unidentified impurity	Complies	--		Not more than 0.10 %
Total of all impurities	0.12	%		Not more than 0.40 %

Voor de Benelux

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Assay (AgNO ₃)	99.3	%	Ph.Eur monograph: "Hyoscine Butylbromide", current edition	Between 98.0% and 101.0%
Sulphated ash	Complies	--	Ph.Eur monograph: "Hyoscine Butylbromide", current edition	Not more than 0.10%
Residual solvents:	Internal method according to EP monograph 5.4			
Methanol	216	ppm		Not more than 3000 ppm
Acetonitrile	<22	ppm		Not more than 50 ppm
1-butyl bromide	46	ppm		Not more than 100 ppm
Microbiology:				
Total aerobic microbial count	Complies	--	2.6.12 Ph Eur, current edition	Not more than 10 ³ cfu/g
Total combined yeast/mould count	Complies	--	2.6.12 Ph Eur, current edition	Not more than 10 ² cfu/g
Escherichia coli	Complies	--	2.6.13 Ph Eur, current edition	Absent/10 g
Bile-tolerant Gram-negative bacteria	Complies	--	2.6.13 Ph Eur, current edition	Not more than 10 ² cfu/g
Salmonella	Complies	--	2.6.13 and 2.6.31 Ph Eur, current edition	Absent/25 g

The product complies with the European Pharmacopoeia, current edition.

Remarks:

Released on: 17-06-2015

Order Number 15/219

FAGRON IBÉRICA, S.A.U
 Corresponde al lote de Fagron:

L16070044

Director Técnico

APPROVED

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Voor de Benelux

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